# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

## Part LIII: Pharmacists

## Chapter 25. Prescriptions, Drugs, and Devices

### Subchapter A. General Requirements

### §2501. Prescription Drugs and Devices

A. Prescription Drugs or Devices. A prescription drug or device is a medication or mechanism that may only be dispensed by a pharmacist on the order of a licensed practitioner and shall bear the "Rx Only" notation or any other designation of similar import required by law on the label of a commercial container.
   1. Dispensing. Prescription drugs or devices shall be dispensed only by a Louisiana-licensed pharmacist.
   2. Possession. Prescription drugs or devices shall be procured and possessed in the course of the practice of pharmacy by a permitted pharmacy.
   3. Storage. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

B. Misbranded Drugs.
   1. Misbranded drugs are:
      a. those drugs whose labeling is false or misleading in any particular manner; or
      b. those drugs whose label does not bear the name and address of the manufacturer, packer, or distributor, and does not have an accurate statement of the quantities of the active ingredients; or
      c. those drugs without an accurate monograph; or
      d. those drugs meeting the qualifications for misbranded drugs as noted in the Federal Food, Drug, and Cosmetic Act, or its successor.
   2. It is unlawful to possess or dispense misbranded drugs.

C. Adulterated Drugs.
   1. Adulterated drugs are contaminated medicinal substances having deleterious foreign or injurious materials, which fail to meet safety, quality, and/or purity standards.
   2. It is unlawful to possess or dispense adulterated drugs.

D. Expired Drugs. Expired drugs shall not be dispensed and shall be removed from the pharmacy drug inventory.

E. Recalled Drugs. Recalled drugs shall be removed from the pharmacy inventory immediately upon notice. Recalls are classified as:
   1. Class I – a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
   2. Class II – a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
   3. Class III – a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

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 29:2101 (October 2003), effective January 1, 2004.

### §2503. Drug Returns

A. Drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

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 29:2102 (October 2003), effective January 1, 2004.

## §2505. Investigational Drugs

A. All investigational drugs stored or dispensed by any pharmacy shall conform to appropriate and applicable federal and state laws and regulations pertaining to their use.

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 29:2102 (October 2003), effective January 1, 2004.

## §2507. Veterinary Prescription Drugs

A. Veterinary prescription drugs are prescription medications for animal use prescribed by a licensed veterinarian pursuant to a valid veterinarian-client-patient relationship and dispensed by a licensed pharmacist to the veterinarian's client, for a legitimate medical purpose, that are unsafe for unsupervised use as defined in 21 CFR §201.105, or its successor.

B. Dispensing Requirements. Veterinary prescription drugs shall be exclusively dispensed by a duly licensed pharmacist upon the order of a licensed veterinarian, unless otherwise provided by law.

C. Labeling Requirements. Veterinary prescription drugs shall be dispensed in an appropriate container, and in addition to the labeling requirements in Chapter 11 of these regulations, shall contain the following information:

1. the commercial label inscription "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and
2. the client's name and patient's animal species.

D. Prescription Form Requirements. Prescriptions issued by a licensed veterinarian shall conform to §2511 of these regulations.

E. Storage. Veterinary prescription drugs shall be maintained in the prescription department of a pharmacy, and shall be kept separate and apart from drugs intended for human use.

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 29:2102 (October 2003), effective January 1, 2004.

## §2509. Prescription Devices

A. In the interest of public health, safety, and welfare, the board may, from time to time, restrict the sale of certain devices to be dispensed only by a licensed pharmacist after a legitimate medical need has been demonstrated. A legitimate medical need includes the prevention of the transmission of communicable diseases.

B. Pharmacy Device. A pharmacy device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component 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 other designation of similar import.

1. Hypodermic Apparatus. Hypodermic means any syringe, needle, instrument, device, or implement intended or capable of being adopted for the purpose of administering drugs by subcutaneous, intramuscular, or intravenous injection.
    a. Sale. Hypodermic syringes and/or needles shall be sold or distributed only by a licensed pharmacist, physician, dentist, veterinarian, podiatrist, embalmer, drug wholesaler, surgical supplier, or other legally authorized distributor.
    b. Storage. Hypodermic syringes and/or needles shall be stored in the prescription department or in another secure area.

