

FAQ Regarding Drug Dispensing Requirements for Veterinarians

This FAQ provides information on the requirements that veterinarians licensed to practice in the State of Georgia must follow in order to be able to dispense “Dangerous Drugs” and/or “Controlled Substances” in the course of their clinical practice. This FAQ does not cover veterinarians’ use of Controlled Substances or Dangerous Drugs for research (i.e., use of a drug as a test article in a research protocol). For information on using Controlled Substances or Dangerous Drugs for research see the link to the “FAQs on State and Federal Requirements at the following site [ORIC: Controlled Substances & Dangerous Drugs](#)

1. What are “Controlled Substances” and what are “Dangerous Drugs” under Georgia law?

“Controlled Substances” are drugs that have the potential for addiction/abuse. Controlled Substances are those drugs, substances, or immediate chemical precursors listed in Schedules I to V of Official Code of Georgia Annotated (OCGA.) Sections 16-13-25 to 16-13-29 and Schedules I to VI of Title 21 of the Code of Federal Regulations (CFR), Section 1308.

“Dangerous Drugs” are drugs that are available only by prescription from a licensed health care professional or the purchase of which is restricted to licensed health care professionals. Dangerous Drugs do not include prescription drugs that are “Controlled Substances.” Dangerous Drugs also do not include over-the-counter drugs (including certain lower dose forms of drugs that would be considered prescription drugs if they were in higher dose forms). In this FAQ we will use the term “Dangerous Drugs” to refer to prescription drugs that are not Controlled Substances. Georgia’s list of Dangerous Drugs can be found in Section 16-13-71 of the OCGA at <http://www.lexisnexis.com/hottopics/gacode/>.

2. What laws govern veterinarian dispensing of Controlled Substances and Dangerous Drugs for clinical purposes?

A mix of federal and state laws govern veterinarian dispensing:

- **DEA Regulations at 21 CFR Part 1300.** These regulations govern veterinarian dispensing of Controlled Substances. Veterinarians must have valid state authority (i.e., be licensed in a state as a veterinarian to prescribe/dispense Controlled Substances) in order to be eligible for registration as a practitioner under the DEA regulations. [See, *DEA Practitioner Manual*, pg. 7 at https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf].
- **Georgia Veterinary Practice Act (VPA) at OCGA § 43-50-1, et. seq. and its implementing regulations, the Rules of the Georgia State Board of Veterinary Medicine, at Chapter 700 of the Rules and Regulations of the State of Georgia (“Ga. Rules”).** These laws govern veterinary practice in Georgia. The VPA states that it

does not apply in the following situations to the extent that it would prohibit an employee described below from performing his/her job

- Any employee of a public or private college or university from performing his or her duties relating to animals owned by or on loan to such employer; and
- The owner of an animal or the owner's full-time regular employee caring for or treating the animal belonging to such owner.

The foregoing exemptions do not completely exempt the veterinarians employed by Emory, or other Emory employees, from the VPA requirements with respect to care for Emory-owned animals. Rather, as noted, the VPA applies to the extent that it does not "prohibit" such an employee from performing his/her job. The VPA sets forth requirements that must be met in order for a veterinarian to prescribe/administer/dispense drugs, and these requirements are discussed below.

- **Georgia Board of Pharmacy Regulations at Chapter 480.** These rules set forth the requirements for practitioner registration for dispensing of Dangerous Drugs and Controlled Substances (Ga. Rules 480-28), including record-keeping requirements. Below, the requirements of these rules are discussed further.

3. What does it mean to "Dispense" a Dangerous Drug or Controlled Substance?

Dispensing a drug means preparing and delivering a drug to a patient or caregiver in a container labeled with appropriate directions for subsequent administration to, or use by, the patient. [See OCGA § 26-4-5]. Administering a drug means providing a unit dose of a medication directly to a patient. Veterinarians, of course, may administer drugs or write prescriptions for drugs that a client can have filled for dispensing by a pharmacy that carries veterinary drugs. Additionally, by taking the steps described below, veterinarians can directly dispense Dangerous Drugs or Controlled Substances to clients for the client to administer to the animal patient, for the patient's clinical care.

