

Article - Health Occupations

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§12–510.

(a) Except as provided in subsection (b) of this section, 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 compounded nonsterile preparations or compounded sterile preparations in accordance with § 2–313(c) of the Agriculture Article if the pharmacist:

(1) Complies with USP 795 or USP 797, as applicable;

(2) Labels the compounded nonsterile preparations or compounded sterile preparations with:

(i) The name and strength of the compounded nonsterile preparations or compounded sterile preparations or a list of the active ingredients and the strength of the active ingredients in the compounded nonsterile preparations or compounded sterile preparations;

(ii) An appropriate beyond-use date as determined by the pharmacist in accordance with USP–NF standards for pharmacy compounding;

(iii) The quantity of compounded nonsterile preparations or compounded sterile preparations; and

(iv) The name, address, and license number of the pharmacy;
and

(3) Complies with applicable federal law and regulations.

(b) (1) This subsection does not apply to dispensing compounded nonsterile preparations or compounded sterile preparations dispensed for a patient-specific prescription.

(2) A pharmacy may not provide compounded nonsterile preparations or compounded sterile preparations compounded using bulk drug substances to a licensed veterinarian:

(i) In an amount greater than 10% of the total amount of drug products sold or dispensed from the pharmacy; or

(ii) If the compounded nonsterile preparations or compounded sterile preparations are copies or close approximations to products approved by the federal Food and Drug Administration.

(3) For purposes of the limitation established in paragraph (2)(i) of this subsection:

(i) The calculation shall be made on an annual basis and use the number of dosage units sold or dispensed; and

(ii) For nonresident pharmacies, the total amount of drug products sold or dispensed shall be the pharmacy's total business within the State.

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