16.19.30.9 OPERATIONAL STANDARDS:

A. General requirements.

(1) Non-sterile drug products may be compounded in licensed pharmacies as a result of a practitioner's prescription order based on the practitioner-patient-pharmacist relationship in the course of professional practice.

(2) Preparing limited quantities of prescription drug orders in anticipation based upon a history of receiving valid prescriptions issued within an established practitioner-patient-pharmacist relationship in the course of professional practice.

(a) The beyond-use date should be based on the criteria outlined in USP Chapter <795>.

(b) Any product compounded in anticipation of future prescription drug or medication orders shall be labeled. Each label shall contain:

(i) name and strength of the compounded medication or list of the active ingredient and strengths;

(ii) facility's lot number;

(iii) beyond-use date;

(iv) quantity or amount in the container.

(3) Commercially available product may be compounded for dispensing to individual patients provided the following conditions are met:

(a) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs; and

(b) the prescribing practitioner has requested that the drug be compounded; or

(c) if the compounded product is changed to produce for that patient a significant difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if use of the compounded product is in the best interest of the patient; "significant difference" would include the removal of a dye for medical reason such as an allergic reaction; when a compounded product is to be dispensed in place of a commercially available product, the prescriber and patient shall be informed that the product will be compounded.

~~(4) Compounding for a prescriber's office use.~~

~~(a) Pharmacies may prepare compounding drug products for a duly authorized prescriber's office use.~~

~~(b) An order by the duly authorized prescriber, indicating the formula and quantity ordered will be filed in the pharmacy.~~

~~(c) The product is to be administered in the office.~~

~~(d) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer or by hard-copy record.~~

~~(e) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.~~

~~(5)~~ (4) Compounding veterinarian products.

(a) Prescriptions for animals may be compounded based on an order or prescription from a duly authorized veterinarian.

(b) These prescriptions are to be handled and filled the same as the human prescriptions.

~~(6)~~ (5) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide non-sterile prescription compounding services which may include specific drug products and classes of drugs.

B. Environment.

(1) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of drug products including the placement of equipment and materials. Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity, which is adequate for safe and orderly compounding.

(2) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(3) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition.

(4) When drug products that require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its' use for the preparation of other drug products, must be used in order to prevent cross-contamination.

C. Equipment and Supplies. The pharmacy shall:

(1) have a class A prescription balance, or analytical balance and weights when necessary which shall be properly maintained and subject to inspection by the New Mexico board of pharmacy and;

(2) have equipment and utensils necessary for the proper compounding of prescription or medication drug orders; such equipment and utensils used in the compounding process shall be:

(a) of appropriate design and capacity, and be operated within designated operational limits;
(b) of suitable composition so that surfaces that contact components, in-process material or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond the desired result;
(c) cleaned and sanitized appropriately prior to each use and;
(d) routinely inspected, calibrated when necessary or checked to ensure proper performance.

D. Labeling. In addition to the labeling requirements of the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription or medication drug order shall contain the following:
(1) the generic name(s) or the designated name and the strength of the compounded preparation;
(2) the quantity dispensed;
(3) the date on which the product was compounded;
(4) a lot or batch number, and;
(5) the beyond-use date after which the compounded preparation should not be used;
(a) in the absence of stability information applicable for a specific drug in the USP/NF the preparation shall adhere to the following maximum beyond-use date guidelines:
(i) non-aqueous liquids and solid formulations (where the manufactured drug product is the source of active ingredient) 25% of the time remaining until the manufacturer's product's expiration date or six (6) months, whichever is earlier;
(ii) water-containing formulations (prepared from ingredients in solid form) not later than fourteen (14) days when refrigerated between 2-8 degrees Celsius or 36-46 degrees Fahrenheit;
(iii) all other formulations: intended duration of therapy or 30 days, whichever is earlier;
(b) beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

E. Drugs, components and material used in non-sterile compounding.
(1) Drugs used in non-sterile compounding shall preferably be a USP/NF grade substance manufactured in a FDA registered facility.
(2) In the event that USP/NF grade substances are not available, documentation of stability and purity must be established and documented.
(3) A pharmacy may not compound a drug product which has been withdrawn or removed from the market for safety reasons.

F. Compounding Process. The safety, quality and performance of compounded prescriptions depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. Each pharmacy shall develop and follow written SOP's based on established compounding procedures as outlined in chapter 795 of the USP/NF concerning pharmacy compounding of non-sterile preparations designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process.

G. Quality Control.
(1) The safety, quality, and monitoring is used to insure that the output of compounded drug products for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity or pH of solutions are met. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795 of the USP/NF concerning pharmacy compounding of non-sterile preparations, chapter 1075 of the USP/NF concerning good compounding practices, and chapter 1160 of the USP/NF concerning pharmaceutical calculations in prescription compounding. Such procedures shall be documented and be available for inspection.
(2) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a compounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.
(3) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit volume and not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.
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