4. What does a veterinarian need to do to be able to dispense a Dangerous Drug or Controlled Substance?

Veterinarians must take the following four steps to dispense Dangerous Drugs or Controlled Substances for the clinical care of animals:

A. Veterinarian Must Have a Valid Veterinarian-Client-Patient Relationship.

Writing a prescription for a drug, administering a prescription drug, or dispensing a prescription drug are all acts that are included within the definition of the term "practice of veterinary medicine" under the VPA. [O.C.G.A. §44-50-3(11)]. In order to administer or dispense a dangerous drug or controlled substance, the veterinarian must have an appropriate veterinarian-client-patient relationship. [Ga. Rules, Rule 700-8-.01(e)]. An "appropriate veterinarian-client-patient relationship" is one in which:

- The veterinarian assumes responsibility for making medical judgments about the health of the animal patient and need for clinical treatment, and the client (owner or caretaker) agrees to follow the instructions of the veterinarian; and
- The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). To establish this sufficient knowledge, the veterinarian must be personally acquainted with the keeping and care of the animal(s) by doing either of the following acts:
 - Examining the animal within the last twelve (12) months, or
 - Making medically appropriate and timely visits to the premises where the patient is kept.
- Additionally, a licensed veterinarian must be available for follow-up care and the relationship cannot be established solely through electronic means (e.g., telephone, internet).

In general, a valid veterinary-client-patient relation will exist when veterinarians employed by Emory provide clinical care for research animals.

B. Veterinarian Must Provide Notification to the State of Georgia of Intent to Dispense

At the time of the veterinarian’s initial request for, or renewal of, his/her license to practice veterinary medicine in the State of Georgia, the veterinarian who intends to dispense drugs must notify the Georgia Board of Veterinary Medicine of his/her intention to dispense drugs. The Georgia Board of Veterinary Medicine, in turn, will notify the Georgia Board of Pharmacy, which may inspect the facility from which the drugs are dispensed. The notification may be in the form of a letter that includes the following information:

- Name and address of the veterinarian;
- The veterinarian’s state professional license number;
- The veterinarian’s DEA registration number (if controlled substances are dispensed); and
- The name and address of the facility from where the drugs will be dispensed, and address of the facility where all relevant records will be maintained.

C. Veterinarian Must Have DEA Registration to Dispense Controlled Substances: To dispense Controlled Substances for clinical treatment of an animal, practitioner registration with the Drug Enforcement Agency (DEA) is required. For the DEA practitioner registration application see <https://apps.dea diversion.usdoj.gov/webforms/>.

D. Veterinarian Must Comply with All Record-Keeping, Labeling, Packaging and Storage Requirements that Pharmacies Must Follow:

There are two sets of regulations governing veterinarian dispensing of prescription drugs. The first is the rule for drugs and pharmacy contained in the Ga. Rules [Rule 700-12-.07]. This Rule

requires compliance with all applicable state and federal regulations regarding the dispensing of prescription drugs. In addition, it requires the following:

- Existence of valid veterinarian-client-patient relationship before issuing a prescription or dispensing a prescription.
- Maintenance on the premises of DEA registration, if controlled substances are dispensed.
- Maintenance of pharmacy area in clean and orderly manner.
- Proper labeling of all pharmaceuticals with drug name, concentration/activity and expiration date.
- Separation and proper return/disposal of expired pharmaceuticals. [NOTE: See Emory Policy 7.25 for requirements regarding disposal of Controlled Substances.]

The Georgia Board of Pharmacy requires veterinarians who directly dispense drugs to clients for the clinical care of animal patients to follow the same record-keeping, labeling, packaging and storage requirements that apply to pharmacies. These requirements are set forth in the Rules for Practitioner Dispensing of Drugs (Ga. Rules, Chapt. 480-28), and are summarized below.

5. What are the record-keeping, labeling, packaging and storage requirements that a veterinarian must follow to dispense Dangerous Drugs and Controlled Substances?

(a) Prescription Drug Orders [Ga. Rules, Rule 480-23-.04(1)]

The veterinarian must write a prescription drug order for each drug dispensed. The prescription must contain the following information:

- Name and address of the patient for whom the drug is dispensed;
- Name, quantity and strength of the drug;
- Directions for taking or giving;
- Date the prescription was written; and
- Signature of the practitioner.
- A practitioner who fills or refills a prescription drug order shall provide on the prescription both the date of filling/refilling and the signature of the practitioner.
- Prescription drug orders dispensed by a practitioner cannot be transferred to another practitioner or pharmacist for subsequent filling.

Controlled Substances: Prescriptions for controlled substances must include the name, address, and DEA number of the dispensing practitioner.

(b) Maintenance of Prescription Drug Orders [Ga Rules, Rule 480-28-.04(5)(c)]. Veterinarians may keep a separate file that contains prescription drug orders, or they may keep the drug order in the patient's chart, but the following special filing rules apply if the veterinarian dispenses Controlled Substances.

