1/16/2018

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

- 4729:7-1-01: Definition section for drug compounding rule chapter. Defines the phrase "immediately administered" or "immediate administration" as used in OAC 4729:7-3-02. Updates references to sections of the United States Pharmacopeia (USP 795, USP 797).
- 4729:7-3-01: Specifies the requirements for prescribers to be exempted from licensure as a terminal distributor of dangerous drugs.
- 4729:7-3-02: Provides the requirements for non-hazardous drugs compounded by a prescriber and the requirements if the prescriber is a veterinarian. Further defines the responsibilities for the responsible person on the terminal distributor license. Requires the adherence to United States Pharmacopeia (USP) Chapters 795 and 797 when compounding drugs.
- 4729:7-3-03: Provides the requirements for immediate-use, sterile non-hazardous drugs compounded by a prescriber and the requirements if the prescriber is a veterinarian. Further defines the responsibilities for the responsible person on the terminal distributor license. Sets forth criteria for exemption from requirements in OAC 4729:7-3-02 for immediate-use sterile compounded drug preparations. Requires the adherence to aseptic technique when compounding drugs. Permits a registered nurse who prepares a compounded drug to administer the drug.
- 4729:7-3-04: Provides the requirements for prescribers who compound or handle hazardous drugs. Defines the physical requirements, environmental quality and control, personal protective equipment and safety techniques, packaging and transport, and quality assurance for the facility in which the compounding of hazardous drugs is occurring. Further defines the responsibility of the responsible person on the terminal distributor license. Permits a registered nurse who prepares a compounded drug to administer the drug.
- 4729:7-3-05: Sets forth the record keeping standards for compounding of dangerous drugs that shall be maintained by the responsible person. All records must be readily retrievable and uniformly maintained at the place where the dangerous drugs are located.

Rescinded:

- 4729-16-04 - Drugs compounded by a prescriber.
- 4729-16-09 - Terminal distributor licenses for compounding drugs and ordering compounded drugs.
- 4729-16-11 - Hazardous drugs compounded by a prescriber.
- 4729-16-13 - Immediate use non-hazardous sterile drugs compounded by a prescriber.

Comments on the proposed rules will be accepted until close of business on **2/1/2018**.

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: Prescriber Drug Compounding

Rule Number(s):

New: 4729:7-1-01; 4729:7-3-01; 02; 03; 04; 05

Rescind: 4729-16-04; 09; 11; 13

Date: 01/16/2018

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

- 4729:7-1-01: Definition section for drug compounding rule chapter. Defines the phrase "immediately administered" or "immediate administration" as used in OAC 4729:7-3-02. Updates references to sections of the United States Pharmacopeia (USP 795, USP 797).

- 4729:7-3-01: Specifies the requirements for prescribers to be exempted from licensure as a terminal distributor of dangerous drugs.
- 4729:7-3-02: Provides the requirements for non-hazardous drugs compounded by a prescriber and the requirements if the prescriber is a veterinarian. Further defines the responsibilities for the responsible person on the terminal distributor license. Requires the adherence to United States Pharmacopeia (USP) Chapters 795 and 797 when compounding drugs.
- 4729:7-3-03: Provides the requirements for immediate-use, sterile non-hazardous drugs compounded by a prescriber and the requirements if the prescriber is a veterinarian. Further defines the responsibilities for the responsible person on the terminal distributor license. Sets forth criteria for exemption from requirements in OAC 4729:7-3-02 for immediate-use sterile compounded drug preparations. Requires the adherence to aseptic technique when compounding drugs. Permits a registered nurse who prepares a compounded drug to administer the drug.
- 4729:7-3-04: Provides the requirements for prescribers who compound or handle hazardous drugs. Defines the physical requirements, environmental quality and control, personal protective equipment and safety techniques, packaging and transport, and quality assurance for the facility in which the compounding of hazardous drugs is occurring. Further defines the responsibility of the responsible person on the terminal distributor license. Permits a registered nurse who prepares a compounded drug to administer the drug.
- 4729:7-3-05: Sets forth the record keeping standards for compounding of dangerous drugs that shall be maintained by the responsible person. All records must be readily retrievable and uniformly maintained at the place where the dangerous drugs are located.

Rescinded:

- 4729-16-04: Specifies requirements for prescribers who compound drugs. Further defines the responsibility of the responsible person on the terminal distributor license. Includes new requirements for single-use and multi-use vials. Specifies the requirements for cleaning and disinfecting areas where drugs are compounded. Requires the adherence to aseptic technique when compounding drugs. References proposed immediate use drug compounding rule 4729-16-13. Permits a registered nurse who prepares a compounded drug to administer the drug. The contents of this rule are being moved to rule 4729:7-3-02.
- 4729-16-09: Requires all prescribers that are ordering compounded drugs and compounding drugs on site to have a terminal distributor license. This is to reflect a recent law change in HB 483 (130th General Assembly).

