10/15/15

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 Ohio State 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.

Amended Rules

- **4729-16-07:** Specifies the rule only applies to compounded drugs that are for human use.
- **4729-16-03:** Updates incorrect cross references in the rule and includes some exceptions for non-patient specific compounded drugs.
- **4729-15-03:** Corrects a grammatical error.
- **4729-16-08:** Clarifies that nonresident pharmacies may provide non-patient specific compounded drugs for animal use.

New

- **4729-16-11**: Implements new safety regulations for prescribers who compound hazardous drugs.
- **4729-16-12:** New compounding rule for in-office use of compounded drugs for animals.
- **4729-16-04:** Creates new requirements for prescribers who compound dangerous drugs that are non-hazardous.

Comments on the proposed rules will be accepted until close of business on November 2, 2015. Please send all comments to the following email address:
Cameron.mcnamee@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: Compounding

Rule Number(s): Amended: 4729-16-07; 4729-16-03; 4729-15-03; 4729-16-08

New: 4729-16-04; 4729-16-11; 4729-16-12

Date: 10/15/2015

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Amended	Rescinded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.

Amended Rules

- **4729-16-07:** Specifies the rule only applies to compounded drugs that are for human use. Animal drugs will be addressed in proposed new rule 4729-16-12.
- **4729-16-03:** Updates incorrect cross references in the rule and includes some exceptions for non-patient specific compounded drugs.
- **4729-15-03:** Corrects a grammatical error.

- **4729-16-08:** Clarifies that nonresident pharmacies may provide non-patient specific compounded drugs for animal use.

New

- **4729-16-11**: Implements new safety regulations for prescribers who compound hazardous drugs.
- **4729-16-12:** New compounding rule for in-office use of compounded drugs for animals.
- **4729-16-04:** Creates new requirements for prescribers who compound dangerous drugs that are non-hazardous.

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. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.01, 4729.51, 4729.52, 4729.54, 4729.55 and 4729.56.

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.

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 the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board of Pharmacy including the distribution of compounded drug products. The State of Ohio Board of Pharmacy regulates all aspects of pharmacy practice. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy traditionally has been left to state boards.

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, which includes the regulation of entities that prepare, possess, store and ship dangerous drugs.

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

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the previously mentioned sections of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Enforce uniform requirements for nonresident pharmacies that ship animal and human compounded drugs into Ohio.
- Enforce uniform requirements for the use of non-patient specific compounded medications for in-office use.
- Enforce uniform requirements for drugs compounded in a pharmacy and a prescriber's office.
- Set minimum standards for drugs prepared by nuclear pharmacies.
- Enforce uniform requirements for the compounding hazardous 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 of dangerous drugs 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 were reviewed and approved by the State of Ohio Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- Select Specialty Hospital – Akron
- Berger Health System
- The Kroger Company
- Meijer
- Nationwide Children's Hospital

- Fort Hamilton Hospital
- Central Ohio Compounding Pharmacy
- Healthspan Physicians and Integrated Care
- Cedarville University School of Pharmacy
- Fairview Hospital – Cleveland Clinic
- The Ohio State University
- Wal-Mart
- Pharmacy Systems, Inc.

4729-16-12 & 4729-16-08 were reviewed by the Ohio Veterinary Medical Association.

4729-16-11 & 4729-16-04 were reviewed by the Ohio Hematology and Oncology Association.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

The Ohio Hematology and Oncology association provided additional feedback regarding the cost of rule 4729-16-11. This rule was then subsequently amended to provide an additional timeframe for implementation of structural changes (i.e. external ventilation of hoods used for compounding).

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?

The Board utilized nationally recognized best practices from the United States Pharmacopeia (also known as USP) and the National Institute for Occupational Safety and Health (NIOSH).

The Board also used several scientific publications to support efforts to increase protections for healthcare workers handling hazardous drugs, including:

- A 2011 retrospective study of occupational exposures and pregnancy outcomes in 8,461 participants in the Nurses' Health Study II found an associated 2-fold increased risk for spontaneous abortion with hazardous drug exposure.

- A recent study, published in the American Journal of Obstetrics and Gynecology, has looked at 7500 pregnant nurses involved in the handling of hazardous materials. It has

shown a relative increase in rates of spontaneous abortion among mothers who handle chemotherapy. They did use PPE and were not involved in obvious exposure. This means that they were unknowingly exposed to constant low levels of exposure during their pregnancy.

