4/9/2019

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

- 4729:7-2-01 – Provides definitions for pharmacy compounding chapter.
- 4729:7-2-02 – Provides exemptions from the chapter for certain sterile compounded drugs.
- 4729:7-2-03 – Provides the general requirements for drugs compounded in a pharmacy.
- 4729:7-2-04 – Provides the record keeping requirements for pharmacies engaged in drug compounding.
- 4729:5-8-04 – Provides the requirements for drugs compounded by a nonresident pharmacy.
- 4729:7-2-05 – Provides the requirements for drugs compounded by a pharmacy for veterinarian office use.

Rescinds:

- 4729-16-01 – Provides definitions for pharmacy compounding chapter.
- 4729-16-03 – Provides the general requirements for drugs compounded in a pharmacy.
- 4729-16-05 – Provides the general requirements for drugs compounded in a fluid therapy pharmacy.
- 4729-16-06 – Provides the record keeping requirements for pharmacies engaged in drug compounding.
- 4729-16-08 – Provides the requirements for drugs compounded by a nonresident pharmacy.
- 4729-16-12 – Provides the requirements for drugs compounded by a pharmacy for veterinarian office use.

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Comments on the proposed rules will be accepted until close of business on **April 26, 2019**. 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: Pharmacy Compounding

Rule Number(s):

New:

- 4729:7-2-01
- 4729:7-2-02
- 4729:7-2-03
- 4729:7-2-04
- 4729:5-8-04
- 4729:7-2-05

Rescinds:

- 4729-16-01
- 4729-16-03
- 4729-16-05
- 4729-16-06
- 4729-16-08
- 4729-16-12

Date: 4/9/2019

Rule Type:

New	5-Year Review
Amended	**Rescinded**

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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

- 4729:7-2-01 – Provides definitions for pharmacy compounding chapter. Exempts preparation of non-hazardous non-sterile, conventionally manufactured products from compounding requirements if a final check is conducted by a pharmacist using positive identification.
- 4729:7-2-02 – Provides exemptions from the chapter for certain sterile compounded drugs. These exemptions are from the proposed exemptions in national sterile compounding standards (USP 797).
- 4729:7-2-03 – Provides the general requirements for drugs compounded in a pharmacy. Requires adherence to national compounding standards (USP 800, USP 795, USP 797). USP 800 is only required for anti-neoplastic drugs (i.e. those commonly used in the treatment of cancer).
- 4729:7-2-04 – Provides the record keeping requirements for pharmacies engaged in drug compounding.
- 4729:5-8-04 – Provides the requirements for drugs compounded by a nonresident pharmacy. Rule requires all nonresident pharmacies that are selling compounded drugs into Ohio to have a responsible person who is an Ohio licensed pharmacist.
- 4729:7-2-05 – Provides the requirements for drugs compounded by a pharmacy for veterinarian office use.

Rescinds:

- 4729-16-01 – Provides definitions for pharmacy compounding chapter.
- 4729-16-03 – Provides the general requirements for drugs compounded in a pharmacy.
- 4729-16-05 – Provides the general requirements for drugs compounded in a fluid therapy pharmacy.

- 4729-16-06 – Provides the record keeping requirements for pharmacies engaged in drug compounding.

- 4729-16-08 – Provides the requirements for drugs compounded by a nonresident pharmacy.

- 4729-16-12 – Provides the requirements for drugs compounded by a pharmacy for veterinarian office use.

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.

These rules exceed federal requirements because the regulation of the pharmacy compounding has traditionally been done at the state level. The Board regulates all aspects of the pharmacy practice, including drug compounding.

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.

Section 3719.28 of the Ohio Revised Code authorizes the Board of pharmacy to adopt rules governing controlled substances.

These rules are necessary to ensure uniform standards for the compounding of dangerous drugs in Ohio.

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 reviewed by a special ad-hoc committee composed of compounding pharmacists from around Ohio.