- 4729-16-11: Requires adherence to certain standards for prescribers who compound hazardous drugs. The contents of this rule are being moved to rule 4729:7-3-04.
- 4729-16-13: Specifies requirements for prescribers who compound drugs for immediate use. Includes requirements for preparing drugs in a clean environment and adherence to aseptic technique to prevent contamination. The rule also includes time restrictions for the use of drugs compounded outside of ISO 5 environment. The contents of this rule are being moved to rule 4729:7-3-03.

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

The proposed rules are authorized by sections 4729.26 & 3719.28 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.01, 4729.51, 4729.53, 4729.54, 4729.541 and 4729.55.

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?

The rule does not implement a federal requirement. However, the rule package does implement a federal standard that is enforceable by the United States Food and Drug Administration (USP 795 and 797).

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 drug compounding (notably by prescribers) is not specifically regulated by any federal or state entity and is authorized in statute to be conducted by the State of Ohio Board of Pharmacy (ORC 4729.541).

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 state board of pharmacy to adopt rules governing the practice of pharmacy and distribution and use of dangerous drugs.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729. of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the State of Ohio Board of Pharmacy would not be able to set uniform requirements for the safe compounding of dangerous drugs by prescribers.

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 and prescribers 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.**

The rules in this package were reviewed by a number of prescriber groups and individual prescribers (including dermatologists, podiatrists, plastic surgeons, dentists). After an initial stakeholder comment process, the Board received 117 comments.

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?**

Input from many of the prescriber organizations focused on the need to compound or prepare specific products without needing to obtain a terminal distributor of dangerous drugs (TDDD) license. While licensure will be required for those engaged in drug compounding (as is required by law), requirements pertaining to the preparation and administration of compounded drugs have been modified by the immediate-use rule (4729:7-3-03) in addition to already reduced licensure fees ($60 annually). The Board does exempt physician offices from licensure if they are reconstituting commercially manufactured drugs or drug devices (4729:7-3-01).

Specific provider groups had concerns about the immediate use-rule (4729:7-3-03) and the requirement to dispose of any compounded drug after six hours of preparation. The six-hour window is consistent with data from the USP Committee on Analytical Microbiology and pertains only to drug preparations that are compounded outside of USP 797 standards. As a result of feedback provided, the immediate-use rule was modified as follows:

- Removed the requirements for the use of sterile gloves (gloves are still required); and
- Removed the requirement for the separate preparation area if the drug is administered within one-hour.

Additional comments were received regarding the recordkeeping rule (4729:7-3-05) and how it may potentially duplicate recordkeeping requirements in OAC 4729-9. The rule was modified to make it clear that the recordkeeping only pertained to compounded drug preparations.

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?

For rule 4729:7-1-01, the Board did utilize scientific expertise in that the rule references The United States Pharmacopeial Convention (USP) drug compounding standards and definitions from those standards.

For rule 4729:7-3-03, the Board utilized the following data from the USP Committee on Analytical Microbiology to develop the 6-hour cut-off for any immediate-use product prepared outside of a primary engineering device (i.e. hood) and clean room. As the chart shows, the rate of microbial growth in a potentially contaminated drug product increases exponentially with time.

Time (Hours)	***Microbial Count (CFU per mL)***
6	*10*
9	*640*
12	*41,000*
18	*1.7 x 107*
24	*6.9 x 109*

Cundell AM, USP Committee on Analytical Microbiology, Pharmacopeial Forum 2002; 28 (6) Stimuli to the Revision Process

Additionally, the Board utilized several studies to support the use of a closed system transfer device (CSTD) in rule 4729:7-3-04.

De Prijck K, D'Haese E, Vandenbroucke J, et al. Microbial challenge of four protective devices for the reconstitution of cytotoxic agents. Lett Appl Microbiol. 2008;47:543-548.
McMichael DM, Jefferson DM, Carey ET, et al. Utility of the PhaSeal closed system drug transfer device.Am J Pharm Benefits. 2011;3:9-16.
Carey ET, Forrey RA, Haughs D, et al. Second look at utilization of a closed-system transfer device (PhaSeal). Am J Pharm Benefits. 2011;3:311-318.

Bouza E, Munoza P, Lopez-Rodrıguez J, et al. A needleless closed system device (Clave) protects from intravascular catheter tip and hub colonization: a prospective randomized study. Journal of Hospital Infection. 2003; 54: 279–287.

Clave Multi-dose Vial Access Microbial Ingress Testing: ICU Medical Laboratory Test Report 01-170T.

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 health and safety by ensuring the safe and uniform requirements for prescriber 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 Board did not consider a performance-based regulation for the rule package. It is the Board's responsibility to ensure that standard definitions for compounding and preparation of compounded drugs by prescribers are consistent throughout the state.

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 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:

- Prescribers who are engaged in drug compounding.

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.