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 29:2102 (October 2003), effective January 1, 2004.

## Subchapter B. Prescriptions

## §2511. Prescriptions

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
*Electronic Prescription* – a prescription transmitted in electronic form.
*Practice Affiliation* – a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine.
*Prescription or Prescription Drug Order* – 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.

B. Written Prescriptions. A written prescription shall conform to the following format:
   1. The prescription form shall not be less than four inches by five inches, and shall bear a single printed signature line.
   2. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and, if applicable, Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling the authorizing prescriber's printed name.
   3. If the authorized prescriber is a non-physician, the prescription form shall clearly indicate the authorized prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.
   4. No prescription form shall contain more than four prescription drug orders. Each prescription drug order on the form shall provide the following:
      a. check box labeled "Dispense as Written", or "DAW", or both; and
      b. the number of refills, if any.
   5. Forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.
   6. Equivalent Drug Product Interchange.
      a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.
      b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written", or "DAW", or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.
      c. For prescriptions reimbursable by Medicaid or Medicare, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary" or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

C. Oral Prescriptions.
   1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist shall reduce the order to a written form prior to dispensing the medication.
   2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.
   3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

D. Electronic Prescriptions.
   1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if applicable, DEA registration number.
   2. If the authorized prescriber is a non-physician, the prescription form shall clearly indicate the authorized prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.

3. The pharmacist shall not select an equivalent drug product when the prescriber indicates in the check box labeled "Dispense as Written", or "DAW", or both, and electronically transmits his signature on the formatted single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.
4. Facsimile Prescription.
    a. The receiving facsimile machine of a prescription transmitted by facsimile shall be located within the pharmacy department.
    b. The prescription transmitted by facsimile shall be on a non-fading legible medium.
    c. All requirements applicable to written prescriptions in Subsection (B) shall apply to facsimile prescriptions, except Subsection (B)(6)(c).

E. Exclusion. The provisions of this section shall not apply to medical orders written for patients in 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), amended LR 29:2102 (October 2003), effective January 1, 2004.

## §2513. Prescription Receipt and Verification

A. Receipt of a Prescription
    1. Written. A pharmacist may receive and dispense a prescription that has been written and/or signed by the practitioner.
    2. Oral. A pharmacist may receive and dispense a prescription that has been orally communicated by the practitioner when the prescription has been reduced to hard copy.
    3. Electronic Transmission. A pharmacist may receive a prescription via electronic or other means, and then reduce to hard copy, if necessary.

B. Verification. Verification of the accuracy and authenticity of any prescription is the responsibility of the pharmacist.

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 29:2103 (October 2003), effective January 1, 2004.

## §2515. Prescriptions Based Upon Electronic Questionnaires

A. A prescription issued solely on the results of answers to an electronic questionnaire, in the absence of a documented patient evaluation including a physical examination, is issued outside the context of a valid physician-patient relationship, and is not a valid prescription.

B. If a pharmacist has reasons to suspect that a prescription was authorized solely on the results of an electronic questionnaire and in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or in violation of the practitioner's standard of practice, include:
    1. the number of prescriptions authorized on a daily basis by the practitioner;
    2. the manner in which the prescriptions are authorized by the practitioner or received by the pharmacy, i.e., electronically;
    3. the geographical distance between the practitioner and the patient(s);
    4. knowledge by the pharmacist that the prescription was issued solely as a result of answers to an electronic questionnaire; or
    5. knowledge by the pharmacist that the pharmacy he works for directly or indirectly participates in an internet site that markets prescription drugs to the public.

C. A pharmacist who has reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or otherwise in violation of the prescriber's standard of practice, shall not fill such prescription until he has obtained proof to a reasonable certainty of the validity of such prescription.

D. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.

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 29:2103 (October 2003), effective January 1, 2004.

## §2517. Prescription Dispensing

A. Prescription dispensing means the issuance, by a licensed pharmacist, of one or more doses of medication in a suitable container, properly labeled for subsequent administration, and shall consist of the following procedures or practices:
    1. receiving and interpretation of the prescription order;
    2. assembling the drug products and an appropriate container;
    3. preparing the prescription by compounding, mixing, counting, or pouring;
    4. affixing the proper label to the final container;
    5. patient counseling as required; and
    6. transfer of possession.

B. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

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 29:2104 (October 2003), effective January 1, 2004.

## §2519. Prescription Refills

A. Refill Authorization. Prescription refills may be dispensed only with the prescriber's authorization, as indicated on the original prescription order. In the absence of the authorized practitioner's instructions on the original prescription, the prescription shall be considered non-refillable. When all refills authorized on the original prescription have been dispensed, then authorization from the prescribing practitioner shall be obtained prior to dispensing; when such authorization has been received, a new prescription shall be prepared and it shall be issued a different prescription number.

B. Controlled Dangerous Substances.
    1. The refilling of a prescription for a drug listed in Schedule II is prohibited.
    2. A prescription for a drug listed in Schedule III, IV, or V may be refilled up to five times, if so indicated at the time issued.

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 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

## §2521. Emergency Refills

A. Using sound professional judgment, a pharmacist may refill adequate medication for a seventy-two (72) hour regimen when an emergency for medication has been adequately demonstrated and the prescribing practitioner is not available.

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 29:2104 (October 2003), effective January 1, 2004.

## §2523. Transfer of Prescription Information

A. Prescription Transfer Requirements
    1. Prescriptions for Controlled Dangerous Substances
        a. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements:

i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
   (a) Invalidation of the prescription.
   (b) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
   (c) Record the date of the transfer and the name of the pharmacist transferring the information.

b. The pharmacist receiving the transferred prescription information shall reduce to writing the following:
   i. Indication of the transferred nature of the prescription.
   ii. Provide all information required for a prescription for a controlled substance (full name and address of patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, and DEA registration number of the prescriber) and include:
      (a) date of issuance of original prescription;
      (b) original number of refills authorized on original prescription;
      (c) date of original dispensing;
      (d) number of valid refills remaining and date(s) and location(s) of previous refill(s);
      (e) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
      (f) name of pharmacist who transferred the prescription; and
      (g) pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.
   iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.

c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

2. Prescriptions for Drugs Other Than Controlled Dangerous Substances
   a. The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies, subject to the following requirements:
      i. Prescriptions may be transferred up to the maximum number of refills permitted by the prescriber on the original prescription.
      ii. The transferring pharmacist, intern or certified technician shall record the information itemized in Clause 1.a.i above, with the exception of DEA registration numbers.
      iii. The receiving pharmacist, intern or certified technician shall record the information itemized in Subparagraph 1.b above, with the exception of DEA registration numbers.
   b. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
   c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

B. Pharmacies Using Common Electronic Files
   1. Pharmacies using a common electronic file are not required to physically or electronically transfer prescriptions for information dispensing purposes between or among pharmacies participating in the same common prescription file; provided, however, any such common file must contain complete and adequate records of such prescriptions, and further, that a hard copy of each prescription transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription or to which the prescription is transferred.
   2. This accommodation shall comply with all state and federal laws and regulations regarding controlled dangerous substance prescription transfers.

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 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), amended LR 36:756 (April 2010).

## §2525. Prescription Expiration

A. A prescription for a drug other than a controlled dangerous substance shall expire one year after the date written.
B. A prescription for a controlled dangerous substance listed in Schedule II, III, IV, or V shall expire six months after the date written.
C. Expired prescriptions shall not be refillable or renewable.

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 29:2104 (October 2003), effective January 1, 2004.

## §2527. Prescription Labeling

A. An appropriate label shall be affixed to a proper container, and shall bear the following minimum information:
    1. pharmacy's name, address, and telephone number;
    2. prescription number;
    3. authorized prescriber's name;
    4. patient's name;
    5. date dispensed;
    6. drug name and strength;
    7. directions for use, as indicated;
    8. pharmacist's name or initials; and
    9. cautionary auxiliary labels, if applicable.

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 29:2104 (October 2003), effective January 1, 2004.

## §2529. Pharmacy Prepackaging

A. *Prepackaging* is the preparation of medication in a unit-of-use container by a pharmacist in a pharmacy prior to the receipt of a prescription for ultimate prescription dispensing 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;
    5. name of manufacturer and/or distributor;
    6. manufacturer's lot or batch number;
    7. date of preparation;
    8. pharmacist's initials; and
    9. 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 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

## Subchapter C. Compounding of Drugs

### §2531. Purpose and Scope

A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug products by Louisiana-licensed pharmacists for dispensing and/or administration to patients.