Prior to filing with CSI, the amended rule was 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 ad-hoc committee reviewed the rules. They provided the following input on the rules:

- Limit the application of USP 800 to anti-neoplastic drugs and provide that clarity throughout the rule.
- Add exemptions in proposed versions of USP 797 and 795.
- Clarify that registered technicians may conduct non-sterile compounding.
- Permit the national drug code in lieu of product name and manufacturer in the required recordkeeping section.
- Require nonresident pharmacies to have an Ohio-licensed pharmacist as the responsible person on the license.

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 but national standards incorporated into the rules (USP 800, 797 and 795) were developed using scientific data.

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 pharmacy compounding, 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 performance-based regulations 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 compounding pharmacies licensed as 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

- 4729:7-2-01 – Provides definitions for pharmacy compounding chapter. Exempts preparation of non-hazardous non-sterile, conventionally manufactured products from compounding requirements if a final check is conducted by a pharmacist using positive identification. While this exempts a pharmacy that is compounding certain non-sterile drugs, it still requires a pharmacist to conduct a final check of the product and document the final check using positive ID. The cost of implementing positive identification can range given that it can be accomplished using simple methods (i.e. a paper record with a hard copy signature) to more technologically sophisticated methods (i.e. biometric scans).

- 4729:7-2-02 – Provides exemptions from the chapter for certain sterile compounded drugs. These exemptions are from the proposed exemptions in national sterile compounding standards (USP 797). As this rule is exempting licensees from requirements of the chapter, it should not have an adverse impact on the pharmacy.

- 4729:7-2-03 – Provides the general requirements for drugs compounded in a pharmacy. Requires adherence to national compounding standards (USP 800, USP 795, USP 797). USP 800 is only required for anti-neoplastic drugs. Pharmacies are currently required to adhere to USP 797 and 795 so this should not have an adverse impact on those already in compliance.

  The costs for new pharmacies to comply with USP 797 is variable, ranging from minimal cost for immediate-use exemption to thousands of dollars for simple low-risk compounding (e.g., laminar flow hood in a segregated area) and to more than $100,000 for medium-risk compounding (e.g., biological safety cabinet in a clean room). Overall, costs for complying with USP 795 from a facility design standpoint are much less, as it

does not mandate any specific requirements for non-sterile hazardous or nonhazardous drugs.

Pharmacies engaged in compounding anti-neoplastic drugs will have to comply with USP 800. According to a recent article in Pharmacy Times, facility improvements should be achievable with an investment of $50,000 or less. Additional costs include approximately $5,000 for personal protective equipment. If facility and engineering changes are needed, it may require 12 to 18 months to complete.

The rule also requires the reporting of the following:

(1) Adverse events or product recalls potentially associated with the quality of a compounded sterile preparation; and

(2) Any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.

The Board plans to use its online reporting tool to allow for licensees to submit this information electronically. This reporting requirement is expected to take anywhere between 30-60 minutes to complete.

- 4729:7-2-04 – Provides the record keeping requirements for pharmacies engaged in drug compounding. Pharmacies conducting drug compounding will experience administrative costs associated with maintaining records in accordance with this rule. It should be noted that except for the addition of documenting the final check with positive identification, the requirements are similar to those currently in effect for compounding pharmacies. As stated previously, the cost of implementing positive identification can range given that it can be accomplished using simple methods (i.e. a paper record with a hard copy signature) to more technologically sophisticated methods (i.e. biometric scans).

- 4729:5-8-04 – Provides the requirements for drugs compounded by a nonresident pharmacy. Rule requires all nonresident pharmacies that are selling compounded drugs into Ohio to have a responsible person who is an Ohio licensed pharmacist. Pharmacists licensed in Ohio may apply to the Board for reciprocity. The cost of an initial license by reciprocity is $337.50.

  The rule also requires the reporting of the following:

  (1) Adverse events or product recalls potentially associated with the quality of a compounded sterile preparation; and

  (2) Any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.

The Board plans to use its online reporting tool to allow for licensees to submit this information electronically. This reporting requirement is expected to take anywhere between 30-60 minutes to complete.