- 4729:7-1-01: This is a definitional section and should have no adverse impact.
- 4729:7-3-02: This rule exempts prescribers from licensure. This should have no adverse impact.
- 4729:7-3-02: Overall this rule will result in increased costs to prescribers that prepare compounded drugs that are not for immediate use. The major cost incurred is the purchase of a compounding hood, which can cost up to $6,000. Additional costs include equipment to maintain an aseptic environment such as gloves, masks, gowns, head and shoe covers. Additional costs also include staff time for training personnel in proper compounding techniques, cleaning and disinfecting compounding areas and ensuring compliance with the rule.
- 4729:7-3-03: Prescribers who are engaged in immediate-use compounding only will not be required to purchase of a hood. However, prescribers who normally prepare patient-specific compounded drugs in advance for more than 6-hours will experience an increase as a result of having to discard the medication to prevent bacterial growth. Prescribers will also be required to prepare drugs using aseptic technique which will require, at minimum, the use of gloves and proper hand hygiene. Additional costs also include staff time for training personnel in proper compounding techniques, cleaning and disinfecting compounding areas and ensuring compliance with the rule.

- 4729:7-3-04: Overall this rule will result in increased costs to prescribers that prepare compounded drugs that are not for immediate use. The major cost incurred is the purchase of an ISO 5 hood, which can cost up to $6,000, and the external ventilation of the hood. Additional costs include equipment to maintain an aseptic environment such as gloves, masks, gowns, head and shoe covers. Additional costs also include staff time for training personnel in proper compounding techniques, cleaning and disinfecting compounding areas and ensuring compliance with the rule.
- 4729:7-3-05: Prescribers will experience increased administrative costs to document activities pertaining to drug compounding as part of this recordkeeping rule.

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 patients deserve uniform standards to ensure that their drugs are compounded safely. This is particularly applicable as it relates to infection control measures. The U.S. Centers for Disease Control and Prevention (CDC) continues to see outbreaks in healthcare settings where providers thought they were preparing and administering injections safely. In the last 5 years alone, CDC is aware of at least 26 outbreaks due to unsafe injection practices. These outbreaks resulted in more than 95,000 patients being referred for testing after potential exposure to infectious diseases. 73% of these outbreaks involved use of single-dose/single-use medications.

All of the outbreaks associated with improper use of single-dose/single-use medications occurred in outpatient settings. These and other suboptimal practices are common, as reported by numerous studies about infection control compliance rates. In one study published in the Journal of the American Medical Association, CDC and Centers for Medicare and Medicaid Services colleagues reported that two-thirds of the outpatient facilities inspected had lapses in basic infection control practices. Moreover, infection surveillance is lacking in most outpatient settings; thus it is likely that outbreaks are occurring at a higher frequency, but going undetected.

More broadly, these regulations seek to address best practices identified by national experts. For example, in 2014, Pew convened an advisory committee of state regulators and experts to examine state oversight of compounding and develop best practices. The advisory committee affirmed that quality standards must be the same wherever compounding occurs and expressed concern that compounding in doctors' offices is not always regulated or tracked well. States should have a mechanism to identify and oversee doctor's office compounding. http://www.pewtrusts.org/~/media/assets/2016/02/best_practices_for-state_oversight_of_drug_compounding.pdf

Therefore, without such quality standards for prescribers, the Board would not be fulfilling its mission to protect the health and safety of Ohioans.

Regulatory Flexibility

16. 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 regulations are 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 preparation/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 are 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, field staff (i.e. compliance officers) are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:7 – Drug Compounding (Rescind 4729-16-04; 09; 11; 13)

4729:7-1-01 – Definitions

(A) As used in this division of the Administrative Code:

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

(2) "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.

(3) "Compounding" means the preparation, mixing, assembling, packaging, 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.

(4) “Dangerous drug” has the same meaning as in section 4729.01 of the Revised Code.

(5) "Hazardous drugs" means any drug identified by at least one of the following criteria:

(a) Carcinogenicity, teratogenicity, or developmental toxicity;

(b) Reproductive toxicity in humans;

(c) Organ toxicity at low dose in humans or animals; or

(d) Genotoxicity or new drugs that mimic existing hazardous drugs in structure or toxicity.

(6) “Immediately administered” or “immediate administration” means administration begins not later than one hour following the start of the preparation of the compounded drug preparation.

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

(8) "Non-resident pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio.

(9) "Non-sterile compounded drug" means a dangerous drug preparation intended to be non-sterile.

(10) "Outsourcing facility" means a facility that is engaged in the compounding and sale of dangerous drugs and is registered as an outsourcing facility with the United States food and drug administration.

(11) “Personally furnish” means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(12)

(a) "Positive identification" means a method of identifying personnel 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:

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

(ii) A magnetic card reader;

(iii) A bar code reader;

(iv) A biometric method;

(v) A proximity badge reader;

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

(vii) 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

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

(b) 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.

(13) “Preparation” is a compounded drug dosage form. This term will be used to describe compounded formulations.

(14) “Product” means a drug in a manufactured pharmaceutical dosage form.

(15) “Readily retrievable” means that records maintained in accordance with this division shall be kept in such a manner that they can be separated out from all other records and, upon request, produced for review no later than three business days to an agent, officer or inspector of the board.

