02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 42: COMPOUNDING DRUGS FOR VETERINARIAN OFFICE USE

Summary: This chapter establishes the terms and conditions for compounding drugs for veterinarian office use pursuant to the 32 M.R.S. § 13722(1)(B-2). This Chapter was developed in consultation with the Maine State Board of Veterinary Medicine, in accordance with P.L. 2021, ch. 289, Sec. 15.

1. **Definitions.**

   1. **Compounding drugs for veterinarian office use.** "Compounding drugs for veterinarian office use" means the compounding of nonpatient-specific drugs for veterinarian office use according to the terms and conditions described in this chapter.

   2. **Nonfood-producing animal.** "Nonfood-producing animal" means any domesticated animal including canine, feline, fowl, bird, fish, or reptile, except those animals intended for consumption or whose products are intended for consumption by humans or other animals.

2. **Pharmacy Requirements and Specifications**. The pharmacy compounding drugs for veterinarian office use shall comply with USP [or] Current Good Manufacturing Practices and all applicable controlled substance laws and regulations.

   [Any pharmacy compounding drugs for veterinarian office use must comply with the operational requirements of compounding pharmacies as set forth in Board rules for either non-sterile compounding pharmacies (Chapter 13, Section 7) or sterile compounding pharmacies (Chapter 37, Section 10).]

3. **General Requirements for Compounding Drugs for Veterinarian Office Use; Content of Orders**.

   1. [**Limit on Use of Bulk Drug Substances**. A pharmacist compounding drugs for veterinarian office use from bulk drug substances should first confirm that the bulk drug substances are on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals, available at https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals].

   2. **Required Information in Order**

      Orders for a compounded drug for veterinarian office use shall contain, at a minimum, the following information:

      A. Name, address and telephone number of the licensed veterinarian;

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B. An acknowledgment, signed by the licensed veterinarian submitting the order, stating the veterinarian understands that the compounded drug is being provided for veterinarian office use and:

i. will only be dispensed or administered to nonfood-producing animals that are patients of the veterinarian with a valid veterinarian-client-patient relationship;

ii. will only be dispensed or administered for the treatment of emergency conditions, when, as determined by the prescribing veterinarian, urgent treatment is needed to avoid animal suffering or death and there is no timely access to a compounding pharmacy to compound and dispense the drug under a patient-specific prescription;

iii. the quantity dispensed by a prescribing veterinarian will not exceed a 120-hour supply; and

iv. the prescribing veterinarian will provide instructions to owners to contact the prescribing veterinarian immediately if a compounded preparation has caused an adverse event or the owner suspects a defective drug product, and the veterinarian will report this information to the compounding pharmacy and the FDA Center for Veterinary Medicine.

For the purposes of this subsection, a signature may either be original or electronic.

3. **Verification**.

The pharmacist who receives an order for compounded drugs for veterinarian office use shall record the order and verify the identity of the licensed veterinarian, and, if applicable, the identity and authority of the veterinarian's agent.

4. **Labeling requirements.** Compounding drugs for veterinarian office use shall be labeled in a conspicuous and legible manner, as appropriate for the size and attributes of the container.

The label shall include:

1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Name, address, and telephone number of the licensed veterinarian who placed the order;
4. The name and strength of the compounded preparation or a list of the active ingredients and the strength of the active ingredients in the compounded preparation;
5. The quantity of compounded preparations;
6. Cautionary statements if appropriate for the drug;

7. An appropriate beyond-use date as determined by the pharmacist in compliance with United States Pharmacopeia and the National Formulary (USP-NF) standards for pharmacy compounding; and,
8. Text reprinted as follows:

Notice: Compounded Preparation For Veterinarian Office Use Only. Intended only for dispensing and administration for nonfood-producing animals for the treatment of emergency conditions, when, as determined by the prescribing veterinarian, timely access to a compounding pharmacy is not available. Intended for dispensing or administration in a quantity not to exceed a 120-hour supply.

Please contact the FDA Center for Veterinary Medicine immediately if a compounded preparation has caused an adverse event or if there is a suspected defective drug product involving these compounded preparations.

4. **Record-keeping requirements.**

The pharmacy compounding a drug pursuant to this chapter shall comply with all other laws and rules of the board concerning record-keeping. Any pharmacy compounding a drug pursuant to this chapter shall maintain an activity records of the distribution of the compounded drug to the veterinarian and have the ability to retrieve compounding and distribution records by both preparation and by specific veterinarian, if requested by the board or its agent.

The board or its authorized agent may inspect and make copies of any and all records of shipment, purchase, compounding record activities, quality control, and sale of these items provided, however, that such inspection shall not extend to financial data or pricing data.

5. **Defective Drug Products and Adverse Events**

If a pharmacist learns of an adverse event or a suspected defective drug product involving compounded preparations it prepared, it shall without delay report this information to the board and any and all licensed veterinarians that, according to the pharmacy's records, the compounded preparation was provided to. The pharmacist should also notify the FDA of any adverse event or product defect associated with the use of the drug within fifteen (15) days.

STATUTORY AUTHORITY:

32 M.R.S. §§ 13720, 13723, 13722(1)(B-2)

EFFECTIVE DATE: