



VETERINARY COMPOUNDED DRUGS - NEW RULES EFFECTIVE 2/22/2016

On February 22, 2016, the following rules will go into effect regarding access to compounded drugs for veterinary use:

- **4729-16-12 - Drugs Compounded by a Pharmacy for Use by a Veterinarian:** This rule specifies requirements for in-office use of compounded products for veterinarians.
- **4729-16-08 - Drugs Compounded by a Nonresident Pharmacy:** Permits out-of-state pharmacies to provide non-patient specific compounded drugs for animal use in accordance with rule 4729-16-12. See paragraph (C) of this rule.

REMINDER:

- **All locations** (no exception) are required to hold a license as a terminal distributor of dangerous drugs in order to possess, have custody or control of, or distribute dangerous drugs that are compounded or used for the purpose of compounding. Pharmacies and wholesalers will not be able to ship compounded drug products or drugs used for the purpose of compounding to an entity that is not licensed by the Board. This applies to compounded drugs sent to prescribers acting as [pick-up stations](#). More information on this requirement can be accessed here: www.pharmacy.ohio.gov/compoundingtddd
- On May 1, 2016, veterinarians that compound hazardous drugs on-site will have to comply with new rule 4729-16-11.

A copy of the new and updated rules can be found on the next page.



4729-16-12

Drugs Compounded by a Pharmacy for Use by a Veterinarian.

- (A) This rule only applies