Virginia Department of Health Professions
Board of Veterinary Medicine

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January 5, 2023
Training Room 2
1:00 p.m.

Agenda
Virginia Board of Veterinary Medicine
Inspection Committee Meeting

Call to Order – Tregel Cockburn, DVM, Chair
- Emergency Egress Procedures
- Welcome and Introductions
  - New Committee Member Katie Smith, LVT
- Mission Statement

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Ordering of Agenda – Dr. Cockburn

Public Comment – Dr. Cockburn
The Board will receive all public comment related to agenda items at this time. The Board will not receive comment on any regulatory process for which a public comment period has closed or any pending or closed complaint or disciplinary matter.

Approval of Minutes – Dr. Cockburn
June 9, 2022 Inspection Committee Meeting **Pages 2-4**

Discussion Items – Dr. Cockburn/Ms. Moss/Taryn Singleton
- Review of regulatory process changes (Ms. Moss) **Pages 5-30**
- Review and revision of veterinary establishments and inspections regulations (pp 5-14)
- Review of draft guidance documents (Ms. Moss/Ms. Singleton)
  - Proposed consolidation/revisions to guidance documents for controlled drugs (pp 15-30)

New Business – Dr. Cockburn

Next Meeting – Ms. Moss

Meeting Adjournment – Dr. Cockburn

This information is in **DRAFT** form and is subject to change.

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Board of Optometry

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MISSION STATEMENT

Our mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

VIRGINIA BOARD OF VETERINARY MEDICINE
VETERINARY ESTABLISHMENT INSPECTION COMMITTEE
MEETING MINUTES
June 9, 2022

TIME AND PLACE:	A meeting of the Veterinary Establishment Inspection Committee (Committee) was called to order at 1:13 p.m. at the Department of Health Professions (DHP), Perimeter Center, 2nd Floor Conference Center, Board Room 2, 9960 Mayland Drive, Henrico, Virginia 23233.
PRESIDING OFFICER:	Tregel Cockburn, DVM, Board President, Committee Chair
COMMITTEE MEMBERS PRESENT:	Jason Bollenbeck, DVM, Virginia Veterinary Medical Association Wendy Ashworth, DHP Senior Inspector Tom Massie, DVM, Board Member
MEMBERS NOT PRESENT:	Heather Carter, LVT
STAFF PRESENT:	Kelli Moss, Deputy Executive Director Heather Pote, Senior Discipline Case Specialist Melody Morton, Inspections Manager, Enforcement Division Taryn Singleton, LVT, Discipline Case Specialist for Inspections Kelly Gottschalk, DVM, Veterinary Review Coordinator
CALL TO ORDER & QUORUM:	Dr. Cockburn welcomed attendees. With four members of the Committee present, a quorum was established. Dr. Cockburn read the Department of Heath Professions' Mission Statement.
ORDERING OF AGENDA:	No changes were made to the agenda and it was accepted as presented.
PUBLIC COMMENT:	No public comment was received.
APPROVAL OF MINUTES:	The minutes from the May 20, 2022, meeting were approved as presented.
DISCUSSION ITEMS:	**Guidance Document 76-21.2.1 – Veterinary Establishment Inspection Report** Ms. Moss and Ms. Singleton presented the final draft of the Committee's amendments to Guidance Document 76-21.2.1. Ms. Singleton reviewed the new Inspection Summary form developed to assist establishments in submitting corrective actions for deficiencies cited during the inspection. Ms. Ashworth confirmed this format is consistent with other DHP boards' inspection forms. The Committee considered suggested changes to the Inspection Summary to clarify the instructions.

Federal Regulations and Board Guidance for Disposal and Destruction of Controlled Drugs

Ms. Singleton discussed proposed guidance for 18 VAC 150-20-190(D) related to proper disposal and destruction of Schedules II through V controlled drugs. After discussion, the Committee rejected the proposed guidance included in the inspection report. Staff suggested that this information may be most accessible in a current controlled drug or establishment guidance document or by developing a separate guidance document. The Committee discussed the best method of informing licensees of requirements for disposing and destroying controlled drugs.

Dr. Bollenbeck moved that the Committee accept the Inspection Summary with the proposed changes and to recommend the full Board accept the final draft of Guidance Document 76-21.2.1 Veterinary Establishment Inspection Report with the Summary as presented, with the exception of the aforementioned proposed guidance. The motion was seconded by Ms. Ashworth and carried unanimously.

Dr. Bollenbeck moved to direct staff to draft a new guidance document for the disposal and destruction of controlled substances with links to general DEA regulations to present at its next meeting. The motion was seconded by Dr. Massie and carried unanimously.

NEW BUSINESS:

Ms. Moss expressed her appreciation to the Committee for its accomplishments and reported an overview of its recommendations for Regulatory amendments, amended Guidance Document, and for the new Veterinarian-in-Charge Guidance document.

Ms. Moss reported the need to appoint a new LVT/multi-practice owner Committee member in light of Ms. Carter's extended absence, and that Board staff has been working to identify a suitable candidate for the Chair's consideration.

Ms. Moss informed the Committee the need to continue reviewing Regulations relating to veterinary establishments for the regulatory review committee while the Board conducts its periodic regulatory review. She stated that staff will continue to conduct educational outreach to ensure licensees and the public are informed of regulatory changes as they occur.

NEXT MEETING:

Ms. Moss informed the Committee that Board staff will poll the Committee for availability to schedule the next meeting in early September 2022.

ADJOURNMENT: With all business concluded, the meeting adjourned at 2:26 p.m.

