16.19.6.30 REPACKAGING AND DISTRIBUTION BY A PHARMACY

A. Scope: This section applies only to repackaging by a pharmacy licensed by the board, under the conditions specified in this section.

B. Definitions as used in this section.

(1) "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.

(2) "board" means the New Mexico Board of Pharmacy

(3) "distribute" means the delivery of a drug or device other than by administering or dispensing.

(4) "**finished drug product**" 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.

(5) "**FD&C Act**" means the Federal Food Drug and Cosmetic Act.

(6) "**repackaging**" means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug, excluding:

(a) placing medication in a different container to dispense directly to the patient pursuant to a patient-specific prescription;

(b) removing a drug product from the original container at the point of care for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient.

(7) "**USP**" means United States Pharmacopoeia.

(8) "**USP standards**" means standards published in the current official United States pharmacopoeia-national formulary.

C. A pharmacy licensed by the board may repackage under the following conditions:

(1) The pharmacy must qualify for an exemption from registration and listing requirements under section 510 of the FD&C Act. Specifically, under section 510(g)(1), the registration and listing requirements of section 510 do not apply to: pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

(2) The drug product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include administration of a repackaged drug product in a health care setting.

(3) The drug repackaged is a finished drug product of a prescription drug that is:

(a) a non-sterile solid or liquid oral dosage form;

(b) approved under section 505 of the FD&C Act;

(c) repackaged by or under the direct supervision of a pharmacist, and undergoes a final check by a pharmacist;

(d) handled and repackaged in accordance with all applicable USP chapters numbered less than <1000>;

(e) assigned a beyond use date in accordance with USP standards;

(f) repackaged, stored, and shipped in a way that does not conflict with approved drug product labeling;

(g) not adulterated by preparing, packing, or holding the drug product under insanitary conditions;

(h) repackaged into a unit-dose container

(4) The repackaged drug product is distributed under the following conditions:

(a) by a managing pharmacy for use in an automated drug distribution system to supply medications for patients of a health care facility licensed under 16.19.11 NMAC, or inpatient hospice facility licensed under 16.19.10.12 NMAC, in accordance with 16.19.6.27 NMAC, or emergency kit.

(b) To a correctional facility, licensed by the board under 16.19.10.11 NMAC, for administration to an inmate pursuant to a patient-specific prescription or order.

(c) To a clinic licensed by the board under 16.19.10.11 NMAC, and under the same ownership as the repackaging pharmacy, for administration to a patient of the clinic pursuant to a patient-specific prescription or order.

(5) All units of repackaged medication must be labeled with the following information.

(a) name, address, and telephone number of repackaging pharmacy, unless the repackaged drug is used in an automated drug distribution system in accordance with 16.19.6.27 NMAC

(b) Name, strength, and quantity of the drug.

(c) Lot number or control number.

(d) Name of manufacturer.

(e) beyond use date

(f) Date drug was repackaged.

(g) Name or initials of repackager.

(h) Federal caution label, if applicable.

(6) A record of drugs repackaged must be maintained, and include the following.

(a) Date of repackaging

(b) Name and strength of drug

(c) manufacturer assigned drug lot number, and expiration date

(d) Name of drug manufacturer

(e) assigned beyond-use date

(f) Total number of dosage units (tabs, caps) repackaged

(g) Quantity per each repackaged unit container

(h) Number of dosage units wasted

(i) Initials of repackager, and of pharmacist performing final check.

(7) Records as required by the Pharmacy Act; the Drug, Device, and Cosmetic Act; the Controlled Substance Act; and board regulations shall be maintained.