4/27/21

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

Amend:

- 4729:5-15-01 - Definition section for animal shelter rule chapter. The rule is amended to define "certified officer," "chemical capture," "chemical capture classification," and "county dog warden."
- 4729:5-15-02 - Provides the requirements of the responsible person on the license which includes establishing standards for security, control, and storage of dangerous drugs. The rule is amended to include controlled substance dangerous drugs that are used to perform chemical capture to be stored in a securely locked cabinet. The rule is also amended to allow certified officer or dog warden access to the dangerous drugs used to perform chemical capture.
- 4729:5-15-03 - Provides the requirements for record keeping at an animal shelter. The rule is amended to add county dog warden to the record keeping requirements if they use dangerous drugs for chemical capture.
- 4729:5-3-13 - Authorizes the temporary removal of dangerous drugs from a licensed location. The rule is amended to allow a certified officer with a chemical capture classification to maintain a supply of dangerous drugs at a separate location.

New:

- 4729:5-15-04 - Specifies the drugs that are approved for euthanasia.
- 4729:5-15-05 - Establishes the process for an animal shelter or county dog warden to apply for a chemical capture classification to their limited license. Also authorizes the drugs that can be administered as part of chemical capture.

Comments on the proposed rules will be accepted until close of business on May 14, 2021. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Cameron McNamee
Cameron.mcnamee@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Chemical Capture

Rule Number(s): 4729:5-15-01, 4729:5-15-02, 4729:5-15-03, 4729:5-15-04, 4729:5-15-05, 4729:5-3-13

Date of Submission for CSI Review: 4/27/21

Public Comment Period End Date: 5/14/21

Rule Type/Number of Rules:

New/ 2 rules
No Change/___ rules (FYR? __)
Amended/ 4 rules (FYR? Y)
Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness,

predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   - 4729:5-15-03 - Requires approval by the Board to store records off-site.
   - 4729:5-15-05 - Requires that to obtain a chemical capture classification they must complete an approved training as required by ORC 4729.534.

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   - 4729:5-3-13, 4729:5-15-02, 4729:5-15-03, 4729:5-15-04, 4729:5-15-05 - Violation of this rule may result in administrative licensure discipline for a licensee. Discipline might include reprimand, continuing education, suspension of a license, denial of a license, monetary fine and/or revocation of a license.

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   - 4729:5-15-03 - Requires written request to store drug records off-site.
   - 4729:5-15-05 - Requires that to obtain a chemical capture classification they must complete an approved training as required by ORC 4729.534.

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

- 4729:5-15-02, 4729:5-15-03 - The security and record keeping provisions in these two rules may result in an increase in compliance costs.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

Amend:

- 4729:5-15-01 - Definition section for animal shelter rule chapter. The rule is amended to define "certified officer," "chemical capture," "chemical capture classification," and "county dog warden."
- 4729:5-15-02 - Provides the requirements of the responsible person on the license which includes establishing standards for security, control, and storage of dangerous drugs. The rule is amended to include controlled substance dangerous drugs that are used to perform chemical capture to be stored in a securely locked cabinet. The rule is also amended to allow certified officer or dog warden access to the dangerous drugs used to perform chemical capture.
- 4729:5-15-03 - Provides the requirements for record keeping at an animal shelter. The rule is amended to add county dog warden to the record keeping requirements if they use dangerous drugs for chemical capture.
- 4729:5-3-13 - Authorizes the temporary removal of dangerous drugs from a licensed location. The rule is amended to allow a certified officer with a chemical capture classification to maintain a supply of dangerous drugs at a separate location.

New:

- 4729:5-15-04 - Specifies the drugs that are approved for euthanasia.
- 4729:5-15-05 - Establishes the process for an animal shelter or county dog warden to apply for a chemical capture classification to their limited license. Also authorizes the drugs that can be administered as part of chemical capture.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.
The proposed rules are amplified by sections 4729.531, 4729.532, 4729.534, and 4729.54 of the Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

The rule does not implement a federal requirement. These rules are required to implement HB 24 (133rd General Assembly).

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule exceeds federal requirements because licensure and regulation of terminal distributors is reserved for state authorities and is required pursuant to Chapter 4729. of the Revised Code [see HB 24 (133rd General Assembly)].

Section 4729.531 of the Ohio Revised Code requires the Board to adopt rules to implement the licensure of animal shelters.

Furthermore, sections 4729.533 and 4729.534 of the Ohio Revised Code requires the Board to adopt rules to implement the chemical capture classification for a limited terminal distributor license.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs which includes licensing requirements for locations that store dangerous drugs on-site such as animal shelters or county dog wardens.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Section 4729.531 of the Ohio Revised Code requires the Board to adopt rules to implement the licensure of animal shelters.

Sections 4729.533 and 4729.534 of the Ohio Revised Code requires the Board to adopt rules to implement the chemical capture classification for a limited terminal distributor license.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

This rule package was distributed to the following stakeholders: Ohio Veterinary Medical Association, Ohio County Commissioner's Association, Ohio Veterinary Medical Licensing Board, and the Ohio Animal Welfare Federation.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

The Board received the following comments that were incorporated into the rule draft:

Entity	Comment	Board Response
OVMA, Ohio Animal Welfare Foundation, Cleveland APL	Relative to the chemical capture drugs outlined in draft rule 4729:5-15-05 (A) (4) we respect the expertise of the members of the Ohio Veterinary Medical Licensing Board in reviewing the appropriateness of the drugs listed. In (D) (2) of the same draft rule the use of the word "potential" , as in …"known *potential* complications/side effects"… may be too broad in scope and should be	Rule updated to reflect comments.

	replaced with " common" so as to read …"known *common* complications/side effects"… Finally in draft rule 4729:5-15-04, to be consistent with statutory language in ORC 4729.532 and to eliminate any possible confusion , we would ask that the following be included after the comma in the first line: …"Code, except for a licensed veterinarian or registered veterinary technician, no agent…" Both veterinarians and registered veterinary technicians are commonly employed at shelters and obviously governed relative to their permissible medical activities in Chapter 4741 of Ohio Revised and Administrative Codes.	
Ohio Animal Welfare Foundation	We would like to specifically call out his last recommendation regarding draft rule 4729:5-15-04 and ask that licensed veterinarians and registered veterinary technicians be added as the exception. We need to ensure that the medical activities of veterinarians and registered veterinary technicians, including the performance of euthanasia, who are employed by animal shelters continue to be governed by ORC/OAC 4741.	Rule updated to reflect comments.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review this rule. The Board did consult chemical capture materials developed by the American Humane Society: https://www.americanhumane.org/app/uploads/2016/08/op-guide-chemicalcapture.pdf.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform security and recordkeeping standards for dangerous drugs utilized by animal shelters and dog wardens, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance-based regulations.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site, incorporated into the Board's animal shelter inspection guide (www.pharmacy.ohio.gov/ASinspect), and information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The rule package impacts the following:

- Veterinarians;
- Veterinarian technicians;
- Euthanasia technicians;
- County dog wardens; and
- Animal Shelters.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Violation of these rules may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Amend:

- 4729:5-15-01 - Definition section for animal shelter rule chapter. The rule is amended to define "certified officer," "chemical capture," "chemical capture classification," and "county dog warden." This rule is a definitional rule and should have no adverse impact.
- 4729:5-15-02 - Provides the requirements of the responsible person on the license which includes establishing standards for security, control, and storage of dangerous drugs. The rule is amended to include controlled substance dangerous drugs thar are used to perform chemical capture to be stored in a securely locked cabinet. The rule is also amended to allow certified officer or dog warden access to the dangerous drugs used to perform chemical capture. The expected adverse impact associated with this rule are the costs of investing in a lockable cabinet or other secure storage area to store dangerous drugs and hypodermics, performing daily checks if drugs are refrigerated or frozen, and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.
- 4729:5-15-03 - Provides the requirements for record keeping at an animal shelter. The rule is amended to add county dog warden to the record keeping requirements if they use dangerous drugs for chemical capture. There may be administrative costs with ensuring proper compliance with documentation requirements of the rule.
- 4729:5-3-13 - Authorizes the temporary removal of dangerous drugs from a licensed location. The rule is amended to allow a certified officer with a chemical capture classification to maintain a supply of dangerous drugs at a separate location. A licensee that seeks to store drugs off-site may incur additional costs to ensure drugs are maintained at the proper temperature and are stored securely.

New:

- 4729:5-15-04 - Specifies the drugs that are approved for euthanasia. The provisions of this rule are currently being moved out of 4729:5-15-01 and therefore should not have an adverse impact on

regulated entities, as these drugs are already currently approved for administration prior to euthanasia.

- 4729:5-15-05 - Establishes the process for an animal shelter or county dog warden to apply for a chemical capture classification to their limited license. Also authorizes the drugs that can be administered as part of chemical capture. Requires submission of an application, which can take between 30-60 minutes to prepare and submit. Additionally, requires development of a protocol for chemical capture and maintaining all security and record keeping provisions applied to drugs used at animal shelters.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform licensing, security, and record keeping requirements for controlled substances and other dangerous drugs maintained by animal shelters and dog wardens.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations. The Board has also developed inspection guides for all license types to help promote self-inspections and voluntary compliance with its rules and laws. An example can be accessed here: www.pharmacy.ohio.gov/ASinspect

4729:5-15-01 Animal shelters and dog wardens - definitions.

As used in Chapter 4729:5-15 of the Administrative Code:

(A) "Animal shelter" means a facility licensed as terminal distributor of dangerous drugs in accordance with section 4729.531 of the Revised Code or section 4729.54 of the Revised Code. An animal shelter shall be operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code and shall comply with all requirements set forth in this chapter.

(1) An animal shelter that does not have a licensed veterinarian serving as the responsible person shall obtain a limited license as terminal distributor of dangerous drugs in accordance with section 4729.531 of the Revised Code.

(2) An animal shelter shall ensure that all agents and employees who perform euthanasia, other than registered veterinary technicians or licensed veterinarians, shall successfully complete a euthanasia technician certification course described in section 4729.532 of the Revised Code.

(3) An animal shelter shall comply with the initial licensure and renewal requirements set forth in rule 4729:5-2-02 of the Administrative Code.

(4) The board may suspend, revoke, restrict, limit, or refuse to grant or renew any license issued to an animal shelter ~~license~~ in accordance with rule 4729:5-4-01 of the Administrative Code.

(B) "Certified officer" means an individual who meets the requirements established under section 4729.534 of the Revised Code.

(C) "Chemical capture" means using an anesthetic drug or sedative on a companion animal to do any of the following:

(1) Immobilize and capture;

(2) Attempt to immobilize and capture; or

(3) Attempt to immobilize or capture.

(D) "Chemical capture classification" means an authorization for a facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.532 of the Revised Code to purchase, possess, and administer a combination of drugs for chemical capture.

(E) "Companion animal" has the same meaning as in section 959.131 of the Revised Code

~~(B)~~(F) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(G) "County dog warden" means a dog warden or deputy dog warden appointed or employed under section 955.12 of the Revised Code.

(1) A county dog warden shall ensure that all agents and employees who perform euthanasia, other than registered veterinary technicians or licensed veterinarians, shall successfully complete a euthanasia technician certification course described in section 4729.532 of the Revised Code.

(2) A county dog warden shall comply with the initial licensure and renewal requirements set forth in rule 4729:5-2-02 of the Administrative Code.

(3) The board may suspend, revoke, restrict, limit, or refuse to grant or renew any license issued to a county dog warden in accordance with rule 4729:5-4-01 of the Administrative Code.

~~(D)~~(H) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

~~Pursuant to division (A) of section 4729.532 of the Revised Code, the board approves xylazine as a substance to be administered by euthanasia technicians only for the purpose of sedating an animal as part of the euthanasia process.~~

~~(E)~~(I) "Euthanasia" has the same meaning as in paragraph (A) of rule 901:12-1-01 of the Administrative Code.

~~(F)~~(J) "Euthanasia technician" is an individual that has successfully completed a euthanasia certification course, the curriculum of which has been approved by the veterinary medical licensing board pursuant to section 4729.532 of the Revised Code, and is in possession of a certificate which documents the successful completion of the certification course. For the purposes of this chapter, a euthanasia technician is considered a certified health care professional.

