Virginia Board of Pharmacy

Allowances to Purchase, Possess, and Administer Drugs within an Animal Shelter

The Board of Pharmacy provides the following guidance regarding drugs maintained and administered within an animal shelter.

1. Pursuant to §54.1-3423 E, an animal shelter may obtain a controlled substances registration (CSR) certificate from the Board of Pharmacy for purchasing, possessing, and administering drugs for two purposes: euthanasia of injured, sick, homeless and unwanted domestic pets and animals; and prevention, control, and treatment of certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. These drugs shall only be stored and administered at the address of the humane society or shelter and shall not be taken off-site for administration. Additionally, the training requirements for persons to administer drugs for these two purposes differ and are highlighted below.

2. Pursuant to the Virginia Department of Wildlife Resources Director Policy to Capture, Possess, Transport, Release, or Humanely Dispatch Wildlife by Animal Control Officers and Local Animal Shelters in Accordance with 4VAC15-30-50, an animal shelter may obtain a CSR or amend its existing CSR from the Board of Pharmacy for purchasing, possessing, and administering drugs to chemically immobilize wildlife for the purpose performing humane dispatch in a manner that prioritizes public safety and animal welfare. Such drugs must be administered by trained animal control officers or trained animal shelter staff at the address of the animal shelter in accordance with the Policy of the Director of the Department of Wildlife Resources (DWR).

Drugs for Euthanasia

Only controlled substances in Schedules II-VI approved by the State Veterinarian for euthanasia of injured, sick, homeless and unwanted domestic pets and animals may be purchased, possessed, and administered. These drugs may be used for euthanasia of domestic animals and shall be administered only in accordance with the facility protocol and only by persons trained and certified as to competency in accordance with the State Veterinarian's directives. These drugs may also be used for euthanasia of wildlife and shall be administered only in accordance with the DWR Director Policy.

Training for administering drugs for euthanasia

The training for persons administering drugs to domestic animals in accordance with protocols established by the State Veterinarian for euthanasia shall be approved by the State Veterinarian. A current certification of competency signed by the supervising veterinarian for the facility shall be maintained at the facility for each person administering drugs and must be retained for not

less than two years after the person ceases administering. To access the most recent State Veterinarian's directive on Methods Prescribed or Approved for Animal Euthanasia and Competency Certification Requirements (Directive 79-1) click on: http://www.vdacs.virginia.gov/pdf/euthansiadirective.pdf

The training for persons administering drugs to wildlife shall be in accordance with the DWR Director Policy.

Drugs for Communicable Disease Prevention, Control and Treatment

Only certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter may be purchased, possessed, or administered unless prescribed to a specific domestic animal by a licensed veterinarian. These drugs shall not be used for the treatment of a non-transmissible malady or condition such as an injury; controlled substances required for the treatment of such conditions must be prescribed to a specific animal by a licensed veterinarian. The drugs shall also not be used for administration to wildlife.

The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the animal shelter shall be determined by the supervising veterinarian of the shelter. Additionally, the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter.

The written protocols established or approved by the supervising veterinarian shall, at a minimum, include the following information:

- name and contact information for the animal shelter and the supervising veterinarian;
- name of communicable disease to be prevented, controlled, or treated;
- name of the species, and other signalments as applicable, for which the protocol is intended;
- symptoms or other qualifiers which must be present prior to administering the drug;
- name of drug and dosage guidelines;
- method of administration;
- dosing frequency, duration of administration, and expected response;
- cautions and contraindications;
- instructions for when to contact the supervising veterinarian or designated veterinarian for additional direction which shall address, at a minimum, the development of side effects of the drug, allergic responses to the drug, and ineffective responses to the drug;
- date and signature of supervising veterinarian.

Training for administering certain Schedule VI for communicable diseases

The person offering the training for administering certain Schedule VI drugs for the prevention and treatment of communicable diseases in accordance with instructions established or approved by the supervising veterinarian shall be a veterinarian, but is not required to be the supervising

veterinarian for the animal shelter. The training records of those persons administering Schedule VI drugs shall be maintained on the premises of the shelter, retained for not less than two years after the person ceases administering, and updated as protocols are amended. Additionally, the training record shall include, at a minimum, the following information:

- name and contact information for the animal shelter;
- name of person being trained and veterinarian offering training;
- name of Schedule VI drugs and routes of administration person has been properly trained to administer in accordance with instructions established or approved by the supervising veterinarian;
- name of species to which drugs may be administered;
- date and signature of veterinarian providing the training.

Controlled Substances Registration Certificate

The application for a controlled substances registration certificate for an animal shelter handling only domestic animals requires the designation and signature of a responsible party and supervising practitioner.

- **Responsible party**

The responsible party shall be an individual who is properly trained to administer and access the controlled substances and shall maintain proper security and required records of all controlled substances obtained and administered. If the responsible party ceases employment with the facility or relinquishes his position, he shall immediately return the controlled substances registration certificate to the board and shall take a complete and accurate inventory of all drugs in stock in compliance with §54.1-3404 of the Drug Control Act . An application for a controlled substances registration certificate indicating a change in responsible party shall be filed within 14 days. At that time, the new responsible party shall take a complete and accurate inventory of all drugs in stock.

- **Supervising practitioner**

The supervising practitioner within the animal shelter shall be a licensed veterinarian who may provide the training for administering Schedule VI drugs for the prevention and treatment of communicable diseases and shall assume the following responsibilities to include, but not limited to,:

1. providing general supervision for the facility;
2. providing a list of Schedule VI drugs used for treatment and prevention of communicable diseases;
3. establishing or approving written protocols for administering the drugs for the prevention and treatment of communicable diseases; and,
4. certifying competency in the performance of euthanasia in accordance with guidelines set forth by the State Veterinarian.

Within 14 days of a change in the supervising practitioner, the Board of Pharmacy shall be notified and an application for the controlled substances registration certificate shall be submitted indicating the name and license number, if applicable, of the new supervising practitioner.

Animal shelters intending to handle both domestic animals and wildlife shall adhere to the information for how to obtain a controlled substances registration as indicated in the DWR Director Policy.

Related Cites from the Code of Virginia and Regulations of the Board of Pharmacy

from the Code of Virginia
§54.1-3423
E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II through VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. Controlled substances used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs and biological products used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological products shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs and biological products, written protocols for administering, and training records of those persons administering drugs and biological products on the premises of the shelter.

from Regulations Governing the Practice of Pharmacy

18VAC110-20-580. Humane societies and animal shelters.

A humane society or animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer controlled substances in accordance with provisions of § 54.1-3423 of the Code of Virginia provided that these procedures are followed:

1. Drugs ordered by a humane society or animal shelter shall only be stored and administered at the address of the humane society or shelter.

2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the person(s) responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

3. The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

4. Drugs shall be stored in a secure, locked place and only the person(s) responsible for administering may have access to the drugs.

5. All invoices and order forms shall be maintained for a period of two years.

6. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity that maintains or intends to maintain a supply of Schedules II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities that may be registered by the board shall include hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date or requests that are received after the application is filed shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedules II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for

the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs that may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation; or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions that meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug that has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedules II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device, or other area that shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area that has a security device for the detection of breaking that meets the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedule II through VI drugs in accordance with provisions of §54.1-3404 of the Code of Virginia and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date. All inventories required by §54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An entity which is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

4. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing

a printout of any data which the registrant is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia).

5. The Department of Forensic Science may exclude from any inventory quantities of controlled substances used to conduct chemical analyses and controlled substances received for analyses as evidentiary material as provided in §54.1-3404 G of the Code of Virginia.