Nonresident pharmacies engaged in compounding anti-neoplastic drugs will have to comply with USP 800. According to a recent article in Pharmacy Times, facility improvements should be achievable with an investment of $50,000 or less. Additional costs include approximately $5,000 for personal protective equipment. If facility and engineering changes are needed, it may require 12 to 18 months to complete.

- 4729:7-2-05 – Provides the requirements for drugs compounded by a pharmacy for veterinarian office use. Rule for in-office use of compounded drugs for animals. This rule was a request by the veterinary community to increase access to specialized medications required by veterinarians.

15. 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 standards for the preparation of compounded drug preparations. Ensuring such standards is essential, as the PEW Charitable Trust explains:

Compounded medications pose a higher level of risk to patients than FDA-approved drugs because they have not been tested for safety and efficacy, have not gone through an approval process, and are typically not made under the same quality standards as approved products are. The Pew Charitable Trusts' drug safety project has identified more than 50 reported compounding errors or potential errors from 2001 to 2017 linked to 1,227 adverse events—undesirable experiences associated with the use of a medical product—including 99 deaths. And because many such events may go unreported, this number is likely to be an underestimation. (https://www.pewtrusts.org/en/research-and-analysis/reports/2018/02/state-oversight-of-drug-compounding)

Regulatory Flexibility

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

The 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.

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 practice of pharmacy or the disposal 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.

4729:7-2-01 – Definitions – Pharmacy Compounding.

As used in this chapter of the Administrative Code:

(A) "Beyond-use date" means the date or time after which a compounded drug preparation shall not be administered, dispensed, stored or transported. The date is determined from the date or time the preparation is compounded.

(B) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(C) "Compounding" means the preparation, mixing, assembling, packaging, or and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance. A pharmacy engaged in the following shall not be required to comply with the provisions of this chapter:

(1) The preparation of non-hazardous, conventionally manufactured non-sterile products in accordance with the directions contained in the approved labeling provided by the product's manufacturer. A pharmacist shall perform the final check of the product and documents that it was conducted using positive identification.

(2) The preparation of radiopharmaceuticals as defined in agency 4729 of the Administrative Code.

(3) Sterile compounded drug preparations in accordance with rule 4729:7-2-02 of the Administrative Code.

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

(E) "Dilution" means a process of reducing the concentration of a solute in solution, usually by mixing with more a solvent.

(F) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(G) "Final check" means the final verification check for accuracy and conformity to the formula of the compounded preparation or product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

(H) "Hazardous drug" means any antineoplastic drug listed in group one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code.

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(J) "Non-resident pharmacy" means any pharmacy, licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-8-01 of the Administrative Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio.

(K) "Non-sterile compounded drug" means a dangerous drug preparation intended to be non-sterile. Non-sterile compounded drugs include, but are not limited to, the preparation of solutions, suspensions, ointments, creams, powders, suppositories, capsules, and tablets.

(L)

(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 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 prescribed, administered, or dispensed the dangerous drug. 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.

(i) 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.

(M) “Preparation” means a drug compounded in a licensed pharmacy or other healthcare-related facility. Preparations may include the compounding of one or more drug products.

(N) “Product” means a drug in a commercially manufactured pharmaceutical dosage form that has been evaluated for safety and efficacy by the United States food and drug administration. Products are accompanied by full prescribing information, which is commonly known as the United States food and drug administration-approved manufacturer's labeling or product package insert.

(O) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(P) "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.

(Q) “Reconstitution” means the process of adding a diluent to a powdered drug to prepare a solution or suspension.

(R) “Responsible person” has the same meaning as in rule 4729:5-2-01 of the Administrative Code who is responsible for 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.

(S) "Sterile" means a dosage form free of living microorganisms (aseptic).

(T) "Sterile compounded drug" means a dangerous drug preparation intended to be sterile.

(U) “United States Pharmacopeia Chapter <795>” or “USP <795>” has the same meaning as in rule 4729:7-1-01 of the Administrative Code.

(V) “United States Pharmacopeia Chapter <797>” or “USP <797>” has the same meaning as in rule 4729:7-1-01 of the Administrative Code.