~~(G)~~(K) "Personal supervision" means the person specified in rule shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

~~(H)~~(L) "Personally furnish" or "personally furnishing" means the distribution of dangerous drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. For the purposes of this chapter, the prescriber shall be a veterinarian. A veterinarian at an animal shelter who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-20-02 of the Administrative Code.

~~(I)~~(M)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

~~(J)~~(N) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

~~(K)~~(O) "Registered veterinary technician" has the same meaning as in section 4741.01 of the Revised Code.

~~(L)~~(P) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

~~(M)~~(Q) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

4729:5-15-02 Security and control of dangerous drugs. (AMEND)

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs.

(B) Controlled substance dangerous drugs used to perform euthanasia or chemical capture shall be stored in a securely locked, substantially constructed cabinet or safe.

(1) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter.

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian, registered veterinary technician, responsible person, euthanasia technician, certified officer, dog warden, or executive director of the shelter. All locks shall be kept in good working order with keys removed therefrom.

(5) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(6) Only a veterinarian, registered veterinary technician, euthanasia technician, executive director of the shelter, certified officer, dog warden, or the ~~shelter's~~ licensee's responsible person shall be able to access the cabinet or safe.

(C) Except as provided in paragraph (E) of this rule, controlled substance dangerous drugs that are not used to perform euthanasia or chemical capture shall be stored in a securely locked, substantially constructed cabinet or safe.

(1) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. The public does not include volunteers of the animal shelter.

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian or

veterinary technician in accordance with paragraph (C)(6)(a), (C)(6)(b), or (C)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.

(5) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(6) Except as provided in paragraph (C)(6)(a), (C)(6)(b), or (C)(6)(c) of this rule, only a veterinarian shall be able to access the cabinet or safe.

(a) A veterinarian may provide a veterinary technician with a temporary key for the purposes of accessing the cabinet or safe. A veterinary technician shall return the key provided in accordance with this paragraph to the veterinarian or a secured location with restricted access (such as a lockbox) no later than the end of the technician's shift or if there is no longer a veterinarian available to provide personal supervision.

(b) A veterinarian may provide a veterinary technician with a key, combination or access code for the purposes of accessing the cabinet or safe, if all the following conditions apply:

(i) The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by a veterinarian;

(ii) The room is locked when not staffed by ~~shelter~~ personnel or when there is no longer a veterinarian available to provide personal supervision.

(c) Any other method approved by the board's executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion.

(D) Except as provided in paragraphs (B) and (E) of this rule, a registered veterinary technician may have access to controlled substances only under the personal supervision of a veterinarian.

(E) Employees or volunteers of an animal shelter or county dog warden that are designated by the responsible person or the shelter's executive director may have unsupervised access to controlled substances only under the following conditions:

(1) The drugs have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal.

(2) The drugs must be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, safe, or room. Access to the cabinet, safe, or room shall be limited to designated staff. The cabinet or safe must be separate from those required in paragraphs (B), (C), and (I) of this rule.

(a) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter or county dog warden.

(b) The cabinet, safe, or room shall remain locked and secured when not in use.

(c) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than designated staff. All locks shall be kept in good working order with keys removed therefrom.

(d) When not staffed by shelter personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(3) A record of drug administration shall be maintained in accordance with paragraph (E) of rule 4729:5-15-03 of the Administrative Code.

(4) The responsible person shall report the theft or significant loss of drugs maintained pursuant to this paragraph in accordance with rule 4729:5-3-02 of the Administrative Code.

(5) The responsible person or shelter's executive director shall maintain a current list of all designated employees or volunteers for immediate inspection by an agent, officer or inspector of the board.

(F) Non-controlled dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration may be administered by an animal shelter or county dog warden employee or volunteer.

(G) Only a veterinarian shall have access to uncompleted prescription blanks used for writing a prescription. Uncompleted prescription blanks shall be secured when not in use.

(H)

(1) For an animal shelter or county dog warden that is licensed in accordance with section 4729.54 of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of a veterinarian. D.E.A. controlled substance order forms shall be secured when not in use.