B. Scope. These requirements are intended to apply to all compounded products, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or physician's office.

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 29:2105 (October 2003), effective January 1, 2004.

### §2533. Definitions

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

*Biological Safety Cabinet* – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49, or its successor.

*Class 100 Environment* – an atmospheric environment that contains fewer than 100 particles, of the size 0.5 microns or less in diameter, per cubic foot of air, according to Federal Standard 209E, or its successor.

*Component* – any ingredient used in the compounding of a drug product.

*Compounding* – 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 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.

*Cytotoxic* – any pharmaceutical that has the capability of killing living cells.

*Practitioner Administered Compounds* – products compounded by a licensed pharmacist, upon the medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic purposes.

*Sterile Compounding* – compounding performed using established aseptic technique and utilizing a laminar air flow hood or other device capable of providing a sterile compounding environment. Sterile compounding shall be used when compounding parenteral medications or products, ophthalmic preparations, or any other preparation requiring sterile techniques.

*Sterile Product* – any dosage form devoid of viable microorganisms including, but not limited to, parenterals, injectables, and ophthalmics.

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 29:2105 (October 2003), effective January 1, 2004.

### §2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. A pharmacy shall have written procedures as necessary for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they are represented to possess.
2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment.
3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.

B. Beyond Use Date. Compounded medications shall be labeled with a beyond use date of no more than one hundred eighty (180) days, unless documentation on file supports a longer beyond use date.

C. Records and Reports. Any procedures or other records required to comply with this section shall be maintained for a minimum of two years.

D. Compounding for Prescriber's Use. Pharmacists may prepare practitioner administered compounds for a prescriber's use with the following requirements:

1. an order by the prescriber indicating the formula and quantity ordered to be compounded by the pharmacist;
2. the product is to be administered by the prescriber and not dispensed to the patient; and
3. the pharmacist shall generate a label and sequential identification number for the compounded drug.

E. Anticipated Use Products. The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.

F. Labeling of Compounded Products.

1. For patient-specific compounded products, the labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.
2. All practitioner administered compounds shall be packaged in a suitable container with a label containing, at a minimum, the following information:
    a. pharmacy's name, address, and telephone number;
    b. practitioner's name;
    c. name of preparation;
    d. strength and concentration;
    e. lot number;
    f. beyond use date;
    g. special storage requirements, if applicable;
    h. assigned identification number; and
    i. pharmacist's name or initials.

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 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004.

## §2537. Requirements for Compounding of Sterile Products

A. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the practice of sterile product compounding shall notify the board prior to beginning that practice, and shall receive approval from the board.

B. Personnel.

1. The pharmacist-in-charge shall be responsible for the following:
    a. procurement, storage, compounding, labeling, dispensing, and distribution of all prescription drugs, devices, and related materials necessary in compounding and dispensing sterile products;
    b. establishment of policies and procedures for the compounding and dispensing of sterile products. The policy and procedure manual shall be current, accessible to all staff, and available for inspection by the board upon request. The policy and procedure manual shall, at a minimum, include:
        i. policies and procedures for the compounding and dispensing of sterile products;
        ii. a quality assurance program for the purpose of monitoring patient care, adverse drug reactions, personnel qualifications, training and performance, product integrity, equipment, record keeping, facilities, infection control;
        iii. guidelines regarding patient education; and
        iv. procedures for the handling and disposal of cytotoxic agents, waste, and spills.
    c. documentation of competency in aseptic techniques. The aseptic technique of each individual compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training, and at least on an annual basis thereafter.
2. Training and Education. All individuals compounding and preparing sterile products shall:

a. obtain practical and/or academic training in the compounding and dispensing of sterile products;
b. complete a minimum of one hour of American Council on Pharmaceutical Education (ACPE) or board-approved continuing education, on an annual basis, related to sterile product compounding, dispensing, and utilization;
c. use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policy and procedure manual;
d. qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to compound and dispense sterile products; and
e. maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
    i. name of the individual receiving the training/evaluation;
    ii. date of the training/evaluation;
    iii. general description of the topics covered;
    iv. signature of the individual receiving the training/evaluation; and
    v. name and signature of the individual providing the training/evaluation.