_____
Kelli Moss, Deputy Executive Director

CURRENT VETERINARY ESTABLISHMENT REGULATIONS

Effective April 1, 2022

Part V. Veterinary Establishments.

18VAC150-20-180. Requirements to be registered as a veterinary establishment.

A. Every veterinary establishment shall apply for registration on a form provided by the board and submit the application fee specified in 18VAC150-20-100. The board may issue a registration as a stationary or ambulatory establishment. Every veterinary establishment shall have a veterinarian-in-charge registered with the board in order to operate.

1. Veterinary medicine may only be practiced out of a registered establishment except in emergency situations or in limited specialized practices as provided in 18VAC150-20-171. The injection of a microchip for identification purposes shall only be performed in a veterinary establishment, except personnel of public or private animal shelters may inject animals while in their possession.

2. An application for registration must be made to the board 45 days in advance of opening or changing the location of the establishment or requesting a change in the establishment category listed on the registration.

3. Any addition or renovation of a stationary establishment or an ambulatory establishment that involves changes to the structure or composition of a surgery room shall require reinspection by the board and payment of the required fee prior to use.

B. A veterinary establishment will be registered by the board when:

1. It is inspected by the board and is found to meet the standards set forth by 18VAC150-20-190 and 18VAC150-20-200 or 18VAC150-20-201 where applicable. If, during a new or routine inspection, violations or deficiencies are found necessitating a reinspection, the prescribed reinspection fee will be levied. Failure to pay the fee shall be deemed unprofessional conduct and, until paid, the establishment shall be deemed to be unregistered.

2. A veterinarian currently licensed by and in good standing with the board is registered with the board in writing as veterinarian-in-charge and ensures that the establishment registration fee has been paid.

18VAC150-20-181. Requirements for veterinarian-in-charge.

A. The veterinarian-in-charge of a veterinary establishment is responsible for:

1. Regularly being on site as necessary to provide routine oversight to the veterinary establishment for patient safety and compliance with law and regulation.

2. Maintaining the facility within the standards set forth by this chapter.

3. Performing the biennial controlled substance inventory and ensuring compliance at the facility with any federal or state law relating to controlled substances as defined in § 54.1-3404 of the Code of Virginia. The performance of the biennial inventory may be delegated to another licensee, provided the veterinarian-in-charge signs the inventory and remains responsible for its content and accuracy.

4. Notifying the board in writing of the closure of the registered facility 10 days prior to closure.

5. Notifying the board immediately if no longer acting as the veterinarian-in-charge.

6. Ensuring the establishment maintains a current and valid registration issued by the board.

B. Upon any change in veterinarian-in-charge, these procedures shall be followed:

1. The veterinarian-in-charge registered with the board remains responsible for the establishment and the stock of controlled substances until a new veterinarian-in-charge is registered or for five days, whichever occurs sooner.

2. An application for a new registration, naming the new veterinarian-in-charge, shall be made five days prior to the change of the veterinarian-in-charge. If no prior notice was given by the previous veterinarian-in-charge, an application for a new registration naming a new veterinarian-in-charge shall be filed as soon as possible, but no more than 10 days, after the change.

3. The previous establishment registration is void on the date of the change of veterinarian-in-charge and shall be returned by the former veterinarian-in-charge to the board five days following the date of change.

4. Prior to the opening of the business, on the date of the change of veterinarian-in-charge, the new veterinarian-in-charge shall take a complete inventory of all Schedules II through V drugs on hand. He shall date and sign the inventory and maintain it on premises for three years. That inventory may be designated as the official biennial controlled substance inventory.

C. Prior to the sale or closure of a veterinary establishment, the veterinarian-in-charge shall:

1. Follow the requirements for transfer of patient records to another location in accordance with § 54.1-2405 of the Code of Virginia; and

2. If there is no transfer of records upon sale or closure of an establishment, the veterinarian-in-charge shall provide to the board information about the location of or access to patient records and the disposition of all scheduled drugs.

18VAC150-20-185. Renewal of veterinary establishment registrations.

A. Every veterinary establishment shall be required to renew the registration by January 1 of each year and pay to the board a registration fee as prescribed in 18VAC150-20-100.

B. Failure to renew the establishment registration by January 1 of each year shall cause the registration to expire and become invalid. Practicing veterinary medicine in an establishment with an expired registration may subject a licensee or registration holder to disciplinary action by the board. The registration may be renewed without reinspection within 30 days of expiration, provided the board receives a properly executed renewal application, renewal fee, and a late fee as prescribed in 18VAC150-20-100.

C. Reinstatement of an expired registration after 30 days shall be at the discretion of the board and contingent upon a properly executed reinstatement application and payment of the late fee, the reinspection fee, the renewal fee and the veterinary establishment registration reinstatement fee. A reinspection is required when an establishment is reinstated.

18VAC150-20-190. Requirements for drug storage, dispensing, destruction, and records for all establishments.

A. All drugs shall be maintained, administered, dispensed, prescribed and destroyed in compliance with state and federal laws, which include § 54.1-3303 of the Code of Virginia, the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), applicable parts of the federal Food, Drug, and Cosmetic Control Act (21 USC § 301 et seq.), the Prescription Drug Marketing Act (21 USC § 301 et seq.), and the Controlled Substances Act (21 USC § 801 et seq.), as well as applicable portions of Title 21 of the Code of Federal Regulations.

B. All repackaged tablets and capsules dispensed for companion animals shall be in approved safety closure containers, except safety caps shall not be required when any person who requests that the medication not have a safety cap, or in such cases in which the medication is of such form or size that it cannot be reasonably dispensed in such containers (e.g., topical medications, ophthalmic, or otic). An owner request for nonsafety packaging shall be documented in the patient record.

