

BOARDS AND COMMISSIONS

Board of Veterinary Examiners

(Amendment)

201 KAR 16:550. Authorization for animal control agencies to apply for a restricted controlled substances certificate from DEA.

RELATES TO: KRS ~~217.177(1), (4)~~~~[217.177(6)]~~, 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 euthanize animals. 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(3) and 321.240(5) authorize the board to promulgate administrative regulations to implement KRS Chapter 321. This administrative regulation establishes the application and renewal~~[certification]~~ requirements for certification as an animal control agency, and the requirements for board inspections at certified animal control agencies~~[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. Definitions. ~~[General Requirements.]~~

- (1) "Animal shelter" means a public agency or private humane society, society for the prevention of cruelty to animals, animal protection shelter or control agency, or other facility that provides shelter and care for homeless, stray, unwanted, or injured animals.
- (2) "Certified Animal Control Agency" means an animal shelter that is certified under the provisions of KRS Chapter 321 and associated regulations.
- (3) "Designated On-site Manager" means a person who registers with the board to assume responsibility for the ordering, management, use, and disposal of controlled substances at a board-certified animal control agency.

Section 2. Application and Renewal Requirements.

- (1) The applicant animal ~~shelter~~~~[control agency]~~ shall apply to the board for authorization as established by KRS 321.207.
- (2) A complete application to the board shall include the following components:
 - (a) A completed Application for Certification as an Animal Control Agency form or online equivalent form, including all required attachments;
 - (b) Identification of the agency designated on-site~~[onsite]~~ manager;
 - (c) A complete and current list of all individuals performing~~[performing]~~ euthanasia or related activities at the animal shelter, whether or not each individual holds a credential from the board~~[control facility]~~; and
 - (d) Payment of the fee in accordance with 201 KAR 16:514.
- (3) Prior to the board's issuance of the animal control agency certificate~~[of authorization]~~, the applicant shall undergo an inspection of the facility by the board, its inspector, or other designee of the board in accordance with Section 5 of this administrative regulation.
- (4) Following board application approval, the applicant shall apply to DEA for registration as a practitioner and designate "animal shelter" on the appropriate DEA form.
- (5) A certified animal control agency shall submit to inspection by a board representative at any time, with or without advanced notice.

(6) A certified animal control agency shall identify a designated on-site~~designate an on-site~~ manager in accordance with 201 KAR 16:552~~of the shelter~~.

(a) The agency shall notify the board in writing within ten (10) days of any change in the designated on-site~~onsite~~ manager of the shelter by submitting a completed Request for a New Designated On-site Manager form or online equivalent form, including all required attachments.

(b) The designated on-site manager shall be responsible for complying with all state and federal laws related to the ordering, purchase, storage, tracking, management, and disposal of the drugs obtained under the DEA controlled substances registration.

(7) Background checks. The board may conduct a national or jurisdictional level background check on each designated on-site manager~~shelter~~. The check shall be processed by a board approved background check provider, and may include a copy of the designated on-site manager's fingerprints captured at a board approved location. The board may accept the results of an employment background check from the county office in lieu of a state or federal background check if the background check results are not more than six (6) months old from the date of application. The board may reject background checks that do not have an official seal or watermark, or that are more than ninety (90) days old. The board may impose additional requirements as a condition of certification for the animal control agency or deny certification following the board's review of findings from a background check.

Section 3. ~~((8))~~ Renewal Requirements for a Certified Animal ~~[Animal]~~ Control Agency~~[certificate renewal requirements]~~.

(1) ~~((a))~~ A board-certified ~~[An]~~ animal control agency shall renew the board certification annually in accordance with 201 KAR 16:572.

(2) ~~((b))~~ Failure to renew the certificate for an animal control agency shall result in the following actions by the board:

(a) ~~((1-))~~ The animal control agency certificate shall be moved to expired status;

(b) ~~((2-))~~ Each 'active' status ~~[All]~~ certified animal euthanasia specialist~~[specialists]~~ under the employment of the ~~expired~~~~[formerly]~~ certified animal control agency shall be moved to 'inactive' status;~~[and]~~

(c) ~~((3-))~~ The DEA shall be notified of the lapse in certification; and

(d) The board shall conduct a closeout inspection within six (6) months of the date of expiration to ensure that the controlled substances and other drugs on-site are properly disposed of. An animal shelter with an expired certificate shall continue to maintain the drugs in accordance with 201 KAR 16:552 and the Kentucky Veterinary Medicine Practice Act until the drugs are transferred in accordance with state and federal laws, or disposed of in accordance with 201 KAR 16:552, Section 7.

Section 4. ~~((e))~~ Reinstatement Requirements for Animal Control Agencies.

(1) ~~((1-))~~ An animal control agency with an expired certificate shall have five (5) years to reinstate their certificate by submitting a completed Reinstatement Application for Animal Control Agencies form or online equivalent form, including all required attachments and payment of the application fee pursuant to 201 KAR 16:514.

(2) ~~((2-))~~ The animal control agency shall undergo inspection by an authorized representative of the board in accordance with subsection (3) of this section prior to the reinstatement of a certificate.

(3) ~~((3-))~~ After five (5) years, the agency shall not be able to reinstate and shall be required to apply for a new certificate in accordance with this administrative regulation and 201 KAR 16:572.