(W) “United States Pharmacopeia Chapter <800>” or “USP <800>” has the same meaning as in rule 4729:7-1-01 of the Administrative Code.

4729:7-2-02 – Sterile Compounding Exemptions.

The following are sterile drug compounding is exempted from the requirements of this chapter:

(A) Preparation of a non-hazardous, conventionally manufactured sterile product in accordance with the directions contained in approved labeling provided by the product's manufacturer if preparation complies with all the following:

(1) Administration of the drug product must begin within one hour of beginning the preparation (e.g., within one hour of initial entry into or puncture of a single-dose container).

(2) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products or compounded sterile preparations.

(3) A pharmacist performs the final check of the product and documents that it was conducted using positive identification.

(4) Any unused starting ingredient that is not labeled as a multiple dose container must be discarded after preparation is complete.

(5) Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(B) Preparation of non-hazardous, compounded sterile preparation for a single patient using only sterile starting ingredients if preparation complies with all the following:

(1) Administration of the preparation must begin within one hour of beginning the preparation (e.g., within one hour of initial entry into or puncture of a single-dose container).

(2) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products or compounded sterile preparations.

(3) A pharmacist performs the final check of the preparation and documents that it was conducted using positive identification.

(4) Any unused starting ingredient that is not labeled as a multiple dose container must be discarded after preparation is complete.

(5) Unless administered immediately, the preparation described in this paragraph shall bear a label listing the name of the drug, date, and time prepared.

4729:7-2-03 Drugs compounded in a pharmacy.

(A) For all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>. This paragraph does not apply to non-sterile compounded drugs exempted from the requirements of this chapter in accordance with rule 4729:7-2-02 of the Administrative Code.

(B) For all sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <797>. This paragraph does not apply to sterile compounded drugs exempted from the requirements of this chapter in accordance with rule 4729:7-2-02 of the Administrative Code.

(C) For all compounded hazardous drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <800>.

(1) Hazardous drug has the same meaning as in rule 4729:7-2-01 of the Administrative Code.

(2) A pharmacy compounding non-antineoplastic hazardous drug preparations listed in the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code may also comply with United States pharmacopeia chapter <800>.

(D) Comply with Title 21 U.S. Code section 353a (11/27/2013).

(E) Only the following may engage in compounding at a pharmacy:

(1) A pharmacist;

(2) A pharmacy intern under the personal supervision of a pharmacist;

(3) A certified pharmacy technician or pharmacy technician trainee under the personal supervision of a pharmacist; and

(4) A registered pharmacy technician under the personal supervision of a pharmacist, but only with respect to non-sterile drug compounding.

(F) For all compounded drug preparations, a pharmacist shall:

(1) Conduct the final check of the compounded drug preparation; and

(2) Is responsible for the dispensing of a compounded drug preparation.

(G) For all compounded drug preparations, the pharmacist shall be responsible for:

(1) All compounding records pursuant to rule 4729:7-2-04 of the Administrative Code;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(H) A drug shall be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(I) In addition to the requirements of this rule, compounded drugs preparations dispensed to an outpatient shall comply with the following requirements:

(1) Be labeled according to rule 4729:5-5-06 of the Administrative Code; and

(2) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(J) In addition to the requirements of this rule, compounded drug preparations dispensed to an inpatient shall comply with the following requirements:

(1) Be labeled according to rule 4729:5-9-10 of the Administrative Code; and

(2) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(K) Labels for a compounded drug that is prepared in anticipation of a prescription drug order shall also contain the following:

(1) The name, strength, and quantity of each ingredient used in the compounded drug preparation;

(2) Pharmacy control number;

(3) The assigned beyond-use date;

(4) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(L) A prescription for a schedule II controlled substance narcotic to be compounded for the direct administration to a patient may be transmitted to a pharmacy by facsimile. The prescription shall comply with the requirements of 21 CFR 1306.11 (3/31/2010).

(M) The pharmacy shall maintain a system for the safe disposal of drug waste in accordance with all state and federal laws, rules and regulations.

(N) The pharmacy shall comply with the drug database reporting requirements pursuant to division 4729:8 of the Administrative Code.

