

Virginia Board of Veterinary Medicine

Use of Compounded Drugs in Veterinary Practice

Applicable Laws

§ 54.1-3401. Definitions.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ [54.1-2900](#) et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § [54.1-2901](#), or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § [54.1-2901](#) shall not be considered compounding.

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § [54.1-3303](#) relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's [Pharmacy] regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § [54.1-3420.2](#).

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the

facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ [54.1-3301](#), [54.1-3304](#), and [54.1-3304.1](#) shall comply with all provisions of this section and the relevant Board regulations.

Guidance

Q: May a veterinarian prescribe a compounded drug product?

A: A Virginia licensed veterinarian may prescribe a compounded drug product by preparing a valid prescription pursuant to federal and state laws and regulations for an individual patient with which there exists a valid veterinarian-client-patient relationship. The client may obtain the compounded drug product from a pharmacy of their choice that is properly licensed by the Virginia Board of Pharmacy. The payment arrangements for a prescribed compounded drug product are not under the purview of the Board of Veterinary Medicine. However, a pharmacist must be compliant with the Virginia Board of Pharmacy regulation, 18VAC110-20-390(A), which states "A Pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, 'kickbacks,' fee-splitting, or special charges in exchange for prescription orders unless fully disclosed in writing to the patient and any third party payor."

Q: May a veterinarian obtain compounded drug products from a pharmacy for administration in their office?

A: Yes, a Virginia licensed veterinarian may obtain compounded drug products from a pharmacy that is properly licensed by the Virginia Board of Pharmacy for *administration* in the course of their professional practice. Pursuant to Virginia Code § 54.1-3410.2(C) the pharmacist is required to label the compounded drug product with the statement "For Administering in Prescriber Practice Location Only."

Q: May a veterinarian dispense a compounded drug product?

A: A veterinarian may dispense a compounded drug product *if compounded by the veterinarian* pursuant to Virginia Code § 54.1-3410.2(J).

Q: May a pharmacy provide compounded drug products to a veterinarian for the veterinarian to dispense to his patients?

A: No, Virginia Code § 54.1-3410.2 prohibits pharmacists from distributing compounded drug products for subsequent distribution or sale to other persons.

Q: What is the penalty for a licensee of the Virginia Board of Veterinary Medicine who is found to be dispensing compounded drug product purchased from a pharmacy?

A: The licensee may be subject to disciplinary action.