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 rules for the oversight of pharmacies and prescribers that compound drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

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

The Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Pharmacy Board's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board 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, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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:

- Pharmacies licensed as Terminal Distributors of Dangerous Drugs that compound drugs.
- Prescriber practices, including veterinarians, which compound or possess compounded 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 pharmacist, prescriber, pharmacy intern or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work (pharmacists/interns), monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

Amended Rules

- **4729-16-07:** Specifies the rule only applies to compounded drugs that are for human use. Animal drugs will be addressed in proposed new rule 4729-16-12. This should have no additional adverse impact as the rule was implemented in May of this year.
- **4729-16-03:** Updates incorrect cross references in the rule and includes some exceptions for non-patient specific compounded drugs. This should have no additional adverse impact as the changes to this rule are intended to clarify provisions in other rules. This rule was originally implemented in May of this year.
- **4729-15-03:** Corrects a grammatical error. This change should have no additional adverse impact. The rule was reviewed earlier this year as part of its 5-year review.
- **4729-16-08:** Clarifies that nonresident pharmacies may provide non-patient specific compounded drugs for animal use. This change will not have an adverse impact on regulated entities. In fact, the change that allows nonresident pharmacies to provide non-patient specific compounded animal products was requested by both nonresident

pharmacies and veterinarians, as many animal specialty pharmacies reside outside of the state.

New

- **4729-16-11**: Implements new safety regulations for prescribers who compound hazardous drugs. This may result in increased compliance costs for prescribers who compound that do not meet certain national standards. This may include the cost of installing special hoods that can be externally vented, employee training, new personal protective equipment for employees and other improvements to ensure employee safety when handling hazardous drugs. While many practices in Ohio already externally vent the hoods required to compound hazardous drugs, there are some practices that will incur this added cost. Thus, the rule allows for a 5-year implementation period to allow practices to comply with these requirements. Additionally, the rule does allow for extensions should a practice be locked into a lease where they are unable to make modifications to the building without breaking the lease.
- **4729-16-12:** New compounding rule for in-office use of compounded drugs for animals. This will not result in any adverse impacts on veterinary practices. Rather, this rule is intended to increase access to specialized medications required by veterinarians.
- **4729-16-04:** Creates new requirements for prescribers who compound dangerous drugs that are non-hazardous. This may result in increased compliance costs for prescribers who compound that do not meet national standards (i.e. United States Pharmacopeia Convention Chapter 795 and 797). This may include the cost of installing special rooms to compound sterile drugs, employee training, sterilization equipment and other improvements to ensure that drugs are compounded safely.

Regulatory Flexibility

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

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

16. 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 is

not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-16-07 Drugs compounded for human use at an in-state pharmacy for direct administration by a prescriber.

(A) This rule only applies to compounded drugs for human use.

(B) The following requirements do not apply to:

(1) A nuclear pharmacy that compounds radiopharmaceuticals. A radiopharmaceutical must be prepared pursuant to Chapter 4729-15 of the Administrative Code.

(2) An outsourcing facility as defined in rule 4729-16-01 of the Administrative Code. An outsourcing facility must comply with the requirements of rule 4729-16-02 of the Administrative Code.

(3) A nonresident pharmacy as defined in rule 4729-16-01 of the Administrative Code. A nonresident pharmacy shall comply with the requirements of rule 4729-16-08 of the Administrative Code.

(4) An in-state pharmacy granted an exemption pursuant to rule 4729-16-10 of the Administrative Code.

(B) For all non-sterile compounded prescriptions, the in-state pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(C) For all sterile compounded prescriptions, the in-state pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(D) A pharmacist working at an in-state pharmacy as defined in rule 4729-16-01 of the Administrative Code 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 prescriber, or by an agent of the prescriber, for a drug to be used by the prescriber for the purpose of the direct administration to patients in the course of the prescriber's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:

(1) The drug is compounded and provided to a prescriber as an occasional exception to the normal practice of dispensing drugs pursuant to patient specific prescriptions:

The in-state pharmacy may provide non-patient specific compounded drug preparations to prescribers for direct administration to patients as long as the total value of those compounded preparations does not exceed five per cent of the pharmacy's total dollar amount of sales of patient specific compounded prescriptions within the past twelve months. If the total value of sales exceeds five per cent, then the pharmacy must become an outsourcing facility pursuant to rule 4729-16-02 of the Administrative Code.

