GENERAL GOVERNMENT CABINET

Kentucky Board of Veterinary Examiners

(New Administrative Regulation)

201 KAR 16:552. Responsibilities for certified animal control agencies; limitations on drugs.

RELATES TO: KRS 321.207, 321.235(7), 321.351

STATUTORY AUTHORITY: KRS 321.207(1), (2), 321.235(3), 321.240(5)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 321.207(1) permits the Kentucky Board of Veterinary Examiners to authorize an animal control agency to apply for a registration certificate by the United States Drug Enforcement Administration (DEA) to order, purchase, manage, and store controlled substances which are authorized by the board for use in animal sedation and euthanasia. KRS 321.207(2) requires the applicant agency to comply with administrative regulations that establish standards for the proper storage and handling of the drugs the board has authorized for use, and other provisions that may be necessary to ensure that the drugs are used safely and solely for the purpose of euthanizing animals. KRS 321.235 and 321.240 authorize the board to promulgate administrative regulations to implement KRS Chapter 321. This administrative regulation establishes the duties for the animal control agency designated on-site manager, standards for proper drug storage, and drugs that may be used by certified animal control agencies and the certified animal euthanasia specialists they employ.

Section 1. Responsibilities of a Certified Animal Control Agency.

(1) A certified animal control agency and staff shall comply with all requirements of KRS Chapter 321 and the administrative regulations promulgated by the board under this chapter.

(2) A certified animal control agency shall identify an agency designated on-site manger and ensure the person complies with the requirements in Section 2 of this administrative regulation.

(3) Any change to the designated on-site manager shall be reported in writing to the board within ten (10) business days by submitting a completed Request for a New Designated On-site Manager form or online equivalent form, including all required attachments.

(4) A certified animal control agency shall ensure that the United States Drug Enforcement Administration (DEA) Controlled Substances Registration is kept in active status as long as there are controlled substances in the possession of the agency.

(5) A certified animal control agency shall submit to inspection by a board representative at any time, with or without advanced notice in accordance with 201 KAR 16:550, Section 5.

Section 2. Responsibilities of a designed on-site manager.

(1) The designated on-site manager shall be responsible for reviewing educational materials provided by the board and submitting a responsive answer sheet for review by the board. A board inspector or representative shall periodically review educational materials with the designated on-site manager.

(2) The designated on-site manager shall:

(a) Ensure proper controls are in place in accordance with all state and federal laws for all controlled substances and other drugs at the animal control agency;

(b) Ensure drugs for euthanasia and drugs used for sedation prior to euthanasia shall be limited to the substances identified in Section 3 of this administrative regulation;

(c) Ensure all employees authorized to conduct animal euthanasia at the certified animal control agency are trained and certified in accordance with the requirements of 201 KAR 16:560, unless the employee is a board-licensed veterinarian or board-licensed veterinary technician;

(d) Ensure all animal euthanasia specialists who conduct euthanasia at the certified animal control agency maintain an active certificate with the board;

(e) Notify the board in writing within ten (10) business days following the termination of a certified animal euthanasia specialist so the certificate of the animal euthanasia specialist may be taken out of 'active' status;

(f) Shall develop and maintain standard operating procedures in writing for carcass disposal in accordance with all state and local laws and ordinances; and

(g) Shall be responsive and cooperative to the board's request for access and information to the certified animal control agency.

(3) The designated on-site manager shall ensure that the animal euthanasia process shall be conducted within the restrictions set forth in this subsection.

(a) Euthanasia shall only be conducted upon animals owned by the certified animal control agency, except in cases of emergency as defined in KRS 321.181.

1. Transfer of ownership or a temporary contract shall not be used for the purpose of circumventing this provision;

2. Wildlife shall be redirected to a board-licensed veterinarian, Certified Wildlife Rehabilitator authorized to operate pursuant to 301 KAR 2:075, or to a Nuisance Wildlife Control Operator authorized to operate pursuant to 301 KAR 3:120.

(b) Euthanasia shall only be conducted upon the premises of the certified animal control agency, except in cases of emergency as defined in KRS 321.181; and

(c) All euthanized animals shall be disposed of in accordance with the certified animal control agency's standard operating procedures for carcass disposal.

Section 3. Approved drugs for animal euthanasia and anesthesia or sedation of animals prior to euthanasia.

(1) A certified animal control agency shall be restricted to the purchase of specific drugs for the purpose of animal euthanasia. The drugs approved by the board for euthanasia are:

(a) Sodium pentobarbital; and

(b) Sodium pentobarbital with lidocaine.

(2) A certified animal control agency shall be restricted to the purchase of specific drugs for the purpose of animal anesthesia or sedation prior to euthanasia. The drugs approved by the board for animal anesthesia or sedation prior to euthanasia are, or any combination thereof:

(a) Acepromazine;

(b) Dexmedetomidine;

(c) Ketamine (30-day supply or less); and

(d) Xylazine.

