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FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 1462

(Delegate Bromwell, *et al.*)

Health and Government Operations

Education, Health, and Environmental Affairs

Veterinarians, Pharmacies, and Pharmacists - Dispensing Compounded
Preparations for Use by Nonfarm Animals

This bill authorizes a licensed veterinarian to dispense compounded nonsterile preparations or compounded sterile preparations to a “nonfarm animal” under specified circumstances. A pharmacy, and a licensed pharmacist under specified circumstances, may provide compounded nonsterile preparations or compounded sterile preparations without a patient-specific prescription to a licensed veterinarian who intends to dispense the preparations to a nonfarm animal in accordance with the bill.

Fiscal Summary

State Effect: Any changes to the regulations or websites of the State Board of Veterinary Medical Examiners or the State Board of Pharmacy can be handled with existing budgeted resources. Revenues are not affected.

Local Effect: None.

Small Business Effect: Minimal impact on small business pharmacies and veterinary practices.

Analysis

Bill Summary: “Compounded nonsterile preparations” means products compounded in accordance with USP 795. “USP 795” means the standards set forth in the United States Pharmacopeia, General Chapter 795, “Pharmaceutical Compounding – Nonsterile Preparations.”

A person may practice veterinary medicine and sell or dispense medication that is not in the original manufacturer's container if (1) the medication is for use by a nonfarm animal and (2) the person affixes to the container in which the medication is sold or dispensed, a label clearly showing the brand, generic or chemical name, and strength, if indicated, of the medication; the type of nonfarm animal for which the medication is designated; and the owner's last name.

A licensed veterinarian may dispense compounded nonsterile preparations or compounded sterile preparations if (1) the preparations are to be used for a nonfarm animal; (2) the nonfarm animal is a patient of the licensed veterinarian; (3) the quantity of the preparations dispensed does not exceed a seven-day supply; (4) the licensed veterinarian determines that timely access to a compounding pharmacy is not available and that the preparations are not otherwise commercially available; (5) the preparations are provided to the licensed veterinarian by a pharmacist in accordance with specified provisions; and (6) the preparations are dispensed in a container with a label clearly showing specified information.

Nothing in the Health Occupations Article prohibits a licensed veterinarian from dispensing, in accordance with the bill, compounded nonsterile preparations or compounded sterile preparations provided by a pharmacy.

A pharmacist may provide compounded nonsterile preparations or compounded sterile preparations without a patient-specific prescription to a licensed veterinarian who intends to dispense the preparations to a nonfarm animal as specified under the bill if the pharmacist (1) complies with USP 795 or USP 797, as applicable; (2) labels the preparations with specified information; and (3) complies with applicable federal law and regulations.

A pharmacist may not provide compounded sterile preparations or compounded nonsterile preparations compounded using bulk substances to a licensed veterinarian (1) in an amount greater than 10% of the total amount of drug products sold or dispensed from the pharmacy or (2) if the preparations are copies or close approximations to products approved by the U.S. Food and Drug Administration (FDA). Calculation of the total amount of drug products sold or dispensed from the pharmacy must be made on an annual basis and use the number of dosage units sold or dispensed. For nonresident pharmacies, the total amount of drug products sold or dispensed must be the pharmacy's total business within the State. These provisions do not apply to dispensing of compounded nonsterile preparations or compounded sterile preparations dispensed for a patient-specific prescription.

Current Law: “Compounded sterile preparations” means biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be compounded using aseptic techniques. In Maryland, a licensed veterinarian may administer compounded products but is specifically prohibited from dispensing or reselling products compounded by a pharmacy. Both Maryland and federal law authorize a pharmacist to compound animal drugs only pursuant to an order of a veterinarian based on a valid veterinarian-client-patient relationship. If a veterinarian is in need of a certain drug for office use inventory, he or she must purchase that drug from a licensed wholesale distributor. A pharmacy may compound animal drugs pursuant to a patient-specific prescription, provided that the drug is not compounded from bulk substances and otherwise conforms with federal requirements.

Background: The State Board of Pharmacy has received numerous letters of concern from Maryland veterinarians concerning the inability to obtain compounds of prescription drugs from pharmacies for office use because many compounded drugs for various species, breeds, and sizes of companion animals are not commercially available.

According to the American Veterinary Medical Association (AVMA), as of August 2015, nine states (including Virginia) have laws or regulations that permit licensed veterinarians to administer *and dispense* compounded products, in some cases under specified conditions. AVMA reports that compounding is critical for veterinary medicine because of the limited number of FDA-approved drug products for the many species and conditions that veterinarians treat.

Additional Information

Prior Introductions: None.

Cross File: Although designated as a cross file, SB 614 (Senator Conway - Education, Health, and Environmental Affairs) is not identical.

Information Source(s): American Veterinary Medical Association, Maryland Department of Agriculture, Department of Health and Mental Hygiene, Department of Legislative Services

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Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510