(2) The in-state pharmacy shall only provide those compounded drugs that are not commercially available to a prescriber which are needed:

(a) To treat an emergency situation;

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

(c) For diagnostic purposes.

(E) The in-state pharmacy shall not supply more than a seventy-two hour supply of a non-patient specific compounded drug to a prescriber at a single location. A prescriber shall not have more than a seventy-two hour supply of a compounded drug at a single location at any given time. The seventy-two hour supply provided to the prescriber, shall be determined by previous administration patterns provided by a prescriber to the pharmacist. The limitation of a seventy-two hour supply shall not apply to the following:

(1) Compounded non-sterile drug preparations for topical administration, pursuant to paragraphs (D)(2)(b) and (D)(2)(c) of this rule, shall be supplied to a prescriber in which the quantity does not exceed sixty grams or sixty milliliters at a single location. A prescriber shall not have more than sixty grams or sixty milliliters of a specific compounded drug at a single location at any given time; or

(2) Compounded non-sterile drug preparations intended to treat an emergency situation, pursuant to paragraph (D)(2)(a) of this rule, may be provided to a prescriber in a quantity required to sufficiently treat individuals in the event of an emergency situation.

(F) The in-state pharmacy shall not sell a compounded drug to another pharmacy or wholesaler.

(G) Prescribers shall only administer a requested non-patient specific compounded drug directly to their own patients. Prescribers shall not:

(1) Dispense a compounded drug to a patient;

(2) Sell a compounded drug to another prescriber;

(3) Sell a compounded drug to a pharmacy; or

(4) Return a compounded drug to the supplying pharmacy.

(H) The labeling of a compounded drug preparation must contain the following:

(1) The statement "For direct patient administration only" displayed prominently;

(2) The statement "Not for resale" displayed prominently;

(3) Proper storage conditions;

(4) Beyond use dates;

(5) The name(s) of the active and inactive ingredients;

(6) The amount or percentage of active drug ingredients;

(7) The quantity of compounded drug provided;

(8) The route of administration;

(9) The pharmacy name, address, and telephone number;

(10) The pharmacy control number assigned to the compounded drug preparation.

(I) Compounded drug preparation containers that are too small to bear a complete label pursuant to paragraph (H) of this rule must bear a label that contains at least the following information:

(1) "Not for resale";

(2) The storage conditions if other than room temperature;

(3) The beyond use date;

(4) The drug name(s);

(5) The drug strength;

(6) The route of administration;

(7) The pharmacy control number;

(8) The pharmacy name.

(J) In all cases, a complete label meeting the requirements of paragraph (H) of this rule must be applied to the outside container in which such compounded preparation is supplied.

(K) The sale of a compounded drug preparation to a prescriber is considered a wholesale sale as defined in section 4729.01 of the Revised Code. A pharmacy is required to follow the record keeping requirements for wholesale sales listed in paragraph (H) of rule 4729-9-16 of the Administrative Code.

(L) A pharmacy shall follow the compounding requirements pursuant to rules 4729-16-03 and 4729-16-06 of the Administrative Code current professional compounding standards, and all applicable federal and state laws, rules, and regulations.

4729-16-03 Drugs compounded in a pharmacy.

(A) For all non-sterile compounded prescriptions, the pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(B) For all sterile compounded prescriptions, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(C) Comply with section 503A of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(D) Only a pharmacist or pharmacy intern under the personal supervision of a pharmacist is permitted to engage in dispensing and compounding.

(E) A qualified pharmacy technician pursuant to section 4729.42 of the Revised Code may assist a pharmacist in the compounding and dispensing of drugs in accordance with section 4729.01 of the Revised Code and according to the following requirements:

(1) May not engage in any procedure requiring professional judgment. The pharmacist is responsible for the drug compounded or dispensed.

(2) The system of drug distribution must provide exact control and assign immediate responsibility only to a pharmacist accountable at every point in the system between receipt of the order for a drug and final delivery for administration or use by the patient.