C. All drugs dispensed for companion animals shall be labeled with the following:

1. Name and address of the facility;

2. First and last name of owner;

3. Animal identification and species;

4. Date dispensed;

5. Directions for use;

6. Name, strength (if more than one dosage form exists), and quantity of the drug; and

7. Name of the prescribing veterinarian.

D. All veterinary establishments shall maintain drugs in a secure manner with precaution taken to prevent theft or diversion. Only the veterinarian, veterinary technician, pharmacist, or pharmacy technician shall have access to Schedules II through V drugs, with the exception provided in subdivision 6 of this subsection.

1. In a stationary establishment, the general stock of Schedules II through V drugs shall be stored in a securely locked cabinet or safe that is not easily movable.

2. The establishment may also have a working stock of Schedules II through V drugs that shall be kept in (i) a securely locked container, cabinet, or safe when not in use or (ii) direct possession of a veterinarian or veterinary technician. A working stock shall consist of only those drugs that are necessary for use during a normal business day or 24 hours, whichever is less.

3. Whenever the establishment is closed, all general and working stock of Schedules II through V drugs and any dispensed prescriptions that were not delivered during normal business hours shall be securely stored as required for the general stock.

4. Prescriptions that have been dispensed and prepared for delivery shall be maintained under lock or in an area that is not readily accessible to the public and may be delivered to an owner by an unlicensed person, as designated by the veterinarian.

5. Whenever a theft or any unusual loss of Schedules II through V drugs is discovered, the veterinarian-in-charge, or in his absence, his designee, shall immediately report such theft or loss to the Board of Veterinary Medicine and the Board of Pharmacy and to the DEA. The report to the boards shall be in writing and sent electronically or by regular mail. The report to the DEA shall be in accordance with 21 CFR 1301.76(b). If the veterinarian-in-charge is unable to determine the exact kind and quantity of the drug loss, he shall immediately take a complete inventory of all Schedules II through V drugs.

6. Access to drugs by unlicensed persons shall be allowed only under the following conditions:

a. An animal is being kept at the establishment outside of the normal hours of operation, and a licensed practitioner is not present in the facility;

b. The drugs are limited to those dispensed to a specific patient; and

c. The drugs are maintained separately from the establishment's general drug stock and kept in such a manner so they are not readily available to the public.

E. Schedules II through V drugs shall be destroyed by (i) transferring the drugs to another entity authorized to possess or provide for proper disposal of such drugs or (ii) destroying the drugs in compliance with applicable local, state, and federal laws and regulations. If Schedules II through V drugs are to be destroyed, a DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the veterinarian practice site with other inventory records.

F. The drug storage area shall have appropriate provision for temperature control for all drugs and biologics. If drugs requiring refrigeration are maintained at the facility, the drugs shall be kept in a refrigerator with the interior thermometer maintained between 36°F and 46°F. If a refrigerated drug is in Schedules II through V, the drug shall be kept in a locked container secured to the refrigerator, or the refrigerator shall be locked. Drugs stored at room temperature shall be maintained between 59°F and 86°F.

G. The stock of drugs shall be reviewed frequently, and expired drugs shall be removed from the working stock of drugs at the expiration date and shall not be administered or dispensed.

H. A distribution record shall be maintained in addition to the patient's record, in chronological order, for the administration and dispensing of all Schedules II through V drugs. This record is to be maintained for a period of three years from the date of transaction. This distribution record shall include the following:

1. Date of transaction;

2. Drug name, strength, and the amount dispensed, administered, and wasted;

3. Owner and animal identification; and

4. Identification of the veterinarian authorizing the administration or dispensing of the drug.

I. Original invoices for all Schedules II through V drugs received shall be maintained in chronological order on the premises where the stock of drugs is held, and the actual date of receipt shall be noted. All drug records shall be maintained for a period of three years from the date of transaction.

J. A complete and accurate inventory of all Schedules II through V drugs shall be taken, dated, and signed on any date that is within two years of the previous biennial inventory. Drug strength must be specified. This inventory shall indicate if it was made at the opening or closing of business and shall be maintained on the premises where the drugs are held for three years from the date of taking the inventory.

K. Inventories and records, including original invoices, of Schedule II drugs shall be maintained separately from all other records, and the establishment shall maintain a continuous inventory of all Schedule II drugs received, administered, or dispensed, with reconciliation at least monthly. Reconciliation requires an explanation noted on the inventory for any difference between the actual physical count and the theoretical count indicated by the distribution record. A continuous inventory shall accurately indicate the physical count of each Schedule II drug in the general and working stocks at the time of performing the inventory.

L. Veterinary establishments shall (i) maintain records of the dispensing of feline buprenorphine and canine butorphanol, (ii) reconcile such records monthly, and (iii) make such records available for inspection upon request.

M. Veterinary establishments in which bulk reconstitution of injectable, bulk compounding, or the prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drugs used; strength, if any; date repackaged; quantity prepared; initials of the veterinarian verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

N. If a limited stationary or ambulatory practice uses the facilities of another veterinary establishment, the drug distribution log shall clearly reveal whose Schedules II through V drugs were used. If the establishment's drug stock is used, the distribution record shall show that the procedure was performed by a visiting veterinarian who has the patient record. If the visiting veterinarian uses his own stock of drugs, he shall make entries in his own distribution record and in the patient record and shall leave a copy of the patient record at the other establishment.

18VAC150-20-195. Recordkeeping.