~~[Section 2.] [Approved Drugs. A certified animal control agency shall be restricted to the purchase of sodium pentobarbital and other euthanasia drugs currently approved by the~~

~~American Veterinary Medical Association (AVMA) for the purpose of euthanizing animals. DEA's Schedule II order forms (titled "DEA-222") shall be used for each purchase of sodium pentobarbital or other AVMA approved euthanasia drugs.]~~

~~[Section 3.] [Records.]~~

~~[(1)] [A certified animal control agency shall maintain records of purchases and administration of sodium pentobarbital and other AVMA approved euthanasia drugs for a period of not less than 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)] [The signature of the person administering the drug;]~~

~~[(e)] [The signature of the onsite manager certifying the accuracy of the administration of sodium pentobarbital and other AVMA approved euthanasia drugs not less than once per month; and]~~

~~[(f)] [The signature of the onsite manager certifying to the accuracy of the records.]~~

~~[(3)] [Records of purchase and destruction of sodium pentobarbital and other AVMA approved euthanasia 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 as a result of substandard controls or records of the drugs.]~~

~~[(5)] [The records of purchase, destruction, and administration shall be maintained at the location of the agency.]~~

~~[Section 4.] [Storage.]~~

~~[(1)] [Sodium pentobarbital and other AVMA approved euthanasia drugs shall be stored in a securely locked cabinet within a locked storage room or other enclosure at the certified animal control agency.]~~

~~[(2)] [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 certified animal control agency.]~~

~~[Section 5.] [Disposal of Needles and Medical Waste. All needles generated in the process of euthanizing animals shall be disposed of pursuant to KRS 217.177(6).]~~

~~[Section 6.] [Disciplinary Action. An animal control agency and its employees shall be subject to disciplinary action pursuant to KRS 321.235(7) and KRS 321.351 for a violation of state or federal statutes or administrative regulations.]~~

Section 5. Inspection Requirements.

(1) A certified animal control agency shall be subject to inspection by the board, its investigator, or a board representative.

(2) An inspection may occur at any time, with or without advance notice. The designated on-site manager shall make themselves available to provide access and information during the inspection.

(3) An inspection shall be required:

(a) Prior to the approval of a new application for certification as an animal control agency;

(b) Prior to the approval of a reinstatement application for a certification as an animal control agency, if the last inspection was completed more than twelve (12) months

prior to the date of the application;

(c) Periodically on a schedule set by the board, not more routinely than every ten (10) months, and at least once every two (2) years;

(d) As needed due to staff turnover at the animal control agency;

(e) Under suspicion of probable cause for violation of KRS Chapter 321; and

(f) Following the expiration, termination, suspension, or surrender of the certificate.

Section 6. [Section 7.] Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Application for Certification as an Animal Control Agency", 12/2022[3/2020];~~and~~

(b) "Reinstatement Application for Animal Control Agencies", 12/2022[3/2020]; and

(c) "Request for a New Designated On-site Manager", 12/2022.

(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[8:00] a.m. to 4:30 p.m. This material may also be obtained at www.kybve.com.

STEVEN J. WILLS, DVM, Board Chair

APPROVED BY AGENCY: December 15, 2022

FILED WITH LRC: December 15, 2022 at 11:45 a.m.

PUBLIC HEARING AND 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, Kentucky 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

Contact Person:Michelle Shane

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the application and renewal requirements for certification as an animal control agency, and the requirements for board inspections at certified animal control agencies.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to establish the application requirements for certification as an animal control agency, as mandated by KRS 321.207.

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

KRS 321.207 specifically requires the board to promulgate administrative regulations related to the application requirements for certification as an animal control agency.

(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 board expectations for applications and renewals of board-issued certificates for animal control agencies, and requirements related inspections of board-certified animal control agencies.

(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:

Adding clarifying definitions, clarifying application and renewal requirements, clarifying flexibility in background check requirements for certified animal control agency employees, and adding transparent inspection requirements. The responsibilities of the designated on-site manager related to controlled substance drug management have been moved to a new administrative regulation, 201 KAR 16:552

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

The Kentucky Board of Veterinary Examiners has determined this amendment is necessary in response to issues discovered during the course of periodic inspections at certified animal control agencies. Because there is high staff turnover in animal control agencies, there is often misunderstanding or lack of knowledge by new hires related to their responsibilities.

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

KRS 321.207 specifically requires the board to promulgate administrative regulations related to board-certified animal control agencies, including standards for proper drug storage, and drugs that may be used by certified animal control agencies and the certified animal euthanasia specialists they employ.

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

This amendment shall ensure transparent standards that can be used by agency employees and board inspectors to ensure compliance with state and federal

requirements related to applications, renewals, and inspections of board-certified animal control agencies.

(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:

Applicants will be required to submit application materials as outlined in this filing. Certified Animal Control Agencies and their designated on-site managers will be required to comply with limited periodic inspections.

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

Minimal costs for appropriate locked and secure storage are anticipated in order to secure and limit access to the controlled substances onsite.

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

Administrative ease of clear communications of the approved requirements.

(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?

No. All regulated entities have the same requirements.

FISCAL NOTE

(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 KBVE-certified county animal shelters.

(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 amendment simply codifies the requirements, 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).