(2) For an animal shelter or county dog warden that is licensed in accordance with section 4729.531 of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of the responsible person. D.E.A. controlled substance order forms shall be secured when not in use.

(I) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a separate safe or steel cabinet equivalent to a U.S. government class V security container from all other controlled substances.

(1) There is no minimum size or weight requirement but if the cabinet or safe weighs less than seven hundred fifty pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.

(2) Except as provided for in this paragraph, the cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, patients, business guests, or visitors to be present in or pass through areas containing the cabinet or safe, a veterinarian or veterinary technician shall provide for adequate observation of the area.

(3) The cabinet or safe shall remain locked and secured when not in use.

(4) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(5) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian. All locks shall be kept in good working order with keys removed therefrom.

(6) When not staffed by ~~shelter~~ personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(7) Only a veterinarian shall be able to access the safe or cabinet.

(J) When not staffed by ~~shelter~~ personnel, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections. Members of the public do not include volunteers of the animal shelter or county dog warden.

(K) When not staffed by ~~shelter~~ personnel, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs. Members of the public do not include volunteers of the animal shelter or county dog warden.

(L) In the event of a change of ownership of an animal, an ~~shelter~~ employee or volunteer may transfer dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal to the animal's new owner or caregiver. The transfer of controlled substances shall be documented in accordance with paragraph (I) of rule 4729:5-15-03 of the Administrative Code.

(M) All records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict access by those who neither work for, or volunteer at, the animal shelter or county dog warden.

(N) All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.

(O) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a date opened. Multiple-dose vials shall be examined prior to use for evidence of physical or chemical contamination. Vials that have any of the following characteristics shall be deemed adulterated:

(1) Contain particulate matter, precipitates, turbidity, or discoloration;

(2) Mislabeled; or

(3) Noticeable coring (damage to the rubber stopper).

(P) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code.

(Q) Disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(R) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

4729:5-15-03 Record keeping. (AMEND)

(A) An animal shelter or county dog warden shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred.

(B) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement.

(C) Records of temperature control monitoring described in paragraph (N) of rule 4729:5-15-02 of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(D) Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name or identification of the animal, name and address of the animal's owner or caregiver if the owner or caregiver is not the animal shelter, the date the drug is personally furnished and, if applicable, the date the drug is received by the animal's owner or caregiver. A veterinarian shall be required to document the final association of a controlled substances dangerous drug with a patient using positive identification.

(E)

(1) Records of administration or use shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name or identification of the animal to whom or for whose use the dangerous drugs were administered, and the date of administration. For controlled substance dangerous drugs, the administration record shall also include the positive identification of the person administering the drug.

(2) Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(3) Orders for the administration of controlled substances shall be documented using positive identification. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(4) Paragraph (E)(3) of this rule does not apply in any of the following instances:

(a) Administration of dangerous drugs authorized under Chapter 4729. of the Revised Code to perform euthanasia by means of lethal injection by a veterinarian, registered veterinary technician, or euthanasia technician; ~~and~~

(b) Administration of dangerous drugs pursuant to paragraph (E) of rule 4729:5-15-02 of the Administrative Code; and

(c) Administration of approved drugs for chemical capture pursuant to rule 4729:5-15-05 of the Administrative Code.

(F) Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the person that performed the disposal.

(G) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance drug inventory, including drugs maintained in accordance with paragraph (E) of rule 4729:5-15-02 of the Administrative Code, is performed on-site, records shall also include the positive identification of two persons conducting and witnessing the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, or certified euthanasia technician.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient or controlled substances maintained in accordance with paragraph (E) of rule 4729:5-15-02 of the Administrative Code, records shall also include the positive identification of two persons conducting and witnessing the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, or certified euthanasia technician.

(H) Records of transfer or sale conducted in accordance with chapter 4729. of the Revised Code and rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, expiration date, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

(I) Records of controlled substances transferred in accordance with paragraph (L) of rule 4729:5-15-02 of the Administrative Code shall contain the name, strength, dosage form, and quantity of the dangerous drugs transferred, the name or identification of the animal, name and address of the animal's owner or caregiver if the owner or caregiver is

not the animal shelter, the positive identification of the animal shelter employee or volunteer transferring the drug, the date the drug is transferred, and the date the drug is received by the animal's owner or caregiver.