A. A legible, daily record of each patient treated shall be maintained by the veterinarian at the registered veterinary establishment and shall include at a minimum:

1. Name of the patient and the owner;

2. Identification of the treating veterinarian and of the person making the entry (Initials may be used if a master list that identifies the initials is maintained.);

3. Presenting complaint or reason for contact;

4. Date of contact;

5. Physical examination findings;

6. Tests and diagnostics performed and results;

7. Procedures performed, treatment given, and results;

8. Drugs administered, dispensed, or prescribed, including quantity, strength and dosage, and route of administration. For vaccines, identification of the lot and manufacturer shall be maintained;

9. Radiographs or digital images clearly labeled with identification of the establishment, the patient name, date taken, and anatomic specificity. If an original radiograph or digital image is transferred to another establishment or released to the owner, a record of this transfer or release shall be maintained on or with the patient's records; and

10. Any specific instructions for discharge or referrals to other practitioners.

B. An individual record shall be maintained on each patient, except that records for economic animals or litters of companion animals under the age of four months may be maintained on a per owner basis. Patient records, including radiographs or digital images, shall be kept for a period of three years following the last office visit or discharge of such animal from a veterinary establishment.

C. An initial rabies certification for an animal receiving a primary rabies vaccination shall clearly display the following information: "An animal is not considered immunized for at least 28 days after the initial or primary vaccination is administered."

18VAC150-20-200. Standards for stationary veterinary establishments.

A. Stationary establishments. A stationary establishment shall provide surgery and encompass all aspects of health care for small or large animals, or both. All stationary establishments shall meet the requirements set forth in this subsection:

1. Buildings and grounds must be maintained to provide sanitary facilities for the care and medical well-being of patients.

a. Temperature, ventilation, and lighting must be consistent with the medical well-being of the patients.

b. There shall be on-premises:

(1) Hot and cold running water of drinking quality, as defined by the Virginia Department of Health;

(2) An acceptable method of disposal of deceased animals, in accordance with any local ordinance or state and federal regulations; and

(3) Refrigeration exclusively for carcasses of companion animals that require storage for 24 hours or more.

c. Sanitary toilet and lavatory shall be available for personnel and owners.

2. Areas within building. The areas within the facility shall include the following:

a. A reception area separate from other designated rooms;

b. Examination room or rooms containing a table or tables with nonporous surfaces;

c. A room that is reserved only for surgery and used for no other purpose. In order that surgery can be performed in a manner compatible with current veterinary medical practice with regard to anesthesia, asepsis, life support, and monitoring procedures, the surgery room shall:

(1) Have walls constructed of nonporous material and extending from the floor to the ceiling;

(2) Be of a size adequate to accommodate a surgical table, anesthesia support equipment, surgical supplies, and all personnel necessary for safe performance of the surgery;

(3) Be kept so that storage in the surgery room shall be limited to items and equipment normally related to surgery and surgical procedures;

(4) Have a surgical table made of nonporous material;

(5) Have surgical supplies, instruments, and equipment commensurate with the kind of services provided;

(6) Have surgical and automatic emergency lighting to facilitate performance of procedures; and

(7) For establishments that perform surgery on small animals, have a door to close off the surgery room from other areas of the practice.

3. The veterinary establishment shall have, at a minimum, proof of use of either in-house laboratory service or outside laboratory services for performing lab tests, consistent with appropriate professional care for the species being treated.

4. For housing animals, the establishment shall provide:

a. An animal identification system at all times when housing an animal;

b. Accommodations of appropriate size and construction to prevent residual contamination or injury;

c. Accommodations allowing for the effective separation of contagious and noncontagious patients; and

d. Exercise areas that provide and allow effective separation of animals or walking the animals at medically appropriate intervals.

5. A veterinary establishment shall either have radiology service in-house or documentation of outside services for obtaining diagnostic-quality radiographs. If radiology is in-house, the establishment shall:

a. Document that radiographic equipment complies with Part VI (12VAC5-481-1581 et seq.), Use of Diagnostic X-Rays in the Healing Arts, of the Virginia Radiation Protection Regulations of the Virginia Department of Health, which requirements are adopted by this board and incorporated herewith by reference in this chapter.

b. Maintain and utilize lead aprons and gloves and individual radiation exposure badges for each employee exposed to radiographs.

6. Minimum equipment in the establishment shall include:

a. An appropriate method of sterilizing instruments;

b. Internal and external sterilization monitors;

c. Stethoscope;

d. Equipment for delivery of assisted ventilation appropriate to the species being treated, including endotracheal tubes;

e. Adequate means of determining patient's weight; and

f. Storage for records.

B. Additional requirements for stationary establishments.

1. A stationary establishment that is open to the public 24 hours a day shall have licensed personnel on premises at all times and shall be equipped to handle emergency critical care and hospitalization. The establishment shall have radiology/imaging and laboratory services available on site.

2. A stationary establishment that is not open to the public 24 hours a day shall have licensed personnel available during its advertised hours of operation and shall disclose to the public that the establishment does not have continuous staffing in compliance with § 54.1-3806.1 of the Code of Virginia.

3. All stationary establishments shall provide for continuity of care when a patient is transferred to another establishment.

C. Limited stationary establishments. When the scope of practice is less than full service, a specifically limited establishment registration shall be required. Upon submission of a completed application, satisfactory inspection, and payment of the veterinary establishment registration fee, a limited establishment registration may be issued. Such establishments shall have posted in a conspicuous manner the specific limitations on the scope of practice on a form provided by the board.

D. A separate establishment registration is required for separate practices that share the same location.

18VAC150-20-201. Standards for ambulatory veterinary establishments.

