5/7/2018

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.

New

- 4729:5-20-01- Definition section for veterinary clinics rule chapter.
- 4729:5-20-02- Establishes the requirements for a veterinarian who personally furnishes dangerous drugs.
- 4729:5-20-03- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs
- 4729:5-20-4- Provides the requirements for record keeping for veterinary clinics.

Comments on the proposed rules will be accepted until close of business on **May 25, 2018**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Veterinary Clinics

Rule Number(s):

New

- 4729:5-20-01
- 4729:5-20-02
- 4729:5-20-03
- 4729:5-20-04

Date: 5/7/2018

Rule Type:

New	5-Year Review
Amended	Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

New

- 4729:5-20-01- Definition section for veterinary clinics rule chapter.

- 4729:5-20-02- Establishes the requirements for a veterinarian who personally furnishes dangerous drugs.
- 4729:5-20-03- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs
- 4729:5-20-4- Provides the requirements for record keeping for veterinary clinics.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

3. 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?

These rules do not implement a federal requirement.

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

This rule package exceeds federal requirements because the regulation of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy.

5. 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 including veterinary clinics.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, prescribe, or administer.

6. 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.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website.

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

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes.

The Ohio Veterinary Medical Association requested three changes. The first was to restore previous language regarding hypodermics that exists currently in OAC 4729-9-11, the second to amend 4729:5-20-02 to account for a litter or heard, and third to request offer to counsel be a verbal offer and not require a written offer to counsel. The draft was amended based on feedback from the first two comments. For the third comment, the written offer to counsel is an option and is not required.

9. 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 package.

10. 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 standards for the distribution of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. 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 performance-based regulations.

12. 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.

13. 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, 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 and quarterly webinars from the Director of Policy and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. 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;

The rule package impacts the following:

- Veterinarians;
- Veterinarian technicians; and
- Terminal distributors of dangerous drugs.

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

Violation of these rules may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New

- 4729:5-20-01- Definition section for veterinary clinics rule chapter.
- 4729:5-20-02- Establishes the requirements for a veterinarian who personally furnishes dangerous drugs. The labeling, final check requirements by a prescriber and the counseling provisions of this rule may result in an increase in the overall time necessary to personally furnish a medication to a patient.
- 4729:5-20-03- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs. 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 monthly checks if drugs are refrigerated or frozen and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.
- 4729:5-20-4- Provides the requirements for record keeping for veterinary clinics. There may be an overall increase in administrative costs associated with complying with the rule.

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

The Board believes that the regulatory intent of the proposed rules is necessary in order to protect the health and safety of all Ohioans by providing uniform regulations for the operation of veterinary clinics.

Regulatory Flexibility

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

This rule package does 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.

17. 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.

18. 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 and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:5-20-01 – Veterinary Clinics – Definitions.

As used in Chapter 4729:5-20 of the Administrative Code:

(A) “Veterinary Clinic” or “clinic” means a facility licensed as a terminal distributor of dangerous drugs in accordance with 4729.51 of the Revised Code where a licensed veterinarian serves as the responsible person on the license and drugs are possessed on-site for administration or personally furnishing. The facility shall comply with all requirements set forth in this chapter.

(B) “Animal aide” has the same meaning as defined in section 4741.01 of the Revised Code.

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

(D) "Direct supervision" or "personal supervision" means licensed veterinarian shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(E) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(F) "Personally furnish" or “personally furnishing” means the final association of a drug with a patient by a veterinarian prior to the distribution to a patient for use outside the veterinarian's practice setting.

(G)

(1) "Positive identification" means a method of identifying a person that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as 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 available on request to those individuals authorized by law to review such records; 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.

(H) “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.

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

(J) "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.

(K) “Sample” means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

(L) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

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

4729:5-20-02 – Personally furnishing dangerous drugs.

(A) A veterinarian who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall affix to the container a label showing:

(1) The name and address of the veterinarian.

(2) The name of the patient or patients for whom the drug is intended, which shall include the name of the owner and identification of the animal.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

(6) If a compounded drug, the statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

(B) A veterinarian who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container, the veterinarian shall also provide written documentation accompanying the sample including the following:

(1) The name and address of the veterinarian.

(2) The name of the patient for whom the drug is intended, which shall include the name of the owner and identification of the animal.

(3) Directions for use.

(C) A veterinarian may designate a registered veterinary technician or animal aide acting within the scope of the professional's practice to prepare and package a dangerous drug that will be personally furnished by the veterinarian. Unless otherwise authorized under Chapter 4701. of the Administrative Code, animal aides shall not prepare and package dangerous drugs that are anesthetic agents and controlled substances.