(16) “Responsible person” has the same meaning as defined pursuant to agency 4729. 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.

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

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

(19) “United States Pharmacopeia Chapter <795>” or “USP <795>” means United States Pharmacopeia Chapter <795>, USP 40-NF 35, or any official supplement thereto (1/1/2018).

(20) “United States Pharmacopeia Chapter <797>” or “USP <797>” means United States Pharmacopeia Chapter <797>, USP 40-NF 35, or any official supplement thereto (1/1/2018).

4729:7-3-01 – Licensing Exemptions.

(A) Persons listed in divisions (A)(1) to (A)(3) of section 4729.541 of the Revised Code shall be exempted from licensure as a terminal distributor of dangerous drugs as required in accordance with division (D) of section 4729.541 for any of the following:

(1) The preparation or reconstitution of a drug device approved by the United States food and drug administration strictly in accordance with the manufacturer's labeling for administration and beyond use dating.

(2) The reconstitution of non-hazardous, commercially manufactured sterile dangerous drug products for administration with no intervening steps in accordance with the manufacturer's labeling for preparation, administration and beyond use dating.

(3) The compounding, preparation or reconstitution of non-hazardous, non-sterile dangerous drug preparations.

(4) The possession of compounded dangerous drug preparations provided by an outsourcing facility licensed pursuant to Chapter 4729. of the Revised Code.

4729:7-3-02 – Non-Hazardous Drugs Compounded by a Prescriber

(A) Non-sterile compounded drug preparations shall be prepared in accordance with the United States pharmacopeia chapter <795>.

(B) Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with the United States pharmacopeia chapter <797>.

(C) For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with rule 4729:7-3-03 of the Administrative Code.

(D) For all hazardous non-sterile and sterile compounded drug preparations, a prescriber shall comply with rule 4729:7-3-04 of the Administrative Code.

(E) The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

(1) Developing and implementing appropriate compounding procedures;

(2) Overseeing facility compliance with this division;

(3) Compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (05/09/2015) and all other applicable federal and state laws and rules;

(4) Ensuring training and competency of compounding personnel;

(5) Ensuring environmental control of the compounding areas;

(6) Ensuring compounded drug preparations maintain their quality and sterility until administered or personally furnished;

(7) All drug compounding records pursuant to rule 4729:7-3-05 of the Administrative Code.

(8) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(9) Ensuring aseptic technique for the preparation of all compounded drugs.

(F) A prescriber may designate an appropriately trained agent to prepare compounded drug preparations.

(G) For all compounded drugs prepared pursuant to this rule, a prescriber shall:

(1) Inspect and approve the compounding process; and

(2) Except as provided in paragraph (H) of this rule, perform medication validation (“final check”) prior to the medication being administered or personally furnished.

(H) The requirements of paragraph (G) of this rule do not apply to either of the following:

(1) A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (I) of this rule; or

(2) A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, the same registered nurse complies with paragraph (I) of this rule.

(I) All of the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

(1) Verify patient identification using at least two identifiers (e.g., medical record number, DOB).

(2) Confirm with the patient the patient’s planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Indicate in the compounding record verification was completed;

(5) A licensed prescriber is on-site and immediately available.

(J) A prescriber shall not compound drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited.

(K) A prescriber shall comply with the drug database reporting requirements for personally furnishing drugs pursuant to section 4729.79 of the Revised Code.

(L)

(1) Except as provided for in paragraph (L)(2) of this rule, the requirements of this rule do not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code.

If preparing or handling compounded hazardous drugs, a prescriber who is a veterinarian shall comply with rule 4729:7-3-04 of the Administrative Code.

(2) A veterinarian engaged in the compounding of sterile and non-sterile drug preparations shall comply with the following:

(a) Unless immediately administered by the person who prepared it or immediate administration is witnessed by the preparer, the compounded drug preparation shall bear a label listing all of the following:

(i) Patient identification information, including the full name of the owner and the name of the animal name;

(ii) The names and amounts of all ingredients;

(iii) The date prepared;

(iv) The beyond-use date;

(iv) The name or initials of the person who prepared the compounded drug preparation.

4729:7-3-03 – Immediate-Use, Sterile Non-Hazardous Drugs Compounded by a Prescriber

(A) The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all of the following:

(1) Developing and implementing appropriate compounding procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (05/09/2015) and all other applicable federal and state laws and rules;

(4) Ensuring training and competency of compounding personnel;

(5) Ensuring that compounded drug preparations maintain their quality and sterility until administered;

(6) All drug compounding records pursuant to rule 4729:7-3-05 of the Administrative Code.

(7) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(8) Ensuring aseptic technique for the preparation of all compounded drugs.

(B) Immediate-use sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-02 of the Administrative Code if all the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(2) Personnel shall adhere to appropriate aseptic technique, including all the following:

(a) Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure; and

(b) Compounding personnel shall don gloves prior to engaging in compounding activities.

(3) If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize, at a minimum: the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces.