(J) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.

(K) In addition to the inventory requirements set forth in rule 4729:5-3-07 of the Administrative Code, the responsible person for an animal shelter that maintains controlled substance dangerous drugs used to perform euthanasia listed in paragraph (B) ~~(C)(2)~~ of rule ~~4729:5-15-01~~ 4729:5-15-04 of the Administrative Code shall be responsible for completing a monthly inventory, in accordance with rule 4729:5-3-07 of the Administrative Code, of those drugs to deter and detect diversion.

(L) An animal shelter or county dog warden licensed as a limited category II or limited category III terminal distributor of dangerous drugs may only possess dangerous drugs that are on the drug list submitted to the board pursuant to section 4729.54 of Revised Code and only at locations licensed by the state board of pharmacy. The responsible person may modify the drugs that may be possessed and administered by the limited facility by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(M) All records maintained in accordance with this rule and rule 4729:5-15-02 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years.

(1) A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(N) All records maintained pursuant to this rule and rule 4729:5-15-02 of the Administrative Code may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features, such as unique user names and passwords, to prevent unauthorized access; and

(4) Contains daily back-up functionality to protect against record loss.

4729:5-15-04 Drugs approved for euthanasia. (NEW)

(A) Pursuant to section 4729.532 of the Revised Code, except for a licensed veterinarian or registered veterinary technician, no agent or employee of an animal shelter and no county dog warden or agent or employee of a county dog warden shall perform euthanasia by means of lethal injection on an animal by use of any substance other than a substance in a manufactured dosage form that the state veterinary medical licensing board has approved under chapter 4741. of the Administrative Code.

(B) Before euthanasia, a euthanasia technician may administer a solution of one or more of the following drugs exclusively for the purpose of inducing anesthesia, sedation, or unconsciousness prior to euthanasia:

(1) Ketamine;

(2) Tiletamine and zolazepam; and

(3) Xylazine.

4729:5-15-05 - Chemical capture classification. (NEW)

(A) Upon application of an animal shelter or county dog warden that holds a limited license issued under section 4729.531 of the Revised Code, the state board of pharmacy may grant a chemical capture classification to the limited license. The classification permits the holder to purchase, possess, and administer a combination of drugs for chemical capture. Unless otherwise approved by the board, no such classification shall authorize or permit the distribution of these drugs to any person other than the originating wholesale distributor of the drugs.

(1) To qualify for a chemical capture classification under this section, an applicant shall appoint or employ a certified officer.

(2) The animal shelter or county dog warden shall maintain documentation that certified officers have completed the required training in accordance with section 4729.534 of the Revised Code.

(3) An animal shelter or county dog warden shall comply with the initial licensure and renewal requirements set forth in rule 4729:5-2-02 of the Administrative Code. As part of this licensing process, the animal shelter or county dog warden shall provide a list of drugs, signed by the responsible person, that will be used for chemical capture.

(4) A certified officer may use any of the following drugs for chemical capture:

(a) Ketamine;

(b) Xylazine; and

(c) Tiletamine and zolazepam.

(B) All areas where drugs and devices used for chemical capture are stored shall comply with the security and storage requirements of rule 4729:5-15-02 of the Administrative Code and rule 4729:5-3-13 of the Administrative Code.

(C) All drugs used for chemical capture shall comply with the following:

(1) Recordkeeping requirements of rule 4729:5-15-03 of the Administrative Code; and

(2) Drug disposal requirements of rule 4729:5-15-02 of the Administrative Code.

(D) The animal shelter or dog warden shall develop and implement a drug dosing protocol for all drugs and equipment used in chemical capture.

(1) The protocol shall be reviewed and signed by a veterinarian licensed under Chapter 4741. of the Revised Code.

(2) The protocol shall include the following: drug, dose, concentration, approved uses for drug delivery, approved equipment for use, circumstances for use, contraindications, any

known ~~potential~~ common complications/side effects, and weight ranges with corresponding volume of drug to be administered.