(3) May not engage in any procedure contrary to the intent of the statutes and rules regulating the dispensing and compounding of drugs.

(F) In order to compound prescriptions, a pharmacy shall meet the minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code.

(G) For all compounded prescriptions, the pharmacist shall:

(1) Inspect and approve the compounding process;

(2) Perform the final check of the finished product.

(H) For all compounded prescriptions, the pharmacist shall be responsible for:

(1) All compounding records pursuant to rule ~~4729-16-07~~ 4729-16-06 of the Administrative Code;

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

(I) Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(J) Except as otherwise provided in rules 4729-15-03, 4729-16-07, 4729-16-10 and 4729-16-12 of the Administrative Code, a ~~A~~ prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(K) The requirements for prescriptions received by a fluid therapy pharmacy are as specified in rule 4729-16-05 of the Administrative Code.

(L) A compounded prescription that is dispensed to an outpatient must be labeled according to rule 4729-5-16 of the Administrative Code. In addition, the label shall comply with paragraphs (N) and (A) or (B) of this rule. The statement "Compounded Drug Product" shall also be displayed prominently on the label.

(M) A compounded prescription that is dispensed to an inpatient must be labeled according to rule 4729-17-10 of the Administrative Code. In addition, the label shall comply with paragraphs (N) and (A) or (B) of this rule. The statement "Compounded Drug Product" shall also be displayed prominently on the label.

(N) The requirements for the labeling of sterile product prescriptions in a fluid therapy pharmacy are as specified in rule ~~4729-16-06~~ 4729-16-05 of the Administrative Code.

(O) Labels for a compounded prescription that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following:

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

(2) The identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier;

(3) Pharmacy control number;

(4) The pharmacy's expiration date or beyond use date;

(5) "Compounded Drug Product."

(P) A sterile compounded product prescription prepared in accordance with federal and state requirements that is for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile or a board approved electronic prescription transmission system pursuant to rule 4729-5-30 of the Administrative Code. The facsimile shall serve as the original written prescription and shall be received and maintained pursuant to

rules 4729-5-21 and 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

(Q) The pharmacy's responsible person shall ~~assure~~ ensure the environmental control of all products shipped to the patient.

(R) The pharmacy's responsible person shall ~~assure~~ ensure that there is a system for the disposal of cytotoxic and/or hazardous drug waste in a manner so as not to endanger the public health.

(S) A pharmacy that prepares hazardous and/or cytotoxic drugs shall do so in accordance with United States pharmacopeia chapter <797> USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(T) The pharmacy shall comply with the drug database reporting requirements for Chapter 4729-37 of the Administrative Code.

(U) This rule does not apply to nuclear pharmacies, unless the pharmacy meets the requirements in paragraph (A) of rule 4729-15-03 of the Administrative Code.

4729-15-03 Minimum standards for a nuclear pharmacy..

(A) A nuclear pharmacy shall comply with all applicable local, state, and federal requirements. If a nuclear pharmacy compounds parenteral or sterile product prescriptions other than radiopharmaceuticals or biohazardous materials, the pharmacy shall also comply with rule ~~4729-19-04~~ 4729-16-03 of the Administrative Code.

(B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile radiopharmaceutical prescriptions. The policy and procedure manual shall include at a minimum:

(1) A quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education;

(2) Justification for the chosen beyond use dates of compounded products;

(3) Proper handling, storage, and disposal of drugs, radiopharmaceuticals, and radioactive waste;

(4) Proper handling, storage, and disposal of biohazardous materials, if applicable;

(5) Handling of spills and exposure to radioactive and biohazardous materials;

(6) Proper documentation and reporting of adverse events;

(7) Procedures to resolve conflicts when sterile product preparation may interfere with radiation safety practices and equipment. These procedures should use the principle of as clean as reasonably achievable.

The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy agent.

(C) Physical requirements

(1) The facility shall have a designated area with access limited to authorized personnel for preparing sterile radiopharmaceutical products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood or other primary engineering control devices that provide a class 100 environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) The facility compounding radiopharmaceutical prescriptions shall have appropriate:

(a) Primary engineering control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; at a minimum, there shall be a physical barrier separating the area where biohazardous products such as human blood are prepared; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air.

