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REGULATIONS COMPILER

1 GENERAL GOVERNMENT CABINET

2 Kentucky Board of Veterinary Examiners

3 (Amendment)

4 201 KAR 16:550.Authorization for animal control agencies to apply for a restricted controlled  
5 substances certificate from DEA.

6 RELATES TO: KRS 217.177 (1) and (4) [~~217.177(6)~~], 321.207, 321.235(7), 321.351

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

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 321.207(1) permits the Kentucky

9 Board of Veterinary Examiners to authorize an animal control agency to apply for a registration  
10 certificate by the United States Drug Enforcement Administration (DEA) to euthanize animals.

11 KRS 321.207(2) requires the applicant agency to comply with administrative regulations that  
12 establish standards for the proper storage and handling of the drugs the board has authorized for  
13 use, and other provisions that may be necessary to ensure that the drugs are used safely and  
14 solely for the purpose of euthanizing animals. KRS 321.235(3) and 321.240(5) authorize the  
15 board to promulgate administrative regulations to implement KRS Chapter 321. This

16 administrative regulation establishes the application and renewal [~~certification~~] requirements for  
17 certification as an animal control agency, and the requirements for board inspections at certified  
18 animal control agencies [~~standards for proper drug storage, and drugs that may be used by~~  
19 ~~certified animal control agencies and the certified animal euthanasia specialists they employ~~].

20 Section 1. Definitions. [~~General Requirements.~~]

1 (1) “Animal shelter” means a public agency or private humane society, society for the prevention  
2 of cruelty to animals, animal protection shelter or control agency, or other facility that provides  
3 shelter and care for homeless, stray, unwanted, or injured animals.

4 (2) “Certified Animal Control Agency” means an animal shelter that is certified under the  
5 provisions of KRS Chapter 321 and associated regulations.

6 (3) “Designated On-site Manager” means a person who registers with the board to assume  
7 responsibility for the ordering, management, use, and disposal of controlled substances at a  
8 board-certified animal control agency.

9 Section 2. Application and Renewal Requirements.

10 (1) The applicant animal shelter [~~control agency~~] shall apply to the board for authorization as  
11 established by KRS 321.207.

12 (2) A complete application to the board shall include the following components:

13 (a) A completed Application for Certification as an Animal Control Agency form or online  
14 equivalent form, including all required attachments;

15 (b) Identification of the agency designated on-site [~~onsite~~] manager;

16 (c) A complete and current list of all individuals performing [~~performing~~] euthanasia or related  
17 activities at the animal shelter, whether or not each individual holds a credential from the  
18 board[~~control facility~~]; and

19 (d) Payment of the fee in accordance with 201 KAR 16:514.

20 (3) Prior to the board's issuance of the animal control agency certificate[~~of authorization~~], the  
21 applicant shall undergo an inspection of the facility by the board, its inspector, or other designee  
22 of the board in accordance with Section 5 of this administrative regulation.

1 (4) Following board application approval, the applicant shall apply to DEA for registration as a  
2 practitioner and designate "animal shelter" on the appropriate DEA form.

3 (5) A certified animal control agency shall submit to inspection by a board representative at any  
4 time, with or without advanced notice.

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

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

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

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

1 ~~(8)~~ Section 3. Renewal requirements for a certified animal [Animal] control agency [certificate  
2 renewal requirements].

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

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

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

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

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

12 (d) The board shall conduct a closeout inspection within six (6) months of the date of expiration  
13 to ensure that the controlled substances and other drugs on-site are properly disposed of. An  
14 animal shelter with an expired certificate shall continue to maintain the drugs in accordance with  
15 201 KAR 16:552 and the Kentucky Veterinary Medicine Practice Act until the drugs are  
16 transferred in accordance with state and federal laws, or disposed of in accordance with 201  
17 KAR 16:552, Section 7.