(D) A veterinarian shall perform the final check (i.e. the final association of a drug with a patient) of the dangerous drug prior to personally furnishing. The final check shall be documented using positive identification.

(E) Counseling.

(1) A veterinarian or the veterinarian’s designee shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (E)(2) of this rule to the owner or

caregiver whenever any dangerous drug is personally furnished. A veterinarian shall not be required to counsel an owner or caregiver when the owner or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

(2) Veterinarian counseling shall include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for monitoring drug therapy;

(g) Proper storage;

(h) Action to be taken in the event of a missed dose; and

(i) The veterinarian's comments relevant to the patient's drug therapy, including other necessary information unique to the specific patient or drug.

(F) Provision of dangerous drugs.

(1) A veterinarian may delegate an individual or individuals to distribute dangerous drugs personally furnished by a veterinarian if all the following apply:

(a) A veterinarian provides direct supervision;

(b) Counseling is offered in accordance with paragraph (E) of this rule;

(c) This task may be delegated in accordance with applicable state laws and rules;

(d) The drugs are sealed in a tamper-evident manner.

(2) Paragraph (F)(1)(a) of this rule does not apply if a non-controlled dangerous drug is provided to the patient by a registered veterinary technician or animal aide and a veterinarian is available for counseling by means of electronic communication during normal hours of operation.

(G) No veterinarian may personally furnish to a patient to whom there is no valid veterinarian patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(H) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a veterinarian pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personal furnishing. No veterinarian that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(I) Paragraph (H) of this rule does not prohibit a veterinarian from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the veterinarian.

4729:5-20-03 – Security and control of dangerous drugs.

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

(B) Controlled substance dangerous drugs, dangerous drugs containing propofol and gabapentin, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, and poisons must be stored in an area or areas secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access to deter and detect unauthorized access.

(1) Only a veterinarian shall have possession of the keys or access codes to the secure area or areas specified in paragraph (B) of this rule. Any additional keys shall be maintained in a secure place that is inaccessible to unauthorized persons.

(2) A registered veterinary technician may have access to controlled substances, dangerous drugs containing propofol and gabapentin, and poisons only under the direct supervision of a veterinarian.

(3) Only a veterinarian shall have access to uncompleted prescription blank(s) used for writing a prescription.

(4) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the direct supervision of a veterinarian.

(5) Only prescribers may have unsupervised access to controlled substance dangerous drugs.

(C) Non-controlled dangerous drugs shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access. 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.

(E) All records relating to the administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(F) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures 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 monthly temperature logs to ensure proper refrigeration temperatures at 36º to 46ºF (2º to 8ºC) and freezer temperatures at 14º to -13ºF (-25º to -10ºC) are maintained at all times;

(2) If a temperature excursion occurs, all affected inventory must be temporarily removed from active inventory and not administered or personally furnished until a documented evaluation of product integrity is completed; and

(3) The responsible person shall develop and monitor a policy that no food or beverage products are permitted to be stored in the refrigerators or freezers.

(G) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or the beyond-use date shall be maintained in a separate record. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

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

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

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

4729:5-20-04 – Record Keeping.

(A) A veterinary clinic shall keep a record of all dangerous drugs received, administered, personally furnished, disposed or transferred.

(B) The acts of prescribing, administering, and disposal controlled substance dangerous drugs shall be documented with positive identification.

(C) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the persons from whom received and the date of receipt.

(D) Temperature logs maintained in accordance with paragraph (E) of rule 4729:5-19-03 shall include the date of observation, the full name or the initials of the individual performing the check, and the temperature recorded.

(E) Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the owner's name, address and the identification of the animal to whom or for whose use the dangerous drug were personally furnished, the positive identification of the veterinarian personally furnishing the drug, the date the drug is personally furnished and the date the drug is received by the owner or caregiver.

(F) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the identification of the animal to whom or for whose use the dangerous drugs were administered, the identification of the person administering the drug and the date of administration.

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

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

(3) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(G) Records of dangerous drug disposal, 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, the identification of the licensed or registered health care professional that performed the disposal.

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

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

(J) All records maintained in accordance with this chapter shall be readily retrievable and shall be kept for a period of three years at the place where the dangerous drugs are located.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place 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 representatives of the terminal distributor of dangerous drugs.

(K) All records maintained pursuant to this rule 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) 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;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(3) Contains security features to prevent unauthorized access to the records; and

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