A. Agricultural or equine ambulatory practice. An agricultural or equine ambulatory establishment is a mobile practice in which health care is performed at the location of the animal. Surgery on large animals may be performed as part of an agricultural or equine ambulatory practice provided the establishment has surgical supplies, instruments, and equipment commensurate with the kind of surgical procedures performed. All agricultural or equine ambulatory establishments shall meet the requirements of a stationary establishment for laboratory, radiology, and minimum equipment, with the exception of equipment for assisted ventilation.

B. House call or proceduralist establishment. A house call or proceduralist establishment is an ambulatory practice in which health care of small animals is performed at the residence of the owner of the small animal or another establishment registered by the board. A veterinarian who has established a veterinarian-owner-patient relationship with an animal at the owner's residence or at another registered veterinary establishment may also provide care for that animal at the location of the patient.

1. Surgery may be performed only in a surgical suite at a registered establishment that has passed inspection. However, surgery requiring only local anesthetics may be performed at a location other than in a surgical suite.

2. House call or proceduralist establishments shall meet the requirements of a stationary establishment for laboratory, radiology, and minimum equipment, with the exception of equipment for assisted ventilation.

C. Mobile service establishment. A mobile service establishment is a veterinary clinic or hospital that can be moved from one location to another and from which veterinary services are provided. A mobile service establishment shall meet all the requirements of a stationary establishment appropriate for the services provided.

D. A separate establishment registration is required for separate practices that share the same location.

18VAC150-20-210. Revocation or suspension of a veterinary establishment registration.

The board may revoke or suspend or take other disciplinary action deemed appropriate against the registration of a veterinary establishment if it finds the establishment to be in violation of any provision of laws or regulations governing veterinary medicine or if:

1. The board or its agents are denied access to the establishment to conduct an inspection or investigation;

2. The holder of a registration does not pay any and all prescribed fees or monetary penalties;

3. The establishment is performing procedures beyond the scope of a limited stationary establishment registration; or

4. The establishment has no veterinarian-in-charge registered with the board.

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Guidance document: 150-13

Revised: March 11, 2021
Effective: May 13, 2021

Virginia Board of Veterinary Medicine

Controlled Substances (Schedule II-VI) in Veterinary Practice

Veterinarians are allowed to prescribe, administer, and dispense controlled substances in keeping with the requirements of the Virginia Drug Control Act, specifically § 54.1-3409 of the *Code of Virginia*, and the statutes and regulations governing the practice of veterinary medicine. A bona fide veterinarian-client-patient relationship (VCPR) as set forth in § 54.1-3303 of the Code of Virginia, must first exist before drugs may be prescribed by a veterinarian.

Veterinary prescriptions

The Board of Veterinary Medicine often receives questions regarding what is required of a veterinarian in prescribing or dispensing a prescription for controlled substances. **In Virginia, the term "controlled substances" is defined as any prescription drug including Schedule VI drugs**. The most frequently asked questions are the following:

1. What authority does a veterinarian have to prescribe?
2. Does a veterinarian have a right to refuse to provide a prescription?
3. May a veterinarian charge a fee for writing the prescription?
4. What information is required on a prescription and in what format?
5. Are there any prescription requirements specific to a Schedule II drug?
6. Does a veterinarian have to honor a prescription request by a pharmacy sent via telephone or fax?
7. What is required of a pharmacist in filling a prescription?
8. May one veterinary establishment "fill a prescription" for a patient seen by a veterinarian at another establishment?
9. May a veterinarian purchase controlled substances for the purpose of reselling?
10. May a veterinarian or veterinary establishment donate an expired or unexpired controlled substance (Schedule II – VI)?
11. May an owner return or donate an unused Schedule II – V drug to a veterinarian that was dispensed to an animal or a human?
12. May an owner return or donate an unused Schedule VI drug to a veterinarian that was dispensed to an animal or a human?
13. May a veterinarian provide a general stock of controlled drugs (Schedule II – VI) for administrating or dispensing by a pet store establishment or boarding kennel?
14. May a veterinarian prescribe cannabis oil?
15. May a veterinarian prescribe opioids?
16. Does a veterinarian have a requirement to report to the Prescription Monitoring Program (PMP) when controlled substances are dispensed from a veterinary establishment?
17. Are there special recordkeeping requirements for feline buprenorphine and canine butorphanol?
18. What schedule is gabapentin?
19. Does the Drug Enforcement Administration (DEA) have guidance documents?

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Guidance document: 150-13

Revised: March 11, 2021
Effective: May 13, 2021

1. What authority does a veterinarian have to prescribe?

Veterinarians are authorized to prescribe Schedule II through VI drugs by federal and state law. While not a comprehensive listing of all relevant federal and state law, the Virginia Drug Control Act provides:

§ 54.1-3409. Professional use by veterinarians.

A veterinarian may not prescribe controlled substances for human use and shall only prescribe, dispense or administer a controlled substance in good faith for use by animals within the course of his professional practice. He may prescribe, on a written prescription or on oral prescription as authorized by § 54.1-3410. . . Such a prescription shall be dated and signed by the person prescribing on the day when issued, and shall bear the full name and address of the owner of the animal, and the species of the animal for which the drug is prescribed and the full name, address and registry number, under the federal laws of the person prescribing, if he is required by those laws to be so registered.

However, the following portions of §§54.1-3408 and 54.1-3303 also apply, and they detail what is required to render a **valid** prescription.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of … veterinary medicine… shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter…

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of . . . veterinary medicine who is authorized to prescribe controlled substances…
B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship.