(O) A pharmacy shall report to the state board of pharmacy, immediately upon discovery and in a manner determined by the board, any adverse events or product recalls potentially associated with the quality of a compounded sterile preparation.

(P) A pharmacy shall report to the state board of pharmacy, within seventy-two hours and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.

4729:7-2-04 Record keeping.

(A) In addition to the record keeping requirements of rules 4729:5-5-04 and 4729:5-9-04 of the Administrative Code, a pharmacy shall maintain a record of all drugs compounded that shall include, at a minimum, all the following:

(1) The name of the patient;

(2) Name of drug, strength or activity, and dosage form;

(3) Assigned internal identification number (e.g., prescription, order, or lot number);

(4) Date and time of preparation;

(5) Name or national drug code, vendor or manufacturer (if national drug code is not used), lot number, and expiration date for each ingredient;

(6) Weight or volume of each ingredient;

(7) Total quantity compounded;

(8) The disposition of unused controlled substances drug(s) and amount;

(9) Assigned beyond-use date; and

(10) The positive identification of the following:

(a) The pharmacy personnel responsible for preparing compounded drugs;

(b) The pharmacist conducting the final check of the compounded drug preparation; and

(c) The pharmacist who dispenses the compounded drug preparation.

(11) All other drug compounding records as required in accordance with USP 795, 797 and 800.

(B) All records maintained in accordance with this rule shall made be readily retrievable and uniformly maintained for at least three years.

(1) Except as provided in paragraph (B)(2) of this rule, all records maintained in accordance with this rule shall be kept on-site.

(2) A pharmacy located in this state intending to maintain records pursuant to this rule at an alternate location must first send a written request to the state board of pharmacy. The request shall contain the pharmacy's name and license number and the name and address of the alternate location. The state board of pharmacy will send written notification to the outpatient pharmacy

documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to authorized personnel or contractors of the pharmacy.

4729:5-8-04 - Drugs compounded by a nonresident pharmacy.

(A) Except as otherwise provided in this paragraph, terms used in this rule have the same meaning as in rule 4729:7-2-01 of the Administrative Code.

(B) For all non-sterile compounded drug preparations, a pharmacy licensed as a nonresident terminal distributor of dangerous drugs shall comply with chapter <795> of United States pharmacopeia. The requirements of this rule do not apply to the preparation of non-hazardous, conventionally manufactured non-sterile products in accordance with the directions contained in the approved labeling provided by the product's manufacturer.

(C) For all sterile compounded drug preparations, a pharmacy licensed as a nonresident terminal distributor of dangerous drugs shall comply with chapter <797> of United States pharmacopeia.

(D) For all compounded hazardous drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <800>.

(1) Hazardous drug has the same meaning as in rule 4729:7-2-01 of the Administrative Code.

(2) A non-resident pharmacy compounding non-antineoplastic hazardous drug preparations listed in the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code may also comply with United States pharmacopeia chapter <800>.

(E) In addition to the labeling requirements set forth in paragraphs (B), (C) and (D) of this rule, the statement "Compounded Drug" or other similar statement shall be displayed prominently on the label of all compounded drug preparations sold in this state.

(F) A pharmacy licensed as a nonresident terminal distributor of dangerous drugs that engages in drug compounding shall comply with the following:

(1) Except as provided in paragraph (F)(2) of this rule, shall not sell, ship, mail, or deliver, in any manner, compounded drugs into Ohio unless it is pursuant to a patient specific prescription.

(2) May sell, ship, mail, or deliver, in any manner, non-patient specific compounded drugs for animal use, pursuant to rule 4729:7-2-04 of the Administrative Code. Such compounding for office use shall comply with applicable federal laws and regulations.

(3) A pharmacy licensed as a non-resident pharmacy that is engaged in drug compounding shall have an Ohio licensed pharmacist as the responsible person on its license.