(4) The beyond-use date for an immediate-use compounded drug preparation is no later than six-hours following preparation of the drug.

(5) If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely destroyed. Records of destruction shall be maintained in accordance with rule 4729:7-3-05 of the Administrative Code.

(6) Unless immediately administered by the person who prepared it or immediate administration is witnessed by the preparer, the compounded drug preparation shall bear a label listing all of the following:

(a) Patient identification information, including the patient's first and last name;

(b) The names and amounts of all ingredients;

(c) The beyond-use date with time; and

(d) The name or initials of the person who prepared the compounded drug preparation.

(7) Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber.

(8) For immediate-use compounded drug preparations administered via injection, a new, sterile needle shall be used to administer the compounded drug preparations to the patient.

(C) Unless immediately administered by the person who prepared it or immediate administration is witnessed by the preparer, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% isopropyl alcohol, which is allowed to dry before compounding begins.

(D) Preparations that are medium-risk level and high-risk level compounded drug preparations as defined in United States Pharmacopeia Chapter <797> shall not be prepared as immediate-use.

(E) Preparations that do not meet all of the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-02 of the Administrative Code.

(F) A prescriber may designate an appropriately trained agent to assist the prescriber in the compounding of drugs.

(G) For all compounded drug preparations prepared pursuant to this rule, a prescriber shall:

(1) Inspect and approve the compounding process; and

(2) Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered.

(H)

(1) A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (I) of this rule; or

(2) A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, the same registered nurse complies with paragraph (I) of this rule.

(I) All of the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

(1) Verify patient identification using at least two identifiers (e.g., medical record number, DOB).

(2) Confirm with the patient the patient’s planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Indicate in the compounding record verification was completed;

(5) A licensed prescriber is on site and immediately available.

(I) For hazardous compounded drugs the prescriber shall comply with rule 4729:7-3-03 of the Administrative Code.

(J)

(1) Except as provided for in paragraph (K)(2) of this rule, this rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code. If preparing or handling **hazardous drug**

preparations, a prescriber who is a veterinarian shall comply with rule 4729:7-3-03 of the Administrative Code.

(2) A veterinarian engaged in the compounding of immediate-use sterile drug preparations shall comply with the following:

(a) Unless immediately administered by the person who prepared it or immediate administration is witnessed by the preparer, the compounded drug preparation shall bear a label listing all of the following:

(i) Patient identification information, including the full name of the owner and identification of the animal;

(ii) The names and amounts of all ingredients;

(iii) The date prepared; and

(iv) The name or initials of the person who prepared the compounded drug preparation.

(K) Immediate-use compounded drug preparations shall be prepared in accordance with this rule except in an emergency, as documented in the medical record, when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(L) A prescriber shall not compound sterile, immediate-use drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited.

(M) Records of drug compounding shall be maintained pursuant to rule 4729:7-3-05 of the Administrative Code.

4729:7-3-04 Hazardous drugs compounded by a prescriber.

(A) The responsible person on the license shall be an Ohio licensed prescriber as defined in section 4729.01 of the Revised Code and is responsible for all the following:

(1) Developing and implementing appropriate compounding policies and procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (05/09/2015) and all other applicable federal and state laws and rules;

(4) Ensuring training and competency of compounding personnel;

(5) Ensuring environmental control of the compounding areas;

(6) Ensuring appropriate equipment cleaning and disposal of all hazardous drug waste;

(7) All drug compounding records pursuant to rule 4729:7-3-05 of the Administrative Code.

(8) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(9) Ensuring aseptic technique for the preparation of all compounded drugs.

(B) A prescriber who compounds or handles hazardous drugs as defined in rule 4729:7-1-01 of the Administrative Code shall meet all of the following requirements:

(1) Policy and procedures

(a) A policy and procedure manual shall be prepared, maintained, and reviewed regularly by the responsible person regarding the compounding, safe handling, personally furnishing, and administration of hazardous drugs. The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education. The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent.

(2) Physical requirements

(a) Sterile compounded hazardous drug preparations shall be compounded within a containment primary engineering control (C-PEC) that meets all of the following requirements:

(i) Provides an ISO class 5 or better air quality, such as a class II or III biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI). Class II BSC types B1 or B2 are acceptable.

(ii) Uses a high-efficiency particulate air filter (HEPA filter) for the exhaust from the control.

(iii) The C-PEC shall be externally vented in a manner where air is not pulled back into the facility by the heating, ventilating, and air conditioning (HVAC) systems or by the windows, doors, or other points of entry. Fans shall be placed downstream of the HEPA filter so that contaminated ducts are maintained under negative pressure.

(iv) Paragraph (B)(2)(a)(iii) of this rule is effective December 1, 2020 or upon any new construction or substantial modifications to the C-PEC or containment secondary engineering control (C-SEC), whichever is earlier. The board may grant a prescriber an extension of the external venting requirements if the board determines, upon petition by the prescriber, that the prescriber is unable to make any structural modifications due to an existing building lease agreement. Any prescriber granted an extension shall provide to the board documentation demonstrating how the prescriber will meet the external venting requirements of this rule by the extension date approved by the board.