For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical

treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

2. Does the veterinarian have the right to refuse to provide a prescription?

The *Regulations Governing the Practice of Veterinary Medicine,* 18VAC150-20-140(6) and (12), provide that it is unprofessional conduct to violate any state law, federal law, or board regulation pertaining to the practice of veterinary medicine and to refuse to release a copy of a valid prescription upon request from a client. **The Board has held consistently that it is unprofessional conduct for a veterinarian to refuse to provide a prescription to a client if he would have dispensed the medication for the patient from his own animal facility.** This does not mean that the veterinarian is compelled to release a prescription when requested if there are medical reasons for not releasing it and he would not dispense the medication from his own practice.

Prior to issuance of a refill authorization of a prescription, the decision to require an examination of the animal is at the discretion of the professional judgment of the treating veterinarian.

3. May a veterinarian charge a fee for writing the prescription?

There is nothing in statute or regulation to prohibit a practitioner from charging a reasonable fee for writing the prescription if he so chooses.

4. What information is required on a prescription and in what format?

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription...If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated

as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. . .

C. The oral prescription referred to in §54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

§ 54.1-3409. Professional use by veterinarians.

He may prescribe, on a written prescription or on oral prescription as authorized by § 54.1-3410...Such a prescription shall be dated and signed by the person prescribing on the day when issued, and shall bear the full name and address of the owner of the animal, and the species of the animal for which the drug is prescribed and the full name, address and registry number, under the federal laws of the person prescribing, if he is required by those laws to be so registered.

5. Are there any prescription requirements specific to a Schedule II drug?

In addition to the prescription requirements found in the response to Question 4 above, the following information is provided for writing prescriptions for Schedule II drugs:

§ 54.1-3411. When prescriptions may be refilled.

Prescriptions may be refilled as follows:

1. A prescription for a drug in Schedule II may not be refilled.

§ 54.1-3408.02. Transmission of prescriptions.

B. Any prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription.

C. The requirements of subsection B shall not apply if:

5. The prescription is issued by a licensed veterinarian for the treatment of an animal;

6. Does a veterinarian have to honor a prescription request by a pharmacy sent via telephone or fax?

A veterinarian may honor such a request if a valid veterinarian-client-patient relationship exists as described previously and the veterinarian is sure that the client has requested it. However, the veterinarian is not compelled to do so. Section 54.1-3408.02 allows the transmission of faxed prescriptions.

> ***§ 54.1-3408.02. Transmission of prescriptions.***
>
> *A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions.*
>
> *B. Any prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription.*
>
> *C. The requirements of subsection B shall not apply if:*
>
> *5. The prescription is issued by a licensed veterinarian for the treatment of an animal;*

7. What is required of a pharmacist in filling a prescription?

> ***§ 54.1-3410. When pharmacist may sell and dispense drugs.***
>
> *A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:*
>
> *1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;*
>
> *2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's* [of Pharmacy] *regulations;*
>
> *3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written;…and such directions as may be stated on the prescription.*

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed…

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section...

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy…

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

E. A dispenser who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in § 54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law.

8. May one veterinary establishment "fill a prescription" for a patient seen by a veterinarian at another establishment?

No. There is no provision in Virginia law that allows for veterinary establishments or any other establishment not duly permitted by the Board of Pharmacy to dispense controlled substances to fill a prescription.

9. May a veterinarian purchase controlled substances (including Schedule VI drugs and devices) for the purpose of reselling?

No. A veterinarian does not have statutory authority to purchase controlled drugs for the purpose of wholesaling to a pharmacy, another practitioner, a veterinary establishment or commercial entity.

10. May a veterinarian or veterinary establishment donate an expired or unexpired controlled substance (Schedule II – VI)?

The meaning of "donation" in this context refers to the transferring of controlled substances without a prescription. A veterinarian may opt to not charge for a properly dispensed controlled substance.
Expired Schedule II – VI Controlled Substances. There is no authority to donate expired substances because they may be considered adulterated and must be destroyed in accordance with federal and state laws and regulations.

Unexpired Schedule II-VI Controlled Substances
The Drug Enforcement Agency (DEA) only permits the transfer of a Schedule II-V drug from one DEA registrant to another DEA registrant regardless of payment method.

11. May an owner return or donate an unused Schedule II – V drug to a veterinarian that was dispensed to a pet or human?

The Drug Enforcement Administration (DEA) only permits the transfer of Schedule II-V drug from one DEA registrant to another DEA registrant. Because the patient/client is not a DEA registrant, he may not transfer a Schedule II-V drug to anyone except during a drug take-back event wherein law enforcement receives the drug from the patient/client for destruction purposes only. Violations of this requirement can result in DEA imposing on the veterinarian a $10,000 fine per incident.

> ***§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.***
>
> *A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:*
>
> *1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;*
>
> *2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or*
>
> *3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.*
>
> *B. The Board of Pharmacy shall promulgate regulations to establish a Prescription Drug Donation Program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in*

subdivision A 2, for the purpose of re-dispensing such drugs to indigent patients, either through hospitals, or through clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured. Such program shall accept eligible prescription drugs from individuals, including those residing in nursing homes, assisted living facilities, or intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, or any facility operated by the Department of Behavioral Health and Developmental Services. Additionally, such program shall accept eligible prescription drugs from an agent pursuant to a power of attorney, a decedent's personal representative, a legal guardian of an incapacitated person, or a guardian ad litem donated on behalf of the represented individual.

C. Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated pursuant to this section unless such donation is prohibited.

D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient, or any other activity undertaken in accordance with a drug distribution program established pursuant to this section.