(G) If a pharmacy is applying for an initial nonresident terminal distributor of dangerous drugs license, renewal, or their license has lapsed, the pharmacy must provide any of the following, in a manner prescribed by the board, as part of the initial or renewal application:

(1) The most recent inspection report that is less than two years old that demonstrates applicable compliance with paragraphs (B), (C) and (D) of this rule conducted by an agent of the regulatory or licensing agency in the pharmacy's resident jurisdiction or an agent of a regulatory or licensing agency from another licensing jurisdiction; or

(2) The most recent inspection report that is less than two years old that demonstrates applicable compliance with paragraphs (B), (C), and (D) of this rule by the national association of boards of pharmacy's verified pharmacy program;

(3) The most recent inspection report that is less than two years old that demonstrates applicable compliance with paragraphs (B), (C), and (D) of this rule conducted by accreditation commission for health care inspection services (a.k.a. ACHC inspection services or AIS); or

(4) Proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the accreditation commission for health care (ACHC).

(H) The state board of pharmacy's executive director of the director's designee may grant a one-year, one-time extension to pharmacies licensed as nonresident terminal distributors in the event an inspection report is not available at the time of application or renewal and documentation, as specified by the board, is presented verifying intent to comply with this rule.

(I) A pharmacy licensed as a nonresident terminal distributor shall report to the state board of pharmacy, immediately upon discovery and in a manner determined by the board, any adverse events or product recalls potentially associated with the quality of a compounded sterile preparation.

(J) A pharmacy licensed as a nonresident terminal distributor shall report to the state board of pharmacy, within seventy-two hours and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.

(K) This rule does not apply to a pharmacy licensed as a nonresident terminal distributor of dangerous drugs that prepares radiopharmaceuticals as defined in agency 4729 of the Administrative Code.

4729:7-2-05 Drugs compounded for veterinarian office use.

(A) This rule only applies to compounded drugs intended for animal use by licensed veterinarian.

(B) Pharmacies located in Ohio shall comply with the applicable compounding requirements of this chapter.

(C) Pharmacies licensed as nonresident terminal distributors shall comply with the applicable requirements of rule 4729:5-8-04 of the Administrative Code.

(D) In accordance with applicable federal laws and regulations, a pharmacy licensed as a terminal distributor of dangerous drugs may compound and provide without a prescription a non-patient specific drug pursuant to a request made by a veterinarian, or by an agent of the veterinarian, for a drug to be used by the veterinarian for the purpose of the direct administration to patients in the course of the veterinarian's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:

(1) The pharmacy shall only provide compounded drug preparations that are not commercially available, as defined division (C)(5) of section 4729.01 of the Revised Code, to a veterinarian which are needed:

(a) To treat an emergency situation;

(b) For an unanticipated procedure or treatment for which a time delay would negatively affect a patient outcome;

(c) For diagnostic purposes.

(2) A limited quantity of the drug is compounded and provided to the veterinarian. "Limited quantity" means a quantity of a compounded drug preparation that meets the following:

(a) Is sufficient for that veterinarian's office use consistent with the beyond-use date of the preparation;

(b) Is reasonable considering the intended use of the compounded preparation and nature of the veterinarian's practice; and

(c) The pharmacist who provides the veterinarian with a compounded drug preparation exercises their professional judgment as to whether the quantity of the drug is appropriate.

(E) A veterinarian may personally furnish up to a seven-day supply of a compounded drug to a patient when, in their professional judgment, failure to provide the drug would result in potential harm to the patient.

(F) The pharmacy shall not sell a compounded drug to another pharmacy or facility licensed in accordance with division 4729:6 of the Administrative Code.

(G) Veterinarians shall not:

(1) Sell a compounded drug to another prescriber;

(2) Sell a compounded drug to a pharmacy;

(3) Sell a compounded drug to an entity licensed in accordance with division 4729:6 of the Administrative Code; or

(4) Return a compounded drug to the supplying pharmacy, unless there is a documented error or recall.

(G) The sale of a compounded drug preparation to a prescriber is considered an occasional sale pursuant to rule 4729:5-3-09 of the Administrative Code. For the purposes of enforcing paragraph (B) of rule 4729:5-3-09 of the Administrative Code, the limit for nonresident terminal distributors shall be based on the pharmacy's total business within this state.