TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 37 MINIMUM STANDARDS FOR OUTSOURCING FACILITIES

16.19.37.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.37.1 NMAC - N, 12-13-15]

16.19.37.2 SCOPE: All outsourcing facilities, resident and nonresident, and all persons or entities that own or operate, or are employed by, an outsourcing facility for the purpose of providing pharmaceutical products or services.
[16.19.37.2 NMAC - N, 12-13-15]

16.19.37.3 STATUTORY AUTHORITY: Section 61-11-6 A(6) NMSA 1978 authorizes the board of pharmacy to provide for the licensing of drug manufacturers and for the inspection of their facilities and activities; and to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978. Pursuant to Section 26-1-18 of the Drug, Device and Cosmetic Act, the board is authorized to promulgate regulations for the efficient enforcement of the act.
[16.19.37.3 NMAC - N, 12-13-15]

16.19.37.4 DURATION: Permanent.
[16.19.37.4 NMAC - N, 12-13-15]

16.19.37.5 EFFECTIVE DATE: December 13, 2015, unless another date is cited at the end of a section.
[16.19.37.5 NMAC - N, 12-13-15]

16.19.37.6 OBJECTIVE: The objective of 16.19.37 NMAC is to establish standards for the safe and competent manufacture and distribution of drugs by outsourcing facilities.
[16.19.37.6 NMAC - N, 12-13-15]

16.19.37.7 DEFINITIONS:

A. "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means as a result of an order of a licensed practitioner.

B. "Board" means the New Mexico board of pharmacy.

C. "CFR" means code of federal regulations.

D. "Compounding" means;

(1) manufacturing by an outsourcing facility in accordance with the conditions and requirements of Section 503B of the Federal Food, Drug, and Cosmetic Act; and

(2) manufacturing by a dual purpose facility in accordance with the conditions and requirements of Section 503A, and 503B as applicable, of the Federal Food, Drug, and Cosmetic Act; and

(3) the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug; by an outsourcing facility or dual purpose facility.

E. "Dispense" means the evaluation and implementation of a prescription, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient.

F. "Distribute" means the delivery of a drug or device other than by administering or dispensing.

G. "Dual purpose facility" an outsourcing facility licensed in the state of New Mexico that is also licensed in the state of New Mexico as a pharmacy or non-resident pharmacy.

H. "Manufacture" means the steps in the preparation, propagation, processing or compounding of a drug - the making by chemical, physical, biological or other procedures of any articles which meet the definition of drugs and includes manipulation, sampling or control procedures resulting in the finished dosage form. Manufacture includes all the steps performed on the product itself, which do not affect intrinsically the safety, purity or potency of the product.

I. "Nonresident outsourcing facility" means any outsourcing facility located outside New Mexico, that ships, mails or delivers, in any manner, prescription drugs into New Mexico.

J. "Outsourcing facility" means a facility that is currently registered with the Food and Drug

Administration (FDA) as an outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act, and that meets the requirements of that agency to engage in the compounding and distribution of sterile drugs.

K. "Pharmacist in charge" means a pharmacist who accepts responsibility for the operation of a dual purpose facility or outsourcing facility in conformance with all laws and rules pertinent to the facility operational standards, the practice of pharmacy, and the distribution or dispensing of drugs and who is personally in full and actual charge of the facility and its personnel.

L. "REMS" means a FDA approved risk evaluation and mitigation strategy.

M. "Resident state" means the state in which the nonresident outsourcing facility is physically located in.

N. "The finished dosage form" of a prescription drug is defined as that form of the drug which is or is intended to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging and labeling.

[16.19.37.7 NMAC - N, 12-13-15]

16.19.37.8 LICENSURE OR REGISTRATION:

A. Any outsourcing facility that is engaged in the compounding of sterile drugs in this state shall be registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act and be licensed as an outsourcing facility in this state.