(b) Shielding of radioactive materials;

(c) Compounding devices and equipment;

(d) Storage conditions for drugs, radiopharmaceuticals, and biohazardous materials;

(e) Appropriate disposal containers for used needles, syringes, etc.

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

(4) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to meet the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to ~~assure~~ ensure the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) Disposal of radioactive and/or biohazardous waste

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to ~~assure~~ ensure that there is a system for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) Health care professional counseling

When appropriate, a nuclear pharmacist shall be involved in discussing with each health care professional responsible for receiving, storing, and administering a radiopharmaceutical product, the following matters:

(1) Dosage form, dosage, calibrated activity, route of administration, and duration of therapy;

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

(3) Proper storage; and

(4) Stability or incompatibilities of the medication.

(G) Quality assurance

(1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities.

(2) At a minimum, there shall be written quality assurance programs developed that address:

(a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;

(b) Continued verification of compounding accuracy and including when possible physical inspection of end products;

(c) Continued verification of automated compounding devices;

(d) Continued verification that appropriate beyond use dates are being assigned to compounded products;

(e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. If bulk compounding of sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine;

(f) All clean rooms and laminar flow hoods 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 operation efficiency shall be maintained for at least three years.

4729-16-12 Drugs compounded for animal use at a pharmacy for direct administration by a veterinarian (NEW).

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

(B) For all non-sterile compounded prescriptions, the pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(C) For all sterile compounded prescriptions, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(D) In accordance with applicable federal laws and regulations, a pharmacist working at an 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 prescriber 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 those compounded drugs that are not commercially available, as defined division (C)(5) of section 4729.01, 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 that meets the following:

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

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

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

(E) A veterinarian may personally furnish up to a seventy-two 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 wholesaler.

(G) Veterinarians shall not:

(1) Sell a compounded drug to another prescriber;

(2) Sell a compounded drug to a pharmacy; or

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

(H) The labeling of a compounded drug preparation must contain the following:

(1) Proper storage conditions;

(2) Beyond use dates;

(3) The name(s) of the active and inactive ingredients;

(4) The amount or percentage of active drug ingredients;

(5) The quantity of compounded drug provided;

(6) The route of administration;

(7) The pharmacy name, address, and telephone number;

(8) The pharmacy control number assigned to the compounded drug preparation.

(I) Compounded drug preparation containers that are too small to bear a complete label pursuant to paragraph (H) of this rule must bear a label that contains at least the following information:

(1) The storage conditions if other than room temperature;

(2) The beyond use date;

(3) The drug name(s);

(4) The drug strength;

(5) The route of administration;

(6) The pharmacy control number;

(7) The pharmacy name.

(J) In all cases, a complete label meeting the requirements of paragraph (H) of this rule must be applied to the outside container in which such compounded drug is supplied.

(K) The sale of a compounded drug preparation to a prescriber is considered a wholesale sale as defined in section 4729.01 of the Revised Code. A pharmacy is required to follow the record keeping requirements for wholesale sales listed in paragraph (H) of rule 4729-9-16 of the Administrative Code.

(L) A pharmacy shall follow the compounding requirements pursuant to rules 4729-16-03 and 4729-16-06 of the Administrative Code, current professional compounding standards, and all applicable federal and state laws, rules, and regulations.

4729-16-08 Drugs compounded by a nonresident pharmacy.

(A) Except as provided in paragraph (J) of this rule, a nonresident pharmacy as defined in rule 4729-16-01 of the Administrative Code is prohibited from shipping compounded drugs into Ohio unless it is pursuant to a patient specific prescription.

(B) A nonresident pharmacy as defined in rule 4729-16-01 of the Administrative Code shall meet all of the following in order to ship, mail, or deliver, in any manner, compounded drugs into Ohio:

(1) Obtain licensure as a nonresident terminal distributor of dangerous drugs pursuant to Chapter 4729-10 of the Administrative Code.

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

(a) The most recent inspection report that is less than two years old that demonstrates compliance with paragraphs (H) and (I) of this rule ~~4729-16-03 of the Administrative Code~~ 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

(b) The most recent inspection report that is less than two years old that demonstrates compliance with paragraphs (H) and (I) of this rule ~~provided~~ conducted by the national association of boards of pharmacy's verified pharmacy program as defined in rule 4729-16-01 of the Administrative Code.