(3) A documented review of the protocol shall be conducted by a veterinarian licensed under Chapter 4741. of the Revised Code at least once every five years.
(E) All equipment used in chemical capture shall:

(1) Be secured to prevent unauthorized access by individuals who are not certified officers;

(2) Maintained and used in accordance with the manufacturer's instructions and the protocol established in accordance with paragraph (D) of this rule.

(3) Be disposed of in accordance with the manufacturer's instructions.

(F) An animal shelter or dog warden with a chemical capture classification shall develop and implement policies and procedures that incorporate the following based upon nationally recognized standards for chemical capture:

(1) Determining when chemical capture is appropriate. Such policies and procedures shall make all reasonable efforts to ensure animal safety, certified officer safety, and the safety of the public.

(2) The care of a companion animal immediately upon capture. Certified officers engaged in chemical capture must have a written animal handling and post capture protocol which includes:

(a) The procedure for removing the dart from a captured animal;

(b) First aid for the animal, with particular reference to the dart wound and potential emergencies (including: hyperthermia, hypothermia, shock, bloat, respiratory distress, and cardiac arrest); and

(c) Appropriate location and handling for the animal during recovery from the capture event.

(G) A terminal distributor of dangerous drugs with a chemical capture classification shall maintain records for every certified officer that has completed training in accordance section 4729.534 of the Revised Code. Such documentation shall be made readily retrievable and shall be maintained for one year from the date the certified officer is no longer employed by or affiliated with the licensee.

4729:5-3-13 Temporary removal of dangerous drugs from a licensed location. (AMEND)

No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs at retail or maintain possession, custody, or control of dangerous drugs for any purpose at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, except as follows:

(A) A licensed health professional authorized to prescribe drugs may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/ NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(B) A person authorized to personally furnish or dispense naloxone in accordance with a physician approved protocol. The naloxone shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The authorized person shall maintain direct supervision and control over the naloxone removed from the terminal distributor. If direct supervision is not provided, the naloxone shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/ or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(C) A licensed health care professional, in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(D) An emergency medical service (EMS) organization providing emergency medical services and in accordance with Chapter 4729:5-14 of the Administrative Code.

(E) A veterinarian licensed pursuant to Chapter 4741. of the Revised Code may maintain a supply of dangerous drugs obtained from a licensed terminal distributor of dangerous drugs at another location in order to treat current or prospective patients. A veterinarian shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal and inventory requirements of division 4729:5 of the Administrative Code. Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-20 of the Administrative Code. The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph. A veterinarian maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs. The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site for more than twenty-four hours: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the veterinarian who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location. All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return. Failure by a veterinarian to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(F) A person licensed or certified under Chapter 4765. of the Revised Code may maintain a supply of medical oxygen and/or naloxone obtained from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients in the event of an emergency. The medical oxygen and/or naloxone shall be maintained for an amount of time as determined by written authorization from the licensee's medical director. Medical oxygen and naloxone shall only be administered in accordance with the licensee's protocol or valid prescriber order. The individuals authorized by to this paragraph shall maintain personal supervision and control over the medical oxygen and/or naloxone removed from the terminal distributor. If personal supervision is not provided, the medical oxygen and/or naloxone shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the medical oxygen and/or naloxone prior to its use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(G) A certified officer, as defined in section 4729.533 of the Revised Code, may maintain a supply of dangerous drugs, as authorized in rule 4729:5-15-05 of the Administrative Code, obtained from a licensed terminal distributor of dangerous drugs with a chemical capture classification at another location in order to engage in chemical capture. A certified officer shall maintain direct supervision and control over the dangerous drugs, equipment, and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs, equipment, and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal and inventory requirements of division 4729:5 of the Administrative Code. Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-15 of the Administrative Code. The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph. A certified officer maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs. The terminal distributor of dangerous drugs shall also maintain the following records for all approved chemical capture drugs removed from the terminal distributor of dangerous drugs. Corresponding records shall also be maintained for any drug used for chemical capture returned to the terminal distributor's inventory of dangerous drugs from the off-site location. All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return. Failure by a certified officer to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(H) As used in this rule, "direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.