E. Nothing in this section shall be construed to create any new or additional liability, or to abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for its products separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient in accordance with a drug distribution program established pursuant to this section.

F. In the absence of bad faith or gross negligence, no person that donates, accepts, or dispenses unused prescription drugs in accordance with this section and Board regulations shall be subject to criminal or civil liability for matters arising from the donation, acceptance, or dispensing of such unused prescription drugs.

12. May an owner return or donate an unused Schedule VI drug to a veterinarian that was dispensed to a pet or a human?

While state law does not prohibit a veterinarian from receiving back an already dispensed Scheduled VI drug for destruction purposes, there is no provision in law for a veterinarian to re-dispense this returned drug.

13. May a veterinarian provide a general stock of controlled drugs (Schedule II – VI) for administrating or dispensing by a pet store establishment or boarding kennel?

There is no allowance in law for a veterinarian to provide a pet store establishment or boarding kennel with a general stock of controlled substances to be given to animals, either by donation or for a fee. **In Virginia, the term "controlled substances" is defined as any prescription drug including Schedule VI drugs**. The meaning of "donation" in this context refers to the transferring of controlled substances without a prescription. However, a veterinarian may opt to not charge for a properly dispensed controlled substance. A veterinarian is allowed to

prescribe, administer, and dispense controlled substances in keeping with the requirements of the Virginia Drug Control Act, specifically § 54.1-3409 of the *Code of Virginia*, and the statutes and regulations governing the practice of veterinary medicine. A veterinarian may prescribe, label and dispense a drug for the treatment of a specific animal after establishing a bona fide veterinarian-client-patient relationship.

14. May a veterinarian issue a written certification for cannabis oil?

Pursuant to the Code of Virginia, a veterinarian is not included in the definition of a "practitioner" who is authorized to issue written certification for possession and use of cannabidiol oil or THC-A oil.

In 2018, legislation was passed amending §§ 54.1-3408.3 and 18.2-250.1, relating to cannabidiol oil or THC-A oil and possession of marijuana.

> ***§ 54.1-3408.3. Certification for use of cannabis oil for treatment.***
>
> *A. As used in this section:*
>
> *"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by a pharmaceutical processer pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it has been acquired and formulated with cannabis plant extract by a pharmaceutical processor.*
>
> *"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.*
>
> *"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.*
>
> *B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances.*

15. May a veterinarian prescribe opioids?

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Guidance document: 150-13

Revised: March 11, 2021
Effective: May 13, 2021

Pursuant to 18VAC150-20-180 of the *Regulations Governing the Practice of Veterinary Medicine*, a veterinarian may prescribe Schedule II-V drugs that contains an opioid, to include tramadol and buprenorphine.

18VAC150-20-174. Prescribing of controlled substances for pain or chronic conditions.

A. Evaluation of the patient and need for prescribing a controlled substance for pain.

1. For the purposes of this section, a controlled substance shall be a Schedules II through V drug, as set forth in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), which contains an opioid, to include tramadol and buprenorphine.

2. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. Prior to initiating treatment with a controlled substance, as defined, the prescriber shall perform a history and physical examination appropriate to the complaint and conduct an assessment of the patient's history as part of the initial evaluation.

3. If a controlled substance is necessary for treatment of acute pain, the veterinarian shall prescribe it in the lowest effective dose appropriate to the size and species of the animal for the least amount of time. The initial dose shall not exceed a 14-day supply.

B. If the prescribing is within the accepted standard of care, a veterinarian may prescribe a controlled substance containing an opioid for management of chronic pain, terminal illnesses, or certain chronic conditions, such as chronic heart failure, chronic bronchitis, osteoarthritis, collapsing trachea, or related conditions.

1. For prescribing a controlled substance for management of pain after the initial 14-day prescription referenced in subsection A of this section, the patient shall be seen and evaluated for the continued need for an opioid. For the prescribing of a controlled substance for terminal illnesses or certain chronic conditions, it is not required to see and reevaluate the patient for prescribing beyond 14 days.

2. For any prescribing of a controlled substance beyond 14 days, the veterinarian shall develop a treatment plan for the patient, which shall include measures to be used to determine progress in treatment, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with physical impairment.

3. For continued prescribing of a controlled substance, the patient shall be seen and reevaluated at least every six months, and the justification for such prescribing documented in the patient record.

C. Prior to prescribing or dispensing a controlled substance, the veterinarian shall document a discussion with the owner about the known risks and benefits of opioid therapy, the responsibility for the security of the drug and proper disposal of any unused drug.

D. Continuation of treatment with controlled substances shall be supported by documentation of continued benefit from the prescribing. If the patient's progress is unsatisfactory, the veterinarian shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

E. The medical record for prescribing controlled substances shall include signs or presentation of the pain or condition, a presumptive diagnosis for the origin of the pain or condition, an examination appropriate to

the complaint, a treatment plan, and the medication prescribed to include the date, type, dosage, and quantity prescribed.

16. Does a veterinarian have a requirement to report to the Prescription Monitoring Program (PMP) when controlled substance are dispensed from a veterinary establishment?

The 2018 General Assembly passed SB226 requiring all veterinarians to report the dispensing of covered substances for a course of treatment to last more than seven days. The 2019 Virginia General Assembly passed SB1653, amending the PMP exemption from reporting to include dispensing of feline buprenorphine and canine butorphanol. Please review Guidance Document 150-21 **Frequently asked questions about reporting to the Prescription Monitoring Program** for more information on reporting requirements.

