Administration and dispensing of compounded veterinary drugs

AVMA State Relations compiled the following summaries of state laws and regulations addressing the administration or dispensing of compounded drugs in a veterinarian’s office or clinic. The summaries are updated on an on-going basis as needed.

Note that these summaries are general in nature. State laws and regulations place restrictions and conditions placed on prescribing, administering or dispensing compounded drugs. We advise veterinarians to be familiar with the statutes and regulations governing compounding in their states.

We also advise veterinarians to check with their state boards of veterinary medicine and pharmacy on how the compounding laws and regulations in their states are interpreted and enforced. In the states with no laws specifically addressing compounding, or where the laws are vague, veterinarians may be at risk in administering or dispensing such products.

State laws and regulations that allow veterinary offices to administer compounded products and dispense the products to clients but may be subject to conditions or limitations in some cases:
California, Colorado, Florida, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, Ohio, Tennessee, Texas, Virginia (13)

State laws and regulations that allow veterinary offices to administer compounded products but do not specifically address or the law is not clear regarding dispensing products compounded by a pharmacy:
Idaho, Illinois, Mississippi, Montana, Nevada, New Hampshire, New Jersey, Oregon, South Carolina (9)

State laws and regulations that allow veterinary offices to administer compounded products but specifically prohibit them from dispensing or reselling products compounded by a pharmacy:

States that prohibit compounding for office use:
Delaware, New Mexico, New York (3)

States in which we did not find laws and regulations addressing compounding:
Hawaii, Indiana, Kansas, Pennsylvania, South Dakota, Wisconsin (6)

Summaries of individual states’ laws and regulations

Alabama
Alabama allows a pharmacy to prepare a compounded drug product for a prescriber’s office use but does not allow the product to be dispensed to the consumer.
Alaska
Alaska allows a pharmacist to offer compounded drug products in the course of professional practice for a prescribing practitioner to administer to an individual patient, but may not offer the product for resale. It is unclear whether or not a practitioner can maintain a quantity of compounded products in the office.

Arizona
The state veterinary practice act was revised in 2013 to state that a veterinarian may dispense drugs and devices kept by the veterinarian under certain conditions. A veterinarian shall dispense only to the animal's owner or person responsible for the animal he or she is treating and only for conditions being treated by that veterinarian. For the purposes of this section, "dispense" is defined to include prescribing, administering, packaging, labeling, compounding, and security necessary to prepare and safeguard the drug or device for delivery. Pharmacy regulations state that pharmacies may provide a compounded product to a medical practitioner to administer to a patient of the medical practitioner.

Arkansas
Pharmacies may prepare compounded drug products for a prescriber's office use but the products can only be administered in the office and not dispensed to the patient. However, compounding for office stock for veterinarians is prohibited except for compounds to be used in life-threatening situations where lack of immediate availability of the product could result in patient harm and no FDA-approved product is commercially available.

California
A pharmacist may furnish a reasonable quantity of compounded drug products to a prescriber for office use by the prescriber. A "reasonable quantity" is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber. A pharmacist who furnishes a prescriber with a "compounded medication" is to exercise his or her best judgment as to whether the quantity of the drug is appropriate considering a number of factors. The State Attorney General issued an opinion that "prescriber office use" includes furnishing drugs for prescribers which can be dispensed for administration outside the prescriber's office or clinic.

Colorado
A prescription-drug outlet may compound a drug for use by a veterinarian to maintain as part of the veterinarian's office stock. A veterinarian may dispense a product, up to a 5-day supply, under a valid veterinarian-client-patient relationship if the drug is used for an emergency condition and a compounding pharmacy cannot be accessed in a timely manner. The amount of drugs compounded and distributed must not exceed 10 percent of the total of the units dispensed annually by the outlet.

Connecticut
A sterile compounding pharmacy may provide compounded products to practitioners to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision, except that the quantity of such compounded products shall be limited to a two-week supply.
Delaware
Board of Pharmacy rules finalized in March 2016 provide that compounded preparations may not be sold to practitioners for office use unless covered by a “federal authority.” Given that there is no federal regulation on compounded medications for use in animals, these regulations may, in effect, prohibit these drugs from being used in veterinary practice.

District of Columbia
Manufacturing does not include the preparation or compounding of a drug by a pharmacist, practitioner, or any other authorized person incidental to administering or dispensing a drug or conducting research, teaching, or chemical analysis on a drug in the course of professional practice.

Florida
The Florida Pharmacy Act and the rules adopted thereunder do not prohibit a licensed veterinarian from administering a compounded drug to a patient, or dispensing a compounded drug to the patient’s owner or caretaker.

Georgia
Pharmacists may offer compounded drugs in the course of professional practice for a prescriber to administer to an individual patient. Dispensing by the practitioner is not allowed.

Idaho
Idaho allows the sale of minimal quantities of prescription drugs to practitioners for office use. Veterinary drug outlets, which includes places that dispense or distribute drugs, or their agents or employees, may possess legend drugs, excluding controlled substances, for use in the usual and lawful course of their business or practice or in the performance of their lawful official duties, without a valid prescription drug order.