B. Any nonresident outsourcing facility, that distributes or causes to be distributed, compounded sterile drugs into New Mexico shall be registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act and be licensed as a nonresident outsourcing facility.

C. No outsourcing facility shall ship, mail or deliver controlled substances in or into this state unless registered by the Drug Enforcement Administration (DEA) and the board for controlled substances.

D. Applications for a nonresident outsourcing facility under this section shall be made on a form furnished by the board. The board may require such information as it deems is reasonably necessary to carry out the purposes of this section.

E. The board shall not issue an initial or renewed license for an outsourcing facility unless the facility furnishes the board with a report, issued by the appropriate regulatory agency of the resident state, or entity approved by the appropriate regulatory agency of the resident state, or by the FDA, of an inspection that has occurred within the 12 months immediately preceding receipt of the license application by the board (with no intervening change in outsourcing facility ownership). The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

F. No license shall be issued or renewed for an outsourcing facility unless the applicant supplies the board with proof of such registration by the FDA.

G. No license shall be issued or renewed for a non-resident outsourcing facility that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of such licensure or registration. The board may establish, by rule, standards for the licensure of an outsourcing facility that is not required to be licensed or registered by the state in which it is physically located.

H. The license fee shall be as specified in 16.19.12 NMAC, and shall be renewed biennially before the last day of December each year.

I. The board may deny, revoke or suspend an outsourcing facility's registration for any violation of the state drug laws.

[16.19.37.8 NMAC - N, 12-13-15]

16.19.37.9 OPERATIONAL STANDARDS: The following minimum standards shall apply to all outsourcing facilities and dual purpose facilities for which licenses have been issued by the board:

A. All drugs and chemicals used in the manufacturing process or held for sale shall conform to the Drug, Device and Cosmetic Act and shall be stored, preserved and disposed of as prescribed by laws regulating the labeling and manufacture of drugs. When necessary, and/or according to label requirements, all drugs and chemicals which require refrigeration shall be stored and preserved under proper temperature.

B. Facilities must comply with applicable FDA current good manufacturing practice requirements as set forth in title 21, CFR, Subsection 211.1 to 211.208 inclusive (or successor regulations). The definitions and interpretations contained in Section 201 of the Federal Food and Drug Act shall be applicable.

C. Facilities must be in compliance with applicable DEA regulations.

D. Facilities must comply with applicable United States Pharmacopeia requirements.

[16.19.37.9 NMAC - N, 12-13-15]

16.19.37.10 MINIMUM REQUIREMENTS:

A. PHARMACIST IN CHARGE.

(1) Any drugs compounded in an outsourcing facility or dual purpose facility licensed pursuant to this rule shall be compounded by or under the direct supervision of a licensed pharmacist and in accordance with all applicable federal and state laws.

(2) Any drugs repackaged in an outsourcing facility licensed pursuant to this rule shall be repackaged by or under the direct supervision of a licensed pharmacist and in accordance with all applicable federal and state laws.

(3) The pharmacist in charge shall be responsible for the maintenance and implementation of appropriate policies and procedures.

(4) The pharmacist in charge shall be responsible for ensuring proper training and competence of personnel for all duties assigned to or undertaken by personnel.

(5) The pharmacist in charge shall be responsible for ensuring personnel are properly licensed or registered with the board.

(6) The pharmacist in charge shall be responsible for compliance with all federal regulations applicable to outsourcing facilities, and all regulations administered by the board.

B. DUAL PURPOSE FACILITY.

(1) No outsourcing facility may dispense any drug to any person pursuant to a prescription unless it is also licensed as a pharmacy (or nonresident pharmacy) in this state and meets all other applicable requirements of federal and state law.

(2) Required records of the outsourcing facility shall be maintained separate from required records of the pharmacy.

C. RESTRICTIONS.

(1) Any drugs compounded in an outsourcing facility licensed pursuant to this rule shall be compounded in accordance with all applicable federal and state laws.