(b) Non-sterile hazardous drug preparations shall be compounded in a C-PEC that is either an externally vented or a redundant-HEPA filtered in series. Nonsterile hazardous compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a "Class I Biological Safety Cabinet (BSC)" or "Containment Ventilated Enclosure" (CVE). A class II BSC or a compounding aseptic containment isolator (CACI) may also be used. For occasional nonsterile hazardous drug compounding, a C-PEC used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC used only for nonsterile compounding does not need to have unidirectional airflow.

(c) C-PECs used for hazardous drug compounding shall be located in a containment secondary engineering control (C-SEC). The C-SEC shall be one of the following:

(i) For non-sterile hazardous drugs and sterile hazardous compounded drugs with a beyond use date that does not exceed twelve hours, an unclassified containment segregated compounding area (C-SCA) that meets all of the following:

(a) Isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area.

(b) Be of sufficient size to accommodate the containment primary engineering control and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(c) If the C-PECs used for sterile and nonsterile compounding are placed in the C-SCA, they must be placed at least 3 feet apart and particle-generating activity must not be performed when sterile compounding is in process.

(d) Has a sink or wash station available for hand washing as well as emergency access to water for removal of hazardous substances from eyes and skin.

(ii) For sterile hazardous compounded drugs with a beyond use date that exceeds twelve hours, a containment secondary engineering control in accordance with the United States Pharmacopeia Chapter <797>.

(d) A C-PEC and C-SEC used for the preparation of hazardous drugs shall not be used for the preparation of a non-hazardous drug.

(e) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(f) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.

(3) Environmental quality and control

(a) Environmental wipe sampling to detect hazardous drug surface residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment). Common hazardous drug markers that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil and platinum-containing drugs.

(b) Surface wipe sampling should include:

(i) Interior of the C-PEC and equipment contained in it;

(ii) Staging or work areas near the C-PEC;

(iii) Areas adjacent to C-PECs (e.g., floors directly under staging and dispensing area);

(iv) Patient administration areas;

(v) Countertops where finished preparations are placed.

(c) If any measurable contamination is found, the responsible person shall identify, document, and contain the cause of contamination. The facility shall perform thorough deactivation, (using an appropriate deactivating agent) decontamination and cleaning. The facility shall also consider, at a minimum, the following steps to prevent further contamination:

(i) Reevaluating work practices;

(ii) Re-training personnel; and

(iii) Improving engineering controls.

(4) Personal protective equipment (PPE) and safety techniques

(a) PPE includes, but is not limited to, gloves, gowns, head covers, hair covers, shoe covers, eye/face protection.

(i) Gloves, gowns, head, hair, and shoe covers (or dedicated shoes) are required for compounding sterile and nonsterile hazardous drugs.

(ii) Chemotherapy gloves are required for compounding, handling and administering hazardous drugs. Sterile chemotherapy gloves are required for compounding of sterile hazardous drugs. Personnel should use double gloving for all activities involving hazardous drugs making sure that the outer glove extends over the cuff of the gown.

(iii) Gowns are required when compounding, handling and administering injectable antineoplastic hazardous drugs.

(iv) For all other activities, the facility's policy procedure manual must describe the appropriate PPE to be worn. The facility must develop policy and procedures for PPE based on the risk exposure and activities performed. Appropriate PPE must be worn handling hazardous drugs during the following:

(a) Receipt

(b) Storage

(c) Transport

(d) Compounding

(e) Administration

(f) Deactivation or decontamination, cleaning, and disinfecting

(g) Spill control

(v) Chemotherapy gloves must be tested to ASTM standard D6978 (or its successor) and must be powder-free. Gloves must be inspected for physical defects before use and must be changed every thirty minutes or when torn, punctured, or contaminated.

(b) All personnel handling hazardous drugs or hazardous drug waste shall wash hands with soap and water before donning protective gloves and immediately after removal.

(c) Disposable gowns shall be tested and shown to resist permeability by hazardous drugs. Gowns shall close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns shall not have seams or closures that could allow hazardous drugs to pass through. Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials shall not be worn as outerwear when handling hazardous drugs. Gowns shall be changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, they shall be changed every two to three hours or immediately after a spill or splash. Gowns worn in hazardous drug handling areas shall not be worn to other areas.

(d) Appropriate eye and face protection must be worn when there is a risk for spills or splashes of hazardous drugs or hazardous drug waste materials (examples include, but are not limited to: administration in a surgical suite, cleaning the C-PEC, working at or above eye level or cleaning a spill). A full-face piece respirator provides eye and face protection. Goggles shall be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from

splashes. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.

(e) When a hazardous drug preparation is completed, personnel shall:

(i) Seal the final product in a plastic bag or other sealed container for transport before taking it out of the C-PEC.

(ii) Seal and wipe all waste containers inside the C-PEC before removing them from the cabinet.