17. Are there special recordkeeping requirements for feline buprenorphine and canine butorphanol?

SB1653 of the 2019 General Assembly included an enactment clause that states the following:

2. That every veterinary establishment licensed by the Board of Veterinary Medicine shall maintain records of the dispensing of feline buprenorphine and canine butorphanol, reconcile such records monthly, and make such records available for inspection upon request.

The Regulations Governing the Practice of Veterinary Medicine state the following:

18VAC150-20-190. Requirements for drug storage, dispensing, destruction, and records for all establishments.

L. Veterinary establishments shall (i) maintain records of the dispensing of feline buprenorphine and canine butorphanol, (ii) reconcile such records monthly, and (iii) make such records available for inspection upon request.

In the Regulations Governing the Practice of Veterinary Medicine, there is a similar requirement for Schedule II controlled substances which states the following:

18VAC150-20-190. Requirements for drug storage, dispensing, destruction, and records for all establishments.

K. Inventories and records, including original invoices, of Schedule II drugs shall be maintained separately from all other records, and the establishment shall maintain a continuous inventory of all Schedule II drugs received, administered, or dispensed, with reconciliation at least monthly. Reconciliation requires an explanation noted on the inventory for any difference between the actual physical count and the theoretical count indicated by the distribution record. A continuous inventory shall accurately indicate the physical count of each Schedule II drug in the general and working stocks at the time of performing the inventory.

Although the requirements are similar, the regulations state that Schedule II records shall be maintained separately. Therefore, the reconciliation records for feline buprenorphine (Schedule III) and canine butorphanol (Schedule IV) cannot be combined with the Schedule II records.

18. What schedule is gabapentin?

The 2019 Virginia General Assembly passed HB2557 which classified gabapentin as a Schedule V controlled substance as of July 1, 2019. Until then, gabapentin was a Schedule VI controlled substance but was a drug of concern, reportable to the PMP.

As of July 1, 2019, veterinary establishments that possess or dispense gabapentin must comply with board regulations in 18VAC150-20-190 for a Schedule V controlled substance.

As of July 1, 2019, pharmacies dispensing and refilling gabapentin are required to comply with the requirements of the *Regulations Governing the Practice of Pharmacy*, 18VAC110-20-320, which provide that a Schedule V controlled substance cannot be dispensed or refilled more than six months after the date on which such prescription was issued, nor may it be refilled more than five times. Active prescriptions on file with a dispenser that have a date of issuance greater than six months or that have been refilled five times or more will be considered expired. After July 1, 2019, if a pharmacist receives a prescription authorizing more than five refills, the prescription will still expire six months after the date of issuance or after five refills, whichever occurs first.

This scheduling action occurred under Virginia law; the Drug Enforcement Administration (DEA) has not yet scheduled gabapentin. Therefore, a prescriber is not required to hold a DEA registration in order to possess or prescribe gabapentin.

19. Does the Drug Enforcement Administration (DEA) have guidance documents?

DEA Guidance Documents are available for review on its website.

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Guidance document: 150 -16

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VIRGINIA BOARD OF VETERINARY MEDICINE

Protocol to follow upon discovery of a loss or theft of drugs

Guidance:
Whenever a theft or any other unusual loss of any controlled substance is discovered, the Veterinarian-in-Charge, or in his absence his designee, shall immediately report such theft or loss to all of the following:

1. Virginia Board of Veterinary Medicine in writing;

2. Virginia Board of Pharmacy in writing; and

3. U.S. Drug Enforcement Agency

The Boards of Veterinary Medicine and Pharmacy request written notification be sent via email, FAX or postal carrier. The Board recommends contacting local law enforcement. Reports to the DEA must be made in accordance with 21 C.F.R. § 1301.76(b).

If the Veterinarian-in-Charge is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedules II through V drugs.

Reference
18VAC150-20-190. Requirements for drug storage, dispensing, destruction, and records for all establishments.

5. Whenever a theft or any unusual loss of Schedules II through V drugs is discovered, the veterinarian-in-charge, or in his absence, his designee, shall immediately report such theft or loss to the Board of Veterinary Medicine and the Board of Pharmacy and to the DEA. The report to the boards shall be in writing and sent electronically or by regular mail. The report to the DEA shall be in accordance with 21 CFR 1301.76(b). If the veterinarian-in-charge is unable to determine the exact kind and quantity of the drug loss, he shall immediately take a complete inventory of all Schedules II through V drugs.

Virginia Board of Veterinary Medicine

Use of Compounded Drugs in Veterinary Practice

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 his/her 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.

Q: May a veterinarian *dispense* a compounded drug product?

A: A veterinarian may dispense a compounded drug product as follows:

Drug Compounded by Veterinarian in Veterinary Facility
A veterinarian may dispense a compounded drug produce *if it is compounded by the veterinarian* pursuant to Virginia Code § 54.1-3410.2(J).

Drug Compounded by Pharmacy and Purchased by Veterinarian
A veterinarian may only dispense a compounded drug obtained from a pharmacy under the conditions set forth in § 54.1-3301(2) which states "… 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 seven-day 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;…"

Q: What is the penalty for a licensee of the Virginia Board of Veterinary Medicine who is found to be dispensing compounded drug product not in accordance with federal law or the Virginia Drug Control Act?

A: The licensee may be subject to disciplinary action.

Applicable Laws

§ 54.1-3301. Exceptions.
This chapter shall not be construed to:
1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;
2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that 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 seven-day 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;

§ 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; however, 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 pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § **54.1-3420.2.***
A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians 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; (v) the name and address of the pharmacy; and (vi) the quantity. Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the 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.*