(C) Notwithstanding submission of an inspection report from a source acceptable to the board, the board may deny an application or suspend a license on the grounds that the nonresident pharmacy failed to comply with applicable laws or regulations. The nonresident pharmacy would have the opportunity for a hearing before the board.

(D) The board may grant a one-year, one-time extension to nonresident pharmacies in the event an inspection report is not available at the time of application or renewal and documentation is presented verifying intent to comply with this rule.

(E) A nonresident pharmacy is required to report to the state board of pharmacy immediately upon discovery, by telephone and follow-up in writing within thirty days, any of the following:

(1) A violation of section 4729.16 of the Revised Code or any other violation of the Ohio Revised Code or Ohio Administrative Code that could potentially cause patient harm;

(2) A citation or violation against the nonresident pharmacy or the owner(s), responsible person, agent, employee or officer of the nonresident pharmacy by any pharmacy regulatory or licensing agency that results in any the following:

(a) Monetary penalty;

(b) Administrative hearing;

(c) Suspension or revocation of a license; or

(d) Violations of laws or regulations that could potentially cause patient harm.

(3) Any criminal conviction(s) of the owner(s), responsible person, agent, employee or officer of the nonresident pharmacy.

(4) Any adverse event related to improper compounding or product defect.

(F) Failure to report the required information in paragraph (E) of this rule may result in a monetary penalty and/or the suspension, revocation, or refusal to grant or renew ~~any~~ a license as a terminal distributor of dangerous drugs.

(G) This rule does not apply to a nuclear pharmacy that compounds radiopharmaceuticals pursuant to rule 4729-15-01 of the Administrative Code.

(H) For all non-sterile compounded prescriptions, the pharmacy shall comply with chapter <795> of the United States pharmacopeia, USP 38 – NF 33, or any official supplement thereto (05/01/2015).

(I) For all sterile compounded prescriptions, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 – NF 33, or any official supplement thereto (05/01/2015).

(J) A nonresident pharmacy may provide licensed veterinarians non-patient specific compounded drugs for animal use, pursuant to rule 4729-16-12. Such compounding for office use shall comply with applicable federal laws and regulations.

4729-16-11 Hazardous Drugs Compounded by a Prescriber (NEW)

(A) A facility where a prescriber is compounding or handling hazardous drugs shall be licensed as a terminal distributor of dangerous drugs. 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 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 competency of personnel; and

(5) Assuring environmental control of the compounding areas.

(B) A prescriber who compounds or handles hazardous drugs as defined in rule 4729-16-01 of the administrative code shall meet all of the following requirements:

(1) Policy and Procedures

(a) A policy and procedure manual shall be prepared and maintained 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 drugs 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) Nonsterile hazardous drugs 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 be 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 nonsterile hazardous drugs and sterile hazardous compounded drugs with a beyond use date that does not exceed 12 hours, a unclassified containment segregated compounding area (C-SCA) that meets all of the following:

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

(bb) 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.

(cc) 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.

(dd) 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 12 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 should be performed at least every six months. 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.

(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 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) & 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 are required for compounding sterile and nonsterile hazardous drugs. Sterile chemotherapy gloves are required for compounding of sterile antineoplastic hazardous drugs.

(ii) Chemotherapy gloves are required for compounding, handling and administering antineoplastic hazardous drugs.

(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:

(aa) Receipt

(bb) Storage

(cc) Transport

(dd) Compounding

(ee) Administration

(ff) Deactivation or decontamination, cleaning, and disinfecting

(gg) Spill control

(b) When required, 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 30 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 2–3 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

(a) Personnel shall use an appropriately fitted 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)

(b) 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 12 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

(a) 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

(a) 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.

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

(11) Decontamination, Deactivation, Cleaning and Disinfection

(a) 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. 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 and also complete an incident report or exposure form.

(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

(a) 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 48 hours. Appropriate eye and face protection shall be worn if splashing is possible.

(15) Patient training

(a) 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:

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

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

(iii) 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 of all personnel in personal cleansing, proper attire, aseptic technique, and C-PEC and C-SEC disinfecting and decontamination procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training.

(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) All C-PEC 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.