Illinois
Commercially available products may be compounded for dispensing to individual patients only if all of the following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient’s needs and (ii) the prescribing practitioner has requested that the drug be compounded.

Iowa
Pharmacists may offer compounded drug products in the course of professional practice for a practitioner to administer to an individual patient. Pharmacists shall not offer compounded drug products to other licensed persons or commercial entities for subsequent resale except in the course of professional practice for a practitioner to administer to an individual patient.

Kentucky
A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug for a practitioner’s office administration, but that product may not be dispensed to the patient. A compounded drug that contains a controlled substance shall not be compounded for office administration.
Louisiana
Board of Pharmacy rules are intended to facilitate the preparation of medications needed for emergency use in a veterinary office practice; pharmacies are authorized to compound drugs for office use without the necessity of a patient-specific prescription. However, any dispensed compounded product must be generated by a pharmacy after receipt of a patient-specific prescription. No Louisiana-licensed pharmacy may distribute any amount of practitioner-administered compounds in excess of five percent of the total amount of drug products dispensed and/or distributed from their pharmacy.

Maine
Manufacturing does not include the preparation or compounding of a drug by an individual for personal use or the preparation, compounding, packaging or labeling of a drug by a pharmacist or practitioner incidental to administering or dispensing a drug in the course of professional practice.

Maryland
A licensed veterinarian may administer compounded products but is specifically prohibited from dispensing or reselling products compounded by a pharmacy. A pharmacist may 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.

**Effective October 1, 2016:** A licensed veterinarian may dispense compounded, nonsterile preparations for their nonfarm animal patients, up to a 7-day supply, if the veterinarian determines that timely access to a compounding pharmacy is not available. Preparations must be clearly labeled according to certain specifications and must not be copies or close approximations to U.S. FDA-approved products; a pharmacist may not provide substances to a veterinarian in an amount greater than 10% of the total amount of drug products sold or dispensed from the pharmacy.

Massachusetts
Manufacturing does not include the preparation, compounding, packaging or labeling of a controlled substance by a practitioner as an incident to the practitioner's administering a controlled substance in the course of his or her professional practice.

**Effective January 1, 2017:** A veterinarian may dispense a compounded drug to a companion animal, within a valid veterinarian-client-patient relationship, if: the quantity dispensed does not exceed a 120-hour supply; the compounded drug is for the treatment of an emergency condition; and timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

Michigan
Manufacturing does not include preparation, compounding, packaging, or labeling of a controlled substance by a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of his or her professional practice.

Minnesota
Practitioners may prepare a supply of a compounded drug product that is sufficient to meet the practitioner's short-term anticipated need for dispensing or administering the drug to patients treated by the practitioner. According to the Board of Pharmacy, until permanent regulations are issued, it will exercise enforcement discretion and not take action against a pharmacy that, in good faith, provides a
compounded drug to a veterinarian, at wholesale and without first receiving a patient-specific prescription, only when:

a. The compounded drug is needed to treat animals in urgent or emergency situations; that is, where the health of an animal is threatened, or where suffering or death of an animal is likely to result from failure to treat.

b. Timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

c. There is no FDA-approved, commercially manufactured drug that is suitable for treating the animal; or there is a documented shortage of such drug.

d. The compounded drug is to be administered by a veterinarian or a bona fide employee of the veterinarian; or dispensed to a client of a veterinarian in an amount not to exceed what is necessary to treat an animal for a period of five days.

e. The pharmacy is licensed by the Board as a drug wholesaler.

f. The pharmacy has selected the sterile or non-sterile compounding licensing category.

**Mississippi**  
Practitioners may obtain compounded medications to administer to patients.

**Missouri**  
A pharmacist shall not offer compounded drug products to practitioners for subsequent resale or administration, except in the course of professional practice for a prescriber to administer to an individual patient by prescription.

**Montana**  
It is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs, but there are exceptions for administration of a unit dose of a drug to a patient by or under the supervision of a medical practitioner, and dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient. According to the International Association of Compounding Pharmacies, the Board of Pharmacy’s executive director interprets the pharmacy law to allow pharmacists to dispense to physicians for office use only.

**Nebraska**  
Legislation enacted in 2015 does not include veterinarians in the definition of “practitioners.” According to the Nebraska VMA, this statutory exclusion means that veterinarians are not prohibited from administering in-office or dispensing compounded drugs.

**Nevada**  
A pharmacy shall not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner, except that a pharmacy may sell or otherwise provide a compounded drug to:

(a) A practitioner who will be administering the drug to a patient; or

(b) A practitioner or another pharmacy if the compounded drug is a highly concentrated drug product that is not commercially available, or needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy. The quantity of a compounded drug that is sold or otherwise provided to a practitioner must not exceed the amount necessary for the practitioner to serve the present needs of the patients of the practitioner or pharmacy.
New Hampshire
According to the International Academy of Compounding Pharmacists, the Board of Pharmacy does allow office-use compounding, providing the sale does not exceed 5 percent of the pharmacy’s sales. The practitioner must order via invoice; if it exceeds 5 percent, a wholesaler’s and manufacturer’s license is required.