18 Section 4. [(e)] Reinstatement requirements for animal control agencies.

19 (1) [4-] An animal control agency with an expired certificate shall have five (5) years to reinstate  
20 their certificate by submitting a completed Reinstatement Application for Animal Control  
21 Agencies form or online equivalent form, including all required attachments and payment of the  
22 application fee pursuant to 201 KAR 16:514.

1 ~~(2) [2:]~~ The animal control agency shall undergo inspection by an authorized representative of  
2 the board in accordance with subsection (3) of this section prior to the reinstatement of a  
3 certificate.

4 (3) ~~[3:]~~ After five (5) years, the agency shall not be able to reinstate and shall be required to  
5 apply for a new certificate in accordance with this administrative regulation and 201 KAR  
6 16:572.

7 ~~[Section 2. Approved Drugs. A certified animal control agency shall be restricted to the purchase~~  
8 ~~of sodium pentobarbital and other euthanasia drugs currently approved by the American~~  
9 ~~Veterinary Medical Association (AVMA) for the purpose of euthanizing animals. DEA's~~  
10 ~~Schedule II order forms (titled "DEA-222") shall be used for each purchase of sodium~~  
11 ~~pentobarbital or other AVMA approved euthanasia drugs.~~

12 ~~Section 3. Records.~~

13 ~~(1) A certified animal control agency shall maintain records of purchases and administration of~~  
14 ~~sodium pentobarbital and other AVMA approved euthanasia drugs for a period of not less than~~  
15 ~~two (2) years.~~

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

17 ~~(a) The date of use;~~

18 ~~(b) Identification of the animal;~~

19 ~~(c) The amount of the drug used;~~

20 ~~(d) The signature of the person administering the drug;~~

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

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

1 (3) Records of purchase and destruction of sodium pentobarbital and other AVMA approved  
2 euthanasia drugs shall be maintained in a separate file from the records of administration of those  
3 substances.

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

8 (5) The records of purchase, destruction, and administration shall be maintained at the location of  
9 the agency.

10 Section 4. Storage.

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

14 (2) Schedule II order forms shall be stored in a securely locked cabinet, separate from the storage  
15 location of the drugs, within a locked storage room or other enclosure at the certified animal  
16 control agency.

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

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

22 Section 5. Inspection Requirements.

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

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

6 (3) An inspection shall be required:

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

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

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

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

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

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

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

17 (1) The following material is incorporated by reference:

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

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

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

21 (2) This material may be inspected, copied, or obtained, subjected to applicable copyright law, at  
22 the Kentucky Board of Veterinary Examiners, 107 Corporate Drive, Frankfort, Kentucky 40601,

- 1 Monday through Friday, 8:30~~[8:00]~~ a.m. to 4:30 p.m. This material may also be obtained at
- 2 [www.kybve.com](http://www.kybve.com).



*Steven J. Wills, DVM*

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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 16:550

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 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? (Explain why or why not)

No. All regulated entities have the same requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT  
201 KAR 16:550

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 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).

## SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

(a) "Application for Certification as an Animal Control Agency", 12/2022, is the 3-page application form that animal shelters use to apply to the Kentucky Board of Veterinary Examiners (KBVE) to become a certified animal control agency, and subsequently to apply to the Drug Enforcement Administration (DEA) for a Controlled Substances Registration to purchase, use, and store controlled substances. KRS 321.207 requires animal shelters seeking a DEA Registration to become certified by KBVE prior to application with the federal agency.

(b) "Reinstatement Application for Animal Control Agencies", 12/2022, is the 3-page application form for reinstatement of an animal shelter's certificate from the Kentucky Board of Veterinary Examiners (KBVE) which provides authorization to apply to the Drug Enforcement Administration (DEA) for a Controlled Substances Registration to purchase, use, and store controlled substances. KRS 321.207 requires animal shelters seeking a DEA Registration to become certified by KBVE prior to application with the federal agency.

(c) "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

(a) "Application for Certification as an Animal Control Agency", 12/2022, is the 3-page application form that animal shelters use to apply to the Kentucky Board of Veterinary Examiners (KBVE) to become a certified animal control agency, and subsequently to apply to the Drug Enforcement Administration (DEA) for a Controlled Substances Registration to purchase, use and store controlled substances.