(C) Records of hazardous drug compounding shall be kept pursuant to rule 4729-16-06 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> 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 is required to perform the final check of the finished hazardous compounded drug 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 licensed health professional in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two licensed personnel approved by the responsible person to prepare or administer compounded drugs do all of 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:

I. Drug name
II. Drug dose
III. Drug volume
IV. Rate of administration
V. Route of administration
VI. Expiration dates/times
VII. Appearance and physical integrity of the drugs

(4) Sign using positive identification pursuant to rule 4729-5-01 of the Administrative Code to indicate 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> USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(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> USP 38 – NF 33, or any official supplement thereto (9/10/2015).

4729-16-04 DRUGS COMPOUNDED BY A PRESCRIBER (NEW)

(A) A facility where a prescriber is compounding drugs shall be licensed as a terminal distributor of dangerous drugs. 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 of the following:

(1) Developing and implementing appropriate 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 competency of personnel; and

(5) Assuring environmental control of the compounding areas.

(B) As used in this rule, a low-risk sterile compounded drug means all of the following:

(1) Does not involve any hazardous drugs as defined in rule 4729-16-01 of the Administrative Code.

(2) The drug is compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.

(3) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile product.

(4) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(5) Administration of the drug shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.

(C) A prescriber who prepares low-risk sterile compounded drugs as defined in paragraph (B) of this rule shall meet all of the following requirements:

(1) A policy and procedure manual shall be prepared and maintained by the responsible person regarding the compounding, personally furnishing, and delivery of sterile product prescriptions. 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) The facility shall have a designated area with access limited to authorized personnel for preparing low risk sterile compounded drugs. This area shall be isolated from other areas; including areas used to prepare hazardous compounded products, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of low risk sterile compounded drugs and provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The facility shall have:

(i) Appropriate primary engineering control devices capable of maintaining an ISO Class 5 environment in the work place where critical objects are exposed and critical activities are performed. These devices shall be capable of maintaining an ISO Class 5 environment during normal activity. Examples of such devices include laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

(ii) Infusion devices and equipment, if appropriate.

(iii) Appropriate temperature controlled transport containers.

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

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

(e) Low-risk sterile compounded drugs shall prepared within an ISO Class 5 environment except in an emergency situation when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(3) Patient training

Whenever possible, a prescriber shall be involved in discussing with each patient receiving a low-risk sterile compounded product, 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.

(4) 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 of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training.

(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) 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.

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

(E) For low-risk with greater than 12 hour beyond use date, medium and high-risk sterile compounded drugs as defined in United States Pharmacopeia Chapter <797>, the prescriber shall comply with United States Pharmacopeia Chapter <797>, USP 38 – NF 33, or any official supplement thereto (9/10/2015).

(F) For hazardous compounded drugs, the prescriber shall comply with rule 4729-16-11 of the Administrative Code.

(G) For all compounded prescriptions, the prescriber shall comply with section 503A of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

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

(I) For all compounded drugs prepared pursuant to this rule, the prescriber shall:

(1) Inspect and approve the compounding process.

(2) Perform the final check of the finished product.

(J) Paragraph (I) of this rule does not apply if a compounded product is being administered to a patient in the facility by a licensed health professional in accordance with their applicable scope of practice pursuant to a prescriber's order and, prior to administration, at least two licensed personnel approved by the responsible person to prepare or administer compounded drugs do all of 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:

(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) Sign using positive identification pursuant to section (N) of rule 4729-5-01 of the Administrative Code to indicate verification was completed;

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

(K) For all compounded prescriptions, the prescriber shall be responsible for:

(1) All compounding records pursuant to rule 4729-16-06 of the Administrative Code, including positive identification requirements pursuant to section (N) of rule 4729-5-01 of the Administrative Code;

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

(L) A 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> and complete list of ingredients. The statement "Compounded Drug Product" shall also be displayed prominently on the label.

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

(N) The prescriber shall comply with the drug database reporting requirements for Chapter 4729-37 of the Ohio Administrative Code.

(O) This rule does not apply to a prescriber who is a veterinarian licensed under Chapter 4741 of the Ohio Revised Code. If preparing or handling compounded hazardous drugs, a prescriber who is a veterinarian shall comply with rule 4729-16-11 of the Administrative Code.