This is an amendment to 16.19.30 NMAC, Section 6, 7, 9 and 10 effective 8/13/2024

16.19.30.6 OBJECTIVE: The objective of part 30 of chapter 19 is to provide standards for the compounding of non-sterile pharmaceuticals. Pharmacies compounding non-sterile pharmaceuticals shall comply with the requirements of this [~~section~~] part in addition to all provisions for their specific license classification. [16.19.30.6 NMAC - N, 9/15/2006; A, 8/13/2024]

16.19.30.7 DEFINITIONS: In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings unless the context clearly indicates otherwise.

A. "Active pharmaceutical ingredient (API)" any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

B. "Beyond-use date (BUD)" the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

C. "Component" any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product labeling.

D. "Compounding" the preparation, mixing, assembling, packaging, or labeling of a drug or device (reconstitution of commercial products is not considered compounding for purposes of this article).

(1) as the 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 orders based upon a history of receiving valid prescriptions issued within an established practitioner-patient-pharmacist relationship in the course of professional practice;

(3) reconstitution of commercial products is not considered compounding for purpose of this article.

(4) the addition of a flavoring agent to a conventionally manufactured product is not considered compounding as long as the following conditions are met:

(a) the flavoring agent is inert, nonallergenic, and produces no effect other than the instillation or modification of flavor;

(b) the flavoring agent does not alter a medication's concentration beyond USP's accepted level of variance;

(c) the addition of flavoring agent(s) is documented in the prescription record.

E. "FDA" Food and Drug administration.

F. "SOP's" standard operating procedures.

G. "USP/NF" the current edition of the United States Pharmacopeia/National Formulary. [16.19.30.7 NMAC - N, 9/15/2006; A, 12/13/2015; A, 9/14/2021; A, 8/13/2024]

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 veterinary preparations.

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

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

(c) Compounding of drugs for animals must be in accordance with the Animal Medicinal Drug Use Clarification Act of 1994 or successor Act.

(d) A licensed pharmacy may compound veterinary drug preparations in reasonable quantities, in accordance with Paragraph (5) of Subsection DDD of 16.19.8.7 NMAC to be used by veterinarians in their office for administration to patients ("office use preparations").

(e) Compounded office use preparations may be dispensed by a veterinarian to clients only under the following conditions:

(i) a valid veterinarian client patient relationship exists;

(ii) the patient has an emergency condition that the compounded drug is necessary to treat;

(iii) dispensed amount is for use in a single course of treatment, not to exceed a 120-hour supply;

(iv) timely access to a compounding pharmacy is not available; and

(v) the medication is not a controlled substance;

(f) Compounded controlled substance veterinary office use preparations may be distributed by a pharmacy under the following conditions:

(i) the preparation is not readily available from an outsourcing facility;

(ii) ordering and distribution occur in compliance with applicable state and federal law;

(iii) the pharmacy shall be registered with the DEA as a manufacturer; and

(iv) in addition to other required labeling, such preparations shall bear a statement "For administration only. Not for dispensing or resale."

(g) Prohibition on wholesaling:

(i) Office use preparations will not be distributed by a person other than the pharmacy that compounded such veterinary drug preparations.

(ii) This does not prohibit administration or dispensing pursuant to a prescription drug order executed in accordance with federal and state law; and the conditions of this Paragraph (4).

(h) Providing samples of compounded veterinary preparations is prohibited.

(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 **or preparation** in the USP/NF the preparation shall adhere to the following maximum beyond-use date guidelines: unless pursuant to methodology and specifications outlined in the current chapter of USP <795>.

(i) for non-aqueous formulations (other than oral liquid) - the BUD is not later than the time remaining until the earliest expiration date of any API or six months, whichever is earlier when stored at controlled room temperature or refrigerator;

(ii) for non-aqueous oral liquids – the BUD is not later than the time remaining until the earliest expiration date of any API or 90 days, whichever is earlier, when stored at controlled room temperature or refrigerator;

[~~**ii**~~] **(iii)** for [~~water-containing oral~~] nonpreserved aqueous formulations - the BUD is not later than the time remaining until the earliest expiration date of any API or 14 days, whichever is earlier, when stored at controlled cold temperatures;

[~~**iii**~~] **(iv)** for [~~water-containing topical/dermal and mucosal liquid and semisolid formulations - the BUD is not later than 30 days.~~] preserved aqueous formulations, the BUD is not later than the time remaining until the earliest expiration date of any API or 35 days, whichever is earlier, when stored at controlled room temperature or refrigerator.

(b) beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation; **the BUD shall not be later than the expiration date on the container of any component.**

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~~] ninety percent and not more than [~~110.0~~] one hundred-ten percent of the theoretically calculated and labeled quantity of active ingredient per unit volume and not less than [~~90.0~~] ninety percent and not more than [~~110.0~~] one hundred-ten percent of the theoretically calculated weight or volume per unit of the preparation.

[16.19.30.9 NMAC - N, 9/15/2006; A, 6/29/2013; A, 12/19/2013; A, 12/13/2015; A, 12/15/2020; A, 9/14/2021; A, 8/13/2024]

16.19.30.10 RECORDS:

A. Maintenance of records. Every record required by this section shall be kept by the pharmacy for at least three (3) years.

B. Compounding records.

(1) Master Formulation records must include:

(a) provides a consistent source document for preparing the preparation (recipe);

(b) is a file of individual compounded preparations;

(c) [~~must~~] list the name, strength, and dosage form of the preparation compounded;

(d) [~~must~~] list all ingredients and their quantities;

(e) [~~must~~] list equipment needed to prepare the preparation, when appropriate, and mixing instructions;

(f) other environmental controls, such as the duration of mixing and other factors pertinent to the replication of the preparation as compounded; [~~and~~]

(g) [~~must contain~~] the beyond-use date and [~~methodology~~] reference source to support the assigned BUD, the container closure system(s) used in dispensing, the storage requirements, [~~and any~~] quality control procedures (e.g., pH testing, visual inspection) and expected results;

(h) physical description of the final compounded nonsterile preparation;

(i) if applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s); and

(j) labeling requirements (e.g. shake well).

(2) Compounding records:

(a) document the [~~actual ingredients in the preparation and the person responsible for the compounding activity~~] name and weight or measurement of each ingredient;

(b) contain the name and strength of the compounded preparation, the formulation record reference for the preparation, [~~and~~] the [~~sources~~] vendors or manufacturers, [~~and~~] lot numbers, and expiration dates of the ingredients;

(c) contain information on the total quantity and number of dosage units compounded, the name of the person who prepared the preparation and the name of the pharmacist who approved the preparation;

(d) contain the date of the preparation, the assigned internal identification number or the prescription number and an assigned beyond-use date; and

(e) for all compounded preparations, results of quality control procedures are to be recorded [~~.~~];

(f) if applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s);

(g) physical description of the final compounded non-sterile preparation.

[16.19.30.10 NMAC - N, 9/15/2006; A, 8/13/2024]