- Page 1 was amended to change the word "must" to "shall" in the instructions, to include the definition of "Designated On-site Manager", to add a hyphen to "On-site" to conform with the regulatory definition of "Designated On-site Manager", to clarify that the application does not need to be completed by the designated on-site manager however a designated on-site manager must be identified in the application, and to update the "Form Last Updated" date to "12/2022".
- Page 2 was amended to add a hyphen to "On-site" to conform with the regulatory definition of "Designated On-site Manager", to add a section to the citation in the Note under Table II, to change instances of capitalized "Board" to "board" when the word was independent, to change in Table III the word "indicated" to "indicate", and to update the "Form Last Updated" date to "12/2022".



- Page 3 was amended to add under heading IV optional plural certification(s) and to change “you” to “the agency”, to change under heading IV “facility” to “animal shelter”, to add a section number to the citation under heading V bullet one “Inspection Agreement”, to clarify the background check information on the board’s website is on “Applications and Forms” page, to change instances of capitalized “Board” to “board” when the word was independent, to change optional forms of payment to remove bank draft and clarify that applicants should not send cash, to update the attestation statement to change “facility” to “agency”, to change the wording from “and all animal euthanasia specialist employees under the facility’s direct supervision” to “and all animal euthanasia specialists employed by or contracted with the agency, if any”, to update the website link to view KBVE statutes and regulations, to change “laws and regulations” to “statutes and administrative regulations”, to change the reference to the website from “the Board’s” to “KBVE”, to add a hyphen to “on-site” to conform with the regulatory definition of “Designated On-site Manager” throughout page, to remove “Designated On-site Manager” from the signature required, to extend the blank line spacing above “Title”, and to update the “Form Last Updated” date to “12/2022”.

(b) "Reinstatement Application for Animal Control Agencies", 12/2022, is the 3-page application form for reinstatement of an animal shelter’s certificate from the Kentucky Board of Veterinary Examiners (KBVE) which provides authorization to apply to the Drug Enforcement Administration (DEA) for a Controlled Substances Registration to purchase, use, and store controlled substances.

- Page 1 was amended to change the word “must” to “shall” in the instructions, to include the definition of “Designated On-site Manager”, to add a hyphen to “On-site” to conform with the regulatory definition of “Designated On-site Manager”, to clarify that the application does not need to be completed by the designated on-site manager however a designated on-site manager must be identified in the application, and to update the “Form Last Updated” date to “12/2022”.
- Page 2 was amended to add a hyphen to “On-site” to conform with the regulatory definition of “Designated On-site Manager”, to add a section to the citation in the Note under Table II, to change instances of capitalized “Board” to “board” when the word was independent, to change in Table III the word “indicated” to “indicate”, to remove one row from the bottom of Table III, and to update the “Form Last Updated” date to “12/2022”.
- Page 3 was amended under heading IV to add a question (new #4) to identify the registered address on the DEA Registration, to add a question (new #5) to identify the registered name on the DEA Registration, to add a section number to the citation under heading V bullet one “Inspection Agreement”, to clarify the background check information on the board’s website is on “Applications and Forms” page, to change instances of capitalized “Board” to “board” when the word was independent, to change optional forms of payment to remove bank draft and clarify that applicants should not send cash, to update the attestation statement to change “facility” to “agency”, in the attestation statement to change the wording from “and all animal euthanasia specialist employees under the facility’s direct supervision” to “and all animal euthanasia specialists employed by or contracted with the agency, if any”, to update the website link to view KBVE statutes and regulations, to change “laws and regulations” to “statutes and administrative regulations”, to change the reference to the website from “the Board’s” to

“KBVE”, to add a hyphen to “on-site” to conform with the regulatory definition of “Designated On-site Manager” throughout page, to remove “Designated On-site Manager” from the signature required, to extend the blank line spacing above “Title”, and to update the “Form Last Updated” date to “12/2022”.

(c) “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.