(f) When the dosage form allows, hazardous drugs shall be administered using a drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system.

(g) Hazardous drugs shall be administered safely using protective techniques, including the spiking or priming of IV tubing in the C-PEC and crushing hazardous tablets in plastic sleeves.

(5) Respiratory protection

Personnel shall use an appropriately fitted national institute for occupational safety approved N95 or equivalent respiratory protection during spill cleanup and whenever there is a significant risk of inhalation exposure to hazardous drug particulates. Surgical masks do not provide respiratory protection from drug exposure and shall not be used.

(6) Disposal of used personal protective equipment (PPE)

All personal protective equipment worn when handling hazardous drugs shall be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE used during compounding should be disposed of in the proper waste container before leaving the C-SEC. Gloves worn during compounding shall be carefully removed and discarded immediately in an approved hazardous waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC. Potentially contaminated clothing shall not be taken home under any circumstances.

(7) Personnel training

(a) All personnel who handle hazardous drugs shall be fully trained based on their job functions (e.g., in the receipt, storage, handling, compounding, dispensing, and disposal of hazardous drugs). Training shall occur before the employee independently handles hazardous drugs. The effectiveness of training for hazardous drugs handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every twelve months and when a new hazardous drug or new equipment is used or a new or significant change in process or standard operating procedure occurs. All training and competency assessment must be documented. The training must include at least the following:

(i) Review of the entity's policies and procedures related to handling of hazardous drugs;

(ii) Proper use of PPE;

(iii) Proper use of equipment and devices (e.g., engineering controls);

(iv) Spill management; and

(v) Response to known or suspected hazardous drug exposure.

(b) Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.

(c) Personnel who handle hazardous drugs shall be reminded that they should undergo medical examinations annually to update their medical, reproductive, and exposure histories. The examinations should be complete, but the skin, mucous membranes, cardiopulmonary and lymphatic systems, and liver should be emphasized.

(8) Facilities

Access to areas where hazardous drugs are unpacked, stored and prepared shall be restricted to authorized staff to protect persons not involved in hazardous drug handling. The location of the hazardous drug compounding area shall be located away from break rooms and refreshment areas for staff, patients, or visitors to reduce risk of exposure. Signs designating the hazard shall be prominently displayed before entry into the hazardous drug area.

(9) Receipt of hazardous drugs

Appropriate PPE shall be used when unpacking hazardous drugs from their shipping containers.

(10) Storage of hazardous drugs

(a) Hazardous drugs shall be stored in a manner that prevents spillage or breakage if the container falls. Hazardous drugs shall not be stored on the floor.

(b) Hazardous drugs shall be stored separately from other inventory, including separate refrigerators.

(c) Hazardous drugs shall be stored in a manner to prevent contamination and personnel exposure.

(11) Decontamination, deactivation, cleaning and disinfection

All areas where hazardous drugs are handled (including during receiving, storage, compounding, transport, administering, and disposal) and all reusable equipment and devices (e.g., C-PEC, carts, and trays) shall be routinely deactivated (using an appropriate deactivating agent for the type of hazardous drugs compounded), decontaminated and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected. Equipment used to perform deactivation, cleaning, and disinfection shall not be used in areas where hazardous drugs are not handled. The facility shall establish written procedures for decontamination, deactivation, cleaning, and disinfection (for sterile compounding areas).

(12) Spill control

(a) All personnel who may be required to clean-up a spill of hazardous drugs shall receive proper training in spill management and the use of PPE. Spills shall be contained and cleaned immediately only by qualified personnel with appropriate PPE. Qualified personnel must be available at all times in facilities

handling hazardous drugs. Signs must be available for restricting access to the spill area. Spill kits containing all of the materials needed to clean hazardous drug spills shall be readily available in all areas where hazardous drugs are routinely handled. If hazardous drugs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator shall be available. All spill materials shall be disposed of as hazardous waste.

(b) Personnel who are potentially exposed during the spill or spill clean-up or who have direct skin or eye contact with hazardous drugs require immediate evaluation by a health care professional. Non-employees exposed to a hazardous drug spill should report to the designated emergency service for initial evaluation.

(c) An eyewash station and other emergency or safety precautions that meet applicable laws and regulations must be readily available.

(13) Disposal

(a) Disposal of all hazardous drug waste (including unused and unusable hazardous drugs) must comply with all applicable federal, state, and local regulations. All personnel who perform routine custodial waste removal and cleaning activities in hazardous drug handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent hazardous drug contamination.

(b) All syringes and needles used in the course of preparation shall be placed in appropriate hazardous waste containers for hazardous disposal without being crushed or clipped.

(14) Maintenance personnel

Personnel that are charged with cleaning the facility shall wear the appropriate personal protective equipment, including appropriate use of gloves or gowns if they handle linens, feces or urine from patients who have received hazardous drugs within the last forty-eight hours. Appropriate eye and face protection shall be worn if splashing is possible.