C. Physical Requirements.
1. The pharmacy shall have a designated area with entry restricted to designated personnel for preparing sterile products, and the designated area shall be:
    a. structurally isolated from other areas with restricted entry or access and shall be configured in such a manner so as to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility;
    b. used only for the preparation of these sterile products; and
    c. sufficient in size to accommodate a laminar air flow hood or other device capable of providing a sterile compounding environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
2. The pharmacy where sterile products are prepared shall have:
    a. a sink with hot and cold running water that shall be located in, or adjacent to, the area where sterile products are compounded;
    b. appropriate environmental control devices capable of maintaining at least Class 100 environment in the workplace where critical objects are exposed and critical operations are performed. These devices, e.g., laminar air flow hoods, and other zonal laminar flow hoods utilizing High Efficiency Particulate Air (HEPA) filters, shall be capable of maintaining Class 100 conditions during normal activity;
    c. appropriate refrigeration for storing supplies and sterile products requiring refrigeration subsequent to their preparation and prior to their dispensing or administration to patients. The pharmacy shall maintain documentation of refrigeration integrity, in accordance with its policies and procedures.
    d. appropriate disposal containers for used needles, syringes, and other sharps, and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes; and
    e. temperature-controlled delivery containers, when required.
3. The pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of sterile products. Within the sterile compounding area, prescription drugs, devices, and related materials shall not be stored in shipping containers constructed of corrugated cardboard or other high particulate-producing materials.
4. The pharmacy shall maintain current reference materials related to sterile products accessible to all personnel.

D. Drug Handling. Any sterile compounded product shall be shipped or delivered to a patient in appropriate temperature-controlled delivery containers as defined by USP standards and appropriately stored.

E. Cytotoxic Drugs. In addition to the minimum standards for a pharmacy established by the board, the following requirements are established for pharmacies that prepare cytotoxic drugs, to insure the protection of the personnel involved.
1. All cytotoxic drugs shall be compounded in a vertical flow, Class II Biological Safety Cabinet. Other products shall not be compounded in this cabinet.

2. Personnel compounding cytotoxic drugs shall wear protective apparel, including disposable masks, gloves, and gowns with tight cuffs.
3. Personnel compounding cytotoxic drugs shall use appropriate safety and containment techniques.
4. Prepared doses of cytotoxic drugs shall:
    a. be dispensed and labeled with proper precautions on the inner and outer containers or other device capable of providing a sterile environment; and
    b. be shipped in a manner to minimize the risk of accidental rupture of the primary container.
5. Disposal of cytotoxic waste shall comply with all applicable federal, state, and local requirements.
6. A "Chemo Spill Kit" shall be readily available in the work area, and shall consist of appropriate materials needed to clean up spills of hazardous drugs. Personnel shall be trained in its appropriate use for handling both minor and major spills of cytotoxic agents.

F. Quality Control.
1. An ongoing quality control program shall be maintained and documented that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile products meeting specifications.
    a. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to federal standards for operational efficiency at least every six months. Appropriate certification records shall be maintained.
    b. Written procedures shall be developed requiring sampling if/when microbial contamination is suspected.
    c. When bulk compounding of sterile solutions is performed using non-sterile chemicals, extensive end-product testing shall be documented prior to the release of the product from quarantine. This process shall include appropriate tests for particulate matter and testing for pyrogens.
    d. Written justification shall be maintained of the chosen "beyond use" dates for compounded products.
    e. Documentation shall be maintained of quality control audits at regular, planned intervals, including infection control and sterile technique audits.

G. Labeling.
1. All practitioner administered sterile compounds shall be packaged in a suitable container, and shall bear a label with the following minimum information:
    a. pharmacy's name, address, and telephone number;
    b. preparation name;
    c. strength and concentration;
    d. lot number;
    e. beyond use date;
    f. practitioner's name;
    g. assigned identification number;
    h. special storage requirements, if applicable; and
    i. pharmacist's name or initials.
2. The labeling for all other sterile compounds shall be in accordance with the prescription labeling requirements in §2527 of this Chapter.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004.