(3) DEA's Schedule II order forms (titled "DEA-222") shall be used for each purchase or transfer of board approved controlled substances.

(4) Expired drugs.

(a) Expired drugs shall not be used.

(b) Expired drugs shall be properly disposed of in accordance with Section 7 of this administrative regulation.

Section 4. Storage.

(1) Board approved euthanasia and sedation drugs shall be stored in a securely locked cabinet within a locked storage room or other enclosure at the DEA address of record for the certified animal control agency. The cabinet shall be bolted securely to the floor or wall.

(2) DEA Controlled Substance Schedule II order forms shall be stored in a securely locked cabinet, separate from the storage location of the drugs, within a locked storage room or other enclosure at the DEA address of record for the certified animal control agency.

Section 5. Disposal of Needles and Medical Waste.

(1) All needles in an animal control agency shall:

(a) Not be accessible to the public;

(b) After use, be rendered incapable of use; and

(c) Be disposed of in an approved biohazard or sharps container.

(2) All syringes used in the process of euthanasia shall be disposed of in an approved biohazard or sharps container.

Section 6. Records.

(1) A certified animal control agency shall maintain records of purchases, administration of board approved euthanasia drugs and sedation drugs, transfer, and destruction of drugs for a minimum of two (2) years.

(2) Records of administration shall include, at a minimum, the following information:

(a) The date of use;

(b) Identification of the animal;

(c) The amount of the drug used;

(d) Any amount wasted;

(e) The signature of the person administering the drug;

(f) The signature of the designated on-site manager certifying the accuracy of the administration of board approved euthanasia drugs and sedation drugs not less than once per month; and

(g) The signature of the designated on-site manager certifying to the accuracy of the records not less than once per month, as well as on the annual inventory.

(3) Records of purchase and destruction of board approved euthanasia drugs and sedation drugs shall be maintained in a separate file from the records of administration of those substances.

(4) The records of purchase, destruction, and administration may be audited by representatives of the DEA or authorized designees of the board to determine adequacy, accuracy, and validity of the recordkeeping. The board may impose restrictions and administrative penalties on certificate holders or designated on-site managers as a result of substandard controls or records of the drugs.

(5) The records of purchase, administration, transfer, and destruction of euthanasia and sedation drugs, shall be maintained at the DEA address of record for the animal control agency.

Section 7. Destruction or disposal of drugs.

Drugs at an animal control agency that require disposal shall be disposed of in accordance with one of the methods set forth in this section. A written receipt with appropriate signatures shall be obtained for methods (1) – (3), and a record of the action taken shall be made for method (4). The record shall be maintained with the drug logs at the animal control agency.

(1) Transfer non-expired, non-controlled drugs to a licensed veterinarian.

(2) Transfer non-expired, controlled drugs to a DEA registered, board-licensed veterinarian using DEA Form 222. Copies of the DEA Form 222 shall be distributed per federal law.

(3) Surrender expired or non-expired drugs to local law enforcement for destruction.

(4) Inject expired or non-expired drugs into and incinerate an animal carcass in accordance with state and local rules on incineration. Written documentation shall describe the amounts disposed of, type of carcass, date of injection and incineration, witnesses, and any other pertinent details.

Section 8. Disciplinary Action. An animal control agency, designated on-site manager, and credentialed animal euthanasia specialists shall be subject to disciplinary action pursuant to KRS 321.235 and KRS 321.351 for a violation of state or federal statutes or administrative regulations.

Section 8. Incorporation by Reference.

(1) "Request for a New Designated On-site Manager", 12/2022, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subjected to applicable copyright law, at the Kentucky Board of Veterinary Examiners, 107 Corporate Drive, Frankfort, Kentucky 40601, Monday through Friday, 8:30 a.m. to 4:30 p.m. This material may also be obtained at www.kybve.com.

Steven J. Wills, DVM
Chair, Kentucky Board of Veterinary Examiners

12/15/2022
Date:

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on February 23, 2023 at 9:00 a.m., at the Kentucky Department of Agriculture, 109 Corporate Drive, Frankfort, KY 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made prior to the end of the hearing. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through February 28, 2023. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Michelle Shane, Executive Director, Kentucky Board of Veterinary Examiners, 107 Corporate Drive, Second Floor, Frankfort Kentucky 40601, phone (502) 782-0273, fax (502) 695-5887, email michelle.shane@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT
201 KAR 16:552

Contact Person: Michelle Shane, Executive Director
Phone: 502-782-0273
Email: michelle.shane@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes, for Board-certified animal control agencies, the standards for proper drug storage, limitations on the drugs that may be used by the agencies and the certified animal euthanasia specialists they employ, limitations on the animals on which the drugs may be used so that the specialists do not practice veterinary medicine outside the scope allowable by the General Assembly. In addition, this regulation outlines the responsibilities of the agency's Designated Onsite Manager, how is in charge of controlled substances, including drug storage requirements, record keeping requirements, and limitations on options for the methods used for the destruction of drugs.

(b) The necessity of this administrative regulation:

As mandated by the General Assembly in KRS 321.207, this administrative regulation is necessary to establish the drugs that may be used by certified animal control agencies and the certified animal euthanasia specialists they employ, and standards for proper drug storage and handling.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 321.207 specifically requires the board to promulgate administrative regulations for board-certified animal control agencies limiting the type of drugs allowable for use by certified animal control agencies and the certified animal euthanasia specialists they employ, and establishing standards for proper drug storage and handling.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation will assist in effective administration by clearly detailing limitations on the operations of certified animal control agencies so that they do not exceed their operating scope as authorized by the General Assembly.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

n/a

(b) The necessity of the amendment to this administrative regulation:

n/a

(c) How the amendment conforms to the content of the authorizing statutes:

n/a

(d) How the amendment will assist in the effective administration of the statutes:

n/a

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

50 board-certified animal control agencies and 161 animal euthanasia specialists, and future applicants.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

All board-certified animal control agencies shall be required to ensure adequate locked and secure storage for the management of controlled substances onsite, limit the orders of controlled drugs to those listed by board in this administrative regulation, use only non-expired drugs, and submit to a board inspection approximately once per year to ensure proper controls exist and educate new staff on requirements. Additionally, board-certified animal control agencies shall ensure employees delegated to perform euthanasia are certified by the board, limit employees to providing euthanasia to agency-owned animals, ensure proper drug records are kept, properly and safely dispose of animal carcasses, needles, medical waste, and drugs.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

Board-certified animal control agencies should already be properly ordering, storing, and managing controlled drugs as a part of requirements established by the Drug Enforcement Administration (DEA), so there should not be any additional costs.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

By complying with this administrative regulation, entities should reduce break-ins and thefts of controlled substances, as well as be able to comply with DEA Requirements related to drug record keeping. Entities should also reduce liability to the public by reinforcing General Assembly mandates related to the scope of practice for board-certified euthanasia specialists, ensuring sharps are properly disposed of, and ensuring proper carcass disposal in compliance with local laws.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No costs are anticipated.

(b) On a continuing basis: No costs are anticipated.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

This administrative regulation does not establish fees. Funding for the KBVE comes from licensure and certification fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

There is no anticipation of an increase in fees or needed funding to implement this administrative regulation, as the KBVE is already running an administrative program to process applications and an inspection program to ensure compliance.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

No fees are established or increased by this administrative regulation.

(9) TIERING: Is tiering applied? (Explain why or why not)

No. All regulated entities have the same requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT
201 KAR 16:552

Contact Person: Michelle Shane, Executive Director
Phone: 502-782-0273
Email: michelle.shane@ky.gov

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Kentucky Board of Veterinary Examiners and board-certified animal control agencies.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 321.207, KRS 321.235, KRS 321.240

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

No revenue will be generated from this filing.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

No revenue will be generated from this filing.

(c) How much will it cost to administer this program for the first year?

This is not a new program. Staff time will be required for record keeping.

(d) How much will it cost to administer this program for subsequent years?

Staff time will be required for record keeping. Costs will be very minimal.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None.

Expenditures (+/-): None or negligible.

Other Explanation: n/a

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

There will be no cost savings; this administrative regulation simply codifies the requirements of drug management and establishes limitations on drug administration, making them easily accessible for regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

There will be no cost savings.

(c) How much will it cost the regulated entities for the first year?

There will be no additional costs involved.

(d) How much will it cost the regulated entities for subsequent years?

There will be no additional costs involved.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-): None.

Expenditures (+/-): None or negligible.

Other Explanation: n/a

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]*

This amendment shall not have a "major economic impact", as defined in KRS 13A.010(13).

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

"Request for a New Designated On-site Manager", 12/2022, is the 2-page request form for a KBVE-certified animal control agency to identify and report to KBVE a new Designated On-site Manager who is the responsible part for controlled substances on-site at the animal control agency. KRS 321.207 requires animal shelters seeking a DEA Registration to become certified by KBVE, and 201 KAR 16:550 requires that the animal control agency designate a responsible party called the "Designated On-site Manager" to be in charge of ordering, using, and storing the controlled substances on-site.

SUMMARY OF CHANGES TO MATERIAL INCORPORATED BY REFERENCE

"Request for a New Designated On-site Manager", 12/2022, is the 2-page request form for a KBVE-certified animal control agency to identify and report to KBVE a new Designated On-site Manager who is the responsible part for controlled substances on-site at the animal control agency. This form is newly incorporated by reference in this administrative regulation.