(2) Any drugs repackaged in an outsourcing facility licensed pursuant to this rule shall be repackaged in accordance with all applicable federal and state laws.

(3) Each repackaged drug product is also accompanied by a copy of the prescribing information that accompanied the original drug product that was repackaged.

(4) The drug product is included on a report submitted to FDA each June and December identifying the drug products made by the outsourcing facility during the previous six month period, and providing the active ingredient(s); source of the active ingredient(s); national drug code (NDC) number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number of individual units produced; and the NDC number of the final product, if assigned.

D. LABELING OF DRUGS COMPOUNDED OR REPACKAGED BY AN OUTSOURCING FACILITY.

(1) The label of any drug compounded by an outsourcing facility shall include, but not be limited to the following:

(a) a statement that the drug is a compounded drug or a reasonable comparable alternative statement that prominently identifies the drug as a compounded drug;

(b) the name, address, and phone number of the applicable outsourcing facility; and

(c) with respect to the drug:

(i) the lot or batch number;

(ii) the established name of the drug;

(iii) the dosage form and strength;

(iv) the statement of quantity or volume, as appropriate;

(v) the date that the drug was compounded;

(vi) the expiration date;

(vii) storage and handling instructions;

(viii) the NDC number, if available;

(ix) the statement that the drug is not for resale, and if the drug product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement "office use only";

(x) a list of the active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient.

(2) The label on the immediate container (primary packaging, e.g., the syringe) of the repackaged product includes the following:

(a) the statement "this drug product was repackaged by (name of outsourcing facility)";

(b) the address and phone number of the outsourcing facility that repackaged the drug product;

(c) the established name of the original, approved drug product that was repackage;

(d) the lot or batch number of the repackaged drug product;

(e) the dosage form and strength of the repackaged drug product;

(f) a statement of either the quantity or volume of the repackaged drug product, whichever is appropriate;

(g) the date the drug product was repackaged;

(h) the beyond use date of the repackaged drug product;

(i) storage and handling instructions for the repackaged drug product;

(j) the NDC number of the repackaged drug product, if available;

(k) the statement "not for resale," and, if the drug product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement "office use only";

(l) when included on the label of the FDA approved drug product from which the drug product is being repackaged, a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described below:

(i) the label on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the repackaged products are distributed) includes;

(ii) the active and inactive ingredients, if the immediate drug product label is too small to include this information;

(iii) the directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

E. CONTAINER. The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include:

(1) a list of active and inactive ingredients, identified by established name, and the quantity or proportion of each ingredient; and

(2) any other information required by regulations promulgated by the commissioner to facilitate adverse event reporting in accordance with the requirements established in Section 310.305 of title 21 of the Code of Federal Regulations (CFR).

F. BULK DRUGS. A drug may only be compounded in an outsourcing facility that does not compound using bulk drug substances as defined in Section 207.3(a)(4) of title 21 of the CFR or any successor regulation unless:

(1) the bulk drug substance appears on a list established by the FDA identifying bulk drug substances for which there is a clinical need;

(2) the drug is compounded from a bulk drug substance that appears on the federal drug shortage list in effect at the time of compounding, distributing, and dispensing;

(3) if an applicable monograph exists under the USP-NF, or another compendium or pharmacopeia recognized by the FDA and the bulk drug substances each comply with the monograph; and

(4) the bulk drug substances are each manufactured by an establishment that is registered with the federal government.

G. INGREDIENTS. When an outsourcing facility uses ingredients, other than bulk drug substances, such ingredients must comply with the standards of the applicable USP-NF monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the FDA for purposes of this subdivision, if any.

H. UNSAFE OR INEFFECTIVE DRUGS. No outsourcing facility may compound or repackage a drug that appears on a list published by the FDA that has been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

I. PROHIBITION ON WHOLESALING. No compounded or repackaged drug will be sold or transferred by any entity other than the outsourcing facility that compounded or repackaged such drug. This does not prohibit the administration of a drug in a health care setting or dispensing a drug pursuant to a properly executed prescription.