New Jersey
Compounding regulations are not intended to limit a prescriber’s ability under pre-existing law to order a compounded medication for use in the prescriber’s practice, as permitted by state and federal law.

New Mexico
Compounding for prescriber office use does not appear to be permitted after the New Mexico Board of Pharmacy amended its compounding regulations in 2013 by deleting language permitting compounding for prescriber office use. Products for animals may only be compounded based on an order or prescription from a duly authorized veterinarian.

New York
According to the Board of Pharmacy, New York does not permit compounding “for physicians’ office use” because it involves the dispensing of non-patient specific orders. It considers this type of activity to be “manufacturing.” However, legislation adopted in 2014 requires that the label of any drug compounded by an outsourcing facility must include the statement that the drug is not for resale, and the statement “Office Use Only.”

North Carolina
Compounded drug products shall not be offered to other entities for resale, but practitioners may obtain them to administer to patients within the scope of their professional practice.

North Dakota
Compounded drugs may be used by practitioners in their office for administration to patients.

Ohio
A pharmacist may compound and provide a reasonable quantity of a non-patient-specific drug pursuant to a request made by a veterinarian, or by an agent of the veterinarian, for the purpose of direct administration to patients. The pharmacy may only provide compounded products that are not commercially available and that are for emergency treatment, situations when a time delay would negatively affect a patient outcome, or diagnostic purposes. A veterinarian may personally furnish up to a seven-day supply of a compounded drug to a patient when, in their professional judgment, failure to provide the drug would result in potential harm to the patient.

Oklahoma
Compounding includes the preparation of drugs or devices in anticipation of prescription-drug orders based on routine, regularly observed prescribing patterns. Pharmacies may prepare compounded drug products for a prescriber’s office use as long as the product is administered in the office and not dispensed to the patient. However, under Oklahoma Bureau of Narcotics rules, a prescription for controlled dangerous substances cannot be filled “for office or medical bag use.”
Oregon
Small quantities can be prepared upon request for in-office use by licensed practitioners. According to the Oregon Board of Pharmacy, a patient-specific prescription is required for all controlled-substance medications whether the medication is compounded by a pharmacy or produced by an FDA-approved manufacturer. Pharmacies outside of Oregon that ship non-patient specific compounded drugs to practitioners in Oregon must hold a manufacturing registration with the Oregon Board of Pharmacy. At this time, Oregon pharmacies may provide non-patient-specific, non-controlled compounded drugs to practitioners under a Shared Service arrangement with the Oregon Board of Pharmacy.

No pharmacy in or outside of Oregon may provide non-patient-specific controlled drugs to a practitioner unless the pharmacy providing the drugs has, at a minimum, a manufacturing license with the FDA; a manufacturing registration with the Oregon Board of Pharmacy; and a DEA manufacturing registration (in addition to the standard registration). Non-patient-specific compounded drugs may be used for administration in the clinic. Practitioners should verify that a pharmacy or facility has all required licenses and registrations.

South Carolina
Pharmacists may compound products based on an order from a practitioner for use by practitioners for patient use in institutional or office settings.

Rhode Island
Pharmacists shall not offer pharmaceutically prepared compounded preparations to other state-licensed persons or commercial entities for subsequent resale.

Tennessee
Compounding is allowed for use by a licensed veterinarian for administration to their non-human patient or patients or for dispensing to non-human patients in the course of the practice of veterinary medicine, upon receipt of an order from a veterinarian and when the product is not commercially available.

Texas
A veterinarian must establish and maintain a veterinarian-client-patient relationship with any animal for which the veterinarian compounds drugs. Drug compounding by veterinarians is limited only to treat a specific occurrence of a disease or condition that the veterinarian has diagnosed in a specific patient. A veterinarian may only compound products made from FDA-approved drugs, and may not promote or distribute compounds that are essentially the same as other FDA-approved drugs. The label for compounded drugs must include both name and strength of medically active ingredients. Compounded drugs dispensed to the client must also state a date dispensed and an expiration date, which should not exceed the length of the prescribed treatment. There are special rules for compounding for food-producing animals.

Utah
A pharmacy may repackage or compound a prescription drug for sale to a practitioner if the prescription drug includes a compounded drug which is not a controlled substance; where the pharmacy labels the prescription drug "for office use only"; the practitioner administers the drug to a patient in the
practitioner’s office or facility; and, except in accordance with Title 58, Chapter 17b, Part 8, the practitioner does not dispense the drug to the patient.

A pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act.

**Vermont**
Pharmacists shall not offer compounded drug products to other state-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a practitioner to administer to an individual patient, in limited quantities.

**Virginia**
A pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals — as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients — shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

A veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

**Washington**
Pharmacists may offer compounded drug products in the course of professional practice to a practitioner to administer to an individual patient.

**West Virginia**
A pharmacy may provide controlled substances to a practitioner for office use, but must do so by providing appropriate documentation through the use of an invoice or other federally required documentation or forms. According to the International Academy of Compounding Pharmacists, the Board of Pharmacy applies this rule to compounded drugs, provided they are based on a commercially available legend drug.

**Wyoming**
Pharmacists may offer compounded medications to practitioners for administration to patients in the practitioner’s office.

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