(15) Patient training

Whenever possible, a prescriber shall be involved in discussing with each patient a hazardous compounded drug, or the caregiver of such individual, the following matters:

(a) Dosage form, dosage, route of administration, and duration of drug therapy;

(b) Special directions and precautions for preparation and administration;

(c) Stability or incompatibilities of the medication.

(16) Quality assurance

(a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities. At a minimum, there shall be written quality assurance programs developed that address:

(i) Adequate training and continuing competency monitoring, including an initial skills assessment and examination as well as annual assessments, of compounding personnel in all of the following areas:

(a) Personal cleansing including proficiency of proper hand hygiene;

(b) Proper attire;

(c) Aseptic technique;

(d) Proper clean room conduct; and

(e) Clean room disinfecting procedures.

(ii) Continued verification of compounding accuracy including physical inspection of end products.

(iii) Continued verification of automated compounding devices.

(iv) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected.

(b) Instructors shall have the appropriate knowledge and experience necessary to conduct the training.

(c) All clean rooms and other primary engineering devices shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency shall be maintained for at least three years.

(17) Packaging and transport

(a) Compounding personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the hazardous drugs during transport. Packaging materials must protect the hazardous drug from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport hazardous drugs. The entity shall have written standard operating procedures to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, mode of transport, and experience of the compounding personnel.

(b) Hazardous drugs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations. Hazardous drugs must be transported in containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be used to transport any liquid or antineoplastic hazardous drugs because of the potential for breakage and contamination.

(C) Records of hazardous drug compounding shall be maintained pursuant to rule 4729:7-3-04 of the Administrative Code.

(D) A hazardous compounded drug that is personally furnished by a prescriber must be labeled according to rule 4729-5-17 of the Administrative Code and must include the appropriate beyond use date, in accordance with United States Pharmacopeia Chapters <797> or <795> USP 38 - NF 33, or any official

supplement thereto (9/10/2015) and complete list of ingredients. The statement "Hazardous Compounded Drug Product" shall also be displayed prominently on the label.

(E) A prescriber shall not compound hazardous drugs in anticipation of prescriptions based on routine prescribing patterns.

(F) A licensed prescriber required to perform medication validation (“final check”) of the finished hazardous compounded drug preparation prior to it being personally furnished or administered to a patient.

(G) Paragraph (F) of this rule does not apply if a hazardous compounded drug is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs complies with the following:

(1) Verify patient identification using at least two identifiers (e.g., medical record number, DOB);

(2) Confirm with the patient his/her planned treatment, drug route, and symptom management;

(3) Verify the accuracy of the following:

(a) Drug name

(b) Drug dose

(c) Drug volume

(d) Rate of administration

(e) Route of administration

(f) Expiration dates/times

(g) Appearance and physical integrity of the drugs

(4) Indicate in the compounding record verification was completed;

(5) Extravasation management procedures are defined;

(6) Antidote order sets and antidotes are accessible; and

(7) A licensed prescriber is on-site and immediately available.

(H) A prescriber may designate an appropriately trained agent to assist the prescriber in the compounding of hazardous drugs.

(I) For non-sterile hazardous compounded drugs, the prescriber shall also comply with the United States Pharmacopeia Chapter <795>.

(J) Sterile hazardous compounded drugs prepared with beyond use dates greater than 12 hours, shall comply with beyond use dating in accordance with the United States Pharmacopeia Chapter <797>.

4729:7-3-05 Record Keeping.

(A) The responsible person shall maintain the following records relating to the compounding of dangerous drugs:

(1) All drug orders and records, including logs, relating to the compounding of drugs. Such drug orders and records may be retained by any process providing an exact duplicate of the original order or prescription.

(2) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record in accordance with the following:

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

(b) 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.

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

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

(3) Records relating to the compounding of drugs, other than personally furnishing, shall include, but are not limited to:

(a) The name of the patient to whom, or for whose benefit, the activity was performed;

(b) The activity performed;

(c) Documentation of all personnel involved in each function of the activity.

(5) A record of all drugs compounded which shall include at least the following:

(a) Name of drug, strength, and dosage form;

(b) Quantity of drug(s) added to each container;

(c) The disposition of unused drug(s) and amount;

(d) Manufacturer's lot number or distributors control number;

(e) Manufacturer's or distributor's name, if a generic drug is used and the record keeping system is capable of specifically tracking the manufacturer's or distributor's name as part of the documentation;

(f) Date of compounding;

(g) Manufacturer's or distributor's expiration date;

(h) The expiration date or beyond-use date; and

(D) All records shall be readily retrievable and uniformly maintained at the place where the dangerous drugs are located in an unalterable and secure manner for at least three years from the date of the last administration or personal furnishing.

(E)

(1) Except as provided for in paragraph (E)(2) of this rule, all required records pursuant to this rule shall be maintained at the place where the dangerous drugs are located.

(2) Any terminal distributor of dangerous drugs intending to maintain records pursuant to this rule at a location other than place must first send a written notification to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs 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 representatives of the terminal distributor of dangerous drugs.