Specifically, if the veterinarian dispenses Schedule II Controlled Substances then he/she may keep prescription drug orders using either one of the following file systems:

3 File System: (i) one file containing Schedule II Controlled Substances prescriptions; (ii) one file containing Schedule III, Schedule IV and Schedule V Controlled Substances prescriptions; and (iii) one file containing Dangerous Drug prescriptions.

2 File System: (i) one file containing Schedule II Controlled Substances prescriptions; and (ii) one file containing Schedule III, Schedule IV, Schedule V Controlled Substances and Dangerous Drug prescriptions; PROVIDED, HOWEVER, that prescriptions for Controlled Substances must be marked with a one-inch high, capital “C” in red ink in the lower right-hand corner.

If the veterinarian dispenses only Schedule III to Schedule V Controlled Substances, then he/she must use the following filing system for prescription drug orders:

2 File System: (i) one file containing Schedule III, Schedule IV, Schedule V Controlled Substances prescriptions, with all such prescriptions marked with a one-inch high, capital “C” in red ink in the lower right-hand corner; and (ii) one file containing prescriptions for Dangerous Drug prescriptions.

(c) Packaging & Labeling [Ga. Rules 480-28-.06 & 480-28-.05]:

All dispensed drugs must be in containers meeting FDA and Consumer Protection Agency requirements, which includes use of child-proof and moisture-proof containers. Containers for prescription drugs must be labeled with the following information:

- Date and identifying serial number;
- Name of patient¹;
- Name of prescribing practitioner;
- Name, address and phone number of the dispensing practitioner;
- Name of the drug and its strength;
- Directions for use;
- Expiration date;
- Prescription legend (i.e., “R only”).
- Any other information required by DEA or FDA.

(d) Purchase & Storage [Ga. Rules, Rules 480-28-.07 & -.11]:

- Controlled Substances and Dangerous Drugs must be purchased from firms that are permitted by the Ga. Board of Pharmacy.
- Prescription drugs shall be stored in a secure area and out of reach of children/animals.

¹ Note that the Georgia Board of Pharmacy regulations do not address the issue of writing a single prescription for a group of animals (e.g., prescription of a de-wormer for a litter of puppies to be administered in the same way for each puppy). The American Veterinary Medical Assoc. recognizes this practice (see, <https://www.avma.org/KB/Resources/FAQs/Pages/Prescriptions-and-Pharmacies->

[Veterinarian-FAQs.aspx](#)), but no mention of it appears on the public site for the Georgia Veterinary Medical Assoc. (see, <http://www.gvma.net/>).

- Storage space shall be large enough to allow for neat and orderly storage, and accommodate for the storage of drugs that require refrigeration.
- Facility conditions shall be clean, sanitary, not overcrowded, and shall not endanger the health, safety, or welfare of the public.
- Drugs that are expired or in a deteriorated condition shall not be dispensed, and shall be removed from stock.

Controlled Substances: The storage, security, and theft/loss reporting requirements for Controlled Substances contained in Emory Policy 7.25 – Research Use of Controlled Substances (<http://policies.emory.edu/7.25>) apply generally to veterinarians who dispense Controlled Substances.

(e) Recordkeeping & Inspection:

- Complete, accurate and legible records regarding animals and veterinary care, including prescription drug order records, must be maintained for a minimum period of three years from the date the record was created. [Ga. Rules, Rule 700- 12-.04]².
- Veterinarians must keep on file for inspection by the Georgia Drugs and Narcotics Agency (GDNA) a copy of the current Georgia State Board of Pharmacy permit for each firm from which they purchase prescription drugs. (Ga. Rules, Rule 480- 28-.11).
- Records shall be kept in a readily retrievable form, recorded contemporaneously, and filed promptly following treatment.
- Prescription drug orders shall be accessible for inspection by the Georgia Board of Pharmacy and agents from the GDNA, as well as by DEA agency in the case of controlled substances. (Ga. Rules, Rule 480-28-.11).
- Whenever more than one practitioner dispenses drugs from a common inventory, one practitioner shall be designated to be “in charge” of the common inventory, and be responsible for all record-keeping, inventory, and storage requirements. (Ga. Rules, Rule 480-28-.09).

Controlled Substances: The recordkeeping requirements for Controlled Substances contained in Emory Policy 7.25 – Research Use of Controlled Substances at <http://policies.emory.edu/7.25> apply generally to veterinarians who dispense Controlled Substances.