J. PROHIBITION AGAINST COPYING AN APPROVED DRUG. No outsourcing facility may compound a drug that is essentially a copy of one or more approved drugs.

K. PROHIBITION AGAINST COMPOUNDING DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES. No outsourcing facility may compound a drug:

(1) that is identified, directly or as part of a category of drugs, on a list published by the FDA that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(2) that is compounded in accordance with all applicable conditions identified on the drug list as conditions that are necessary to prevent the drug or category of drugs from presenting demonstrable difficulties.

L. DISPENSING, COMPOUNDING, AND SALE OF DRUGS; LIMITATIONS. A resident pharmacy shall limit the interstate dispensing of compounded sterile human drug preparation to five percent of the total prescriptions dispensed by that pharmacy, unless registered with the FDA and the board as an outsourcing facility. This requirement will be effective at the time it becomes enforced by the FDA in states that have not entered into a memorandum of understanding with the FDA.

M. ADVERSE EVENT REPORTS.

(1) Outsourcing facilities shall submit a copy of all adverse event reports submitted to the FDA in accordance with the content and format requirements established in section 310.305 of title 21 of the CFR, or any successor regulation, to the executive director of the board. Upon request, follow up reports required by the FDA shall be submitted to the executive director of the board.

(2) Outsourcing facilities shall develop and implement written processes for the surveillance, receipt, evaluation, and reporting of adverse events for the drug products it compounds or repackages as described in 310.305(a) and 211.198 of title 21 of the CFR.

N. DRUG THAT IS THE SUBJECT OF A REMS. If the outsourcing facility compounds from a drug that is the subject of a REMS approved with elements to assure safe use, or from a bulk drug substance that is a component of such drug, the outsourcing facility must demonstrate to FDA before beginning to compound that it will use controls comparable to the controls applicable under the REMS.

O. DRUG RECORDS.

(1) Outsourcing facilities shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of compounded sterile drugs. These records shall include the following information:

(a) the identity and quantity of the drugs received and distributed or disposed of;

(b) the dates of receipt and distribution or other disposition of the drugs;

(c) the name, location and license number of the business, health care practitioner or other entity appropriately licensed to possess, dispense, distribute, administer or destroy prescription drugs.

(2) There shall be a mechanism for tracking and retrieving products that have been recalled.

(3) Resident outsourcing facilities shall maintain compounded sterile preparation batch records in accordance with Subsection B of 16.19.36.15 NMAC.

(4) A record of drugs repackaged must be kept, and include the following: the name and strength of the drug, lot number, name of manufacturer or distributor, beyond use date, date of repackaging, total number of dosage units repackaged, quantity or volume per repackaged container, number of dosage units wasted, initials of repackager and of pharmacist performing final check.

(5) All drugs repackaged by a pharmacist intern or pharmacy technician must undergo a final check by the pharmacist.

(6) Every registrant under the Controlled Substances Act, manufacturing, distributing or dispensing a controlled substance shall maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold or delivered by him in accordance with regulations of the board.

(7) Records shall be kept by all persons licensed pursuant to the Pharmacy Act of all dangerous drugs, their receipt, withdrawal from stock and use or other disposal. The records shall be open to inspection by the board or its agents, and the licensee shall be responsible for the maintenance of the records in proper form.

(8) Records required by board-administered law or regulation shall be available for inspection and photocopying by the board's state drug inspectors for three years.

P. SUCCESSOR REGULATIONS OR FEDERAL FOOD, DRUG AND COSMETIC ACT SECTIONS. 16.19.37 NMAC shall apply to any successor or re-designated CFR, or Federal Food, Drug, and Cosmetic Act section referenced in this part.

[16.19.37.10 NMAC - N, 12-13-15]

HISTORY OF 16.19.37 NMAC: [RESERVED]