Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

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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~~ formulations by Louisiana-licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or administration to patients.

B. Scope. These requirements are intended to apply to all compounded ~~products~~ preparations and pharmacy-generated drugs, 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, amended LR

§2533. Definitions

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

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Manufacturing – means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

Pharmacy-generated Drug – a drug made by a pharmacy.

~~*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.~~

Preparation – a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations; the term *product* will be used to describe manufactured pharmaceutical dosage forms.

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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, amended LR

§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~~ preparations and the making of pharmacy-generated drugs to assure that the finished preparations and products have the identity, strength, quality, and purity they are represented to possess.
2. All ~~compounding~~ drug preparation activities shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment.
    a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of USP Chapter 797.
    b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of USP Chapter 795.
    c. Subject to the allowance provided in Paragraph D of this Section, the making of pharmacy-generated drugs pursuant to the receipt of a non patient-specific practitioner's order shall comply with the provisions of the *Current Good Manufacturing Practices*, as published in 21 CFR 211 or its successor.
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~~ All ~~medications compounded or generated by a pharmacy 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.~~

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

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

Training and Education. All individuals compounding ~~and preparing~~ sterile preparations and generating sterile ~~products~~ drugs shall:

1. Obtain practical and/or academic training in the ~~compounding and dispensing~~ preparation of sterile ~~products~~ drugs;
2. Complete a minimum of one hour of ~~American Council on Pharmaceutical Education~~ Accreditation Council for Pharmacy Education (ACPE) or board-approved continuing education, on an annual basis, related to sterile ~~product~~ drug preparation ~~compounding,~~ dispensing, and utilization;
3. Use proper aseptic technique in all sterile product preparation ~~compounding~~ as defined by the pharmacy practice site's policy and procedure manual;
4. 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~~ make and dispense sterile preparations and products; and
5. 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:
    a. name of the individual receiving the training/evaluation;
    b. date of the training/evaluation;
    c. general description of the topics covered;
    d. signature of the individual receiving the training/evaluation; and
    e. name and signature of the individual providing the training/evaluation.

D. ~~Compounding for Prescriber's Use~~ Pharmacy-generated Drug. Pharmacists may prepare ~~practitioner administered compounds~~ pharmacy-generated drugs for a ~~prescriber's~~ practitioner's use with the following requirements:

1. an order ~~by the prescriber~~ from the practitioner indicating the formula and quantity ordered to be ~~compounded~~ made by the ~~pharmacist~~ pharmacy;
2. the product is to be administered by the ~~prescriber~~ practitioner and not dispensed to the patient;

3. the pharmacist shall generate a label ~~and sequential identification number for the compounded drug~~ for the product which complies with the requirements of Paragraph G of this Section; and
4. a pharmacy may prepare such ~~products~~ drugs in compliance with the compounding standards in USP Chapter 795 for non-sterile preparations or USP Chapter 797 for sterile preparations, provided such drugs made according to these standards shall not ~~to~~ exceed ten percent of the total number of ~~drug dosage units~~ prescriptions dispensed and orders distributed by the pharmacy on an annual basis.
    a. The purpose of this limitation is to ensure at least ninety percent of the total number of prescriptions and orders released from the pharmacy on an annual basis shall be dispensed pursuant to patient-specific prescriptions, and further, no more than ten percent shall be distributed pursuant to non patient-specific orders from a practitioner.
    b. With respect to Louisiana-licensed non-resident pharmacies, the ten percent limitation shall be calculated from the total number of prescriptions and orders sent to Louisiana residents and/or clients.
    c. No pharmacy shall distribute any pharmacy-generated drug products to a state other than the state within which the pharmacy is located.
5. The pharmacy shall label any pharmacy-generated drug product held in the pharmacy 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.
6. The pharmacy shall establish and maintain a record of practitioners receiving pharmacy-generated drugs. Such records shall contain, at a minimum, the name of the practitioner, the name of the drug, the lot number of the drug, and the date of formulation of the drug.

E. Anticipated Use ~~Products~~ Preparations. The pharmacist shall label any excess compounded ~~product~~ preparation 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. Compounding Commercial Products Not Available
A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:
1. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
2. Products temporarily unavailable from ~~distributors~~ manufacturers, as documented by invoice or other communication from the distributor or manufacturer.

G. Labeling of Compounded ~~Products~~ Preparations and Pharmacy-generated Drugs.
1. For patient-specific compounded ~~products~~ preparations, the labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.
2. All ~~practitioner-administered compounds~~ pharmacy-generated drugs 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, amended LR 39: 236 (Emergency Rule effective January 31, 2013), amended LR

§2537. Requirements for Compounding and Generating ~~of~~ Sterile Preparations and Products

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

~~B. Personnel.~~

~~1. The pharmacist in charge shall be responsible for the following:~~

~~a. procurement, storage, compounding, generating, labeling, dispensing, and distribution of all prescription drugs, devices, and related materials necessary in compounding and dispensing the preparation of sterile products drugs;~~

~~b. establishment of policies and procedures for the compounding of sterile preparations and generating 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 preparations as well as the generation and distribution 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 sterile preparations and dispensing generating 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 preparations and generating sterile products shall:~~

~~a. obtain practical and/or academic training in the compounding and dispensing preparation of sterile products drugs;~~

~~b. complete a minimum of one hour of American Council on Pharmaceutical Education Accreditation Council for Pharmacy Education (ACPE) or board-approved continuing education, on an annual basis, related to sterile product drug preparation compounding, dispensing, and utilization;~~

~~c. use proper aseptic technique in all sterile product preparation 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 make and dispense sterile preparations and 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 compounding sterile products preparations and generating 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 drugs; 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 preparations and products are prepared made shall have:

a. a sink with hot and cold running water that shall be located in, or adjacent to, the area where sterile preparations and products are compounded made;

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 as well as sterile preparations and products requiring refrigeration subsequent to their preparation and prior to their dispensing, distribution, 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 preparations and 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 preparations and products accessible to all personnel.

D. Drug Handling. Any sterile compounded preparation or 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 preparations and 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.~~

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 29:2106 (October 2003), effective January 1, 2004, ~~amended~~ repealed LR