6. When a vet provides a Controlled Substance for pain relief to an animal, who may administer the drug? Can administration be delegated to a vet tech?”

Administration of Controlled Substances for pain relief can be delegated to a vet tech who is under the indirect supervision of an attending veterinarian.

Ga. Rule 700-14-.03(2) states in pertinent as follows:

² Note: Georgia Board of Pharmacy Rule 480-28-.04 requires prescription drug orders to be kept for a

minimum of 2 years from the date the prescription is filled but Veterinary Board Rules impose a 3-year retention period.

A veterinary technician working under the direction, supervision and control of a duly licensed veterinarian may provide the following animal patient care under indirect supervision:

- (a) administration and application of treatments, drugs, medications and immunological agents by oral, IM and subcutaneous (*sic*) routes, excluding rabies vaccine for animals required to receive a rabies vaccine by Georgia law;
- (b) Administration and application of treatments, drugs, medications and immunological agents by intravenous routes.

The Rule also states that “indirect supervision” means “the duly licensed veterinarian is not on the premises but has given either written or oral instructions for the treatment of the animal patient and the animal has been examined by a licensed veterinarian at such times as acceptable veterinary medical practice requires, consisted with the particular delegated health care task.” [Rule 700-14-.03(1)].

7. Can administration of a Controlled Substance for pain relief to a research animal be delegated to a laboratory technician or other research staff?

The practice of veterinary medicine excludes “administration or dispensing [of any prescription drug, medicine, biologic, apparatus, application, anesthetic, or other therapeutic or diagnostic substance or technique on, for, or to any animal] ***pursuant to prescription or direction of a licensed veterinarian.***” [OCGA §40-50-3(11)(emphasis added)]. Accordingly, if an Emory veterinarian appropriately prescribes a Controlled Substance for an animal’s clinical pain relief, then administration of the prescribed drug can be carried out by a technician in a laboratory.

Note, however, that although the governing laws do not specifically name the types of Controlled Substances or prescription drugs that may be prescribed, care must be taken to avoid activities that may be construed as being an “end-run” around the Georgia statutory requirement at OCGA § 26-04-49 that:

“Every person, firm, corporation, agency, department, or other entity located within this state which handles, possesses or utilizes controlled substances or dangerous drugs as defined in Chapter 13 of Title 16, for the purpose of conducting research, analysis, animal training or drug education, as such purposes may be further defined by the board and is not otherwise registered as a pharmacist, pharmacy, drug wholesaler, distributor, supplier or practitioner shall biennially register with the State Board of Pharmacy for a drug researcher permit which shall entitle the holder thereof to purchase receive possess, or dispose of such controlled substances and dangerous drugs for such purposes.”

To ensure veterinary prescriptions for clinical care of an animal are being viewed as consistent with Georgia regulatory requirements, the drugs prescribed for administration by a researcher or laboratory technician should (a) not be the test article of the research protocol; and (b) be for the animal’s clinical care; and (c) be of a type and dosage form that can be administered to animals

by following the prescription labeling and veterinary instruction, as opposed to drugs that require special training to administer (e.g., orally administered pain killers v. inhalation anesthesia). Additionally, clear statements in the protocol to the effect that specific drugs will be prescribed by veterinarians for clinical care of the animals required as a result of or in preparation for research procedures would help to eliminate any possibility of confusion regarding which rules apply to specific activities.

8. Can an Emory veterinarian offer the clinical administration of Controlled Substances (as prescribed by an Emory veterinarian) as a service for Emory investigators?"

Emory veterinarians may administer Controlled Substances for the clinical care of animals when the vet has an "appropriate Veterinarian/Client/Patient Relationship" as discussed above under Question 4. [See, OCGA § 43-50-3(11); Ga. Rule 700-12-.07(1)(g)]. In such cases the protocol should be clear that the Controlled Substances are being provided by veterinarians for the clinical care of the animals necessitated as the result of the research procedures (e.g., pain relief after surgery) or for the clinical care of animals required to be able to perform the research procedure (e.g., administration of anesthetic prior to protocol-required research surgery being performed).

If the Controlled Substance is being administered as a test article in a research protocol, however, the veterinarian must hold both a DEA researcher registration and a Georgia researcher permit and should be included on the research protocol.

Subject to the limitations described above, and as discussed in Question 7, veterinarians also may prescribe Controlled Substances for the clinical care of animals due to or in preparation for research procedures (e.g., pre-or post-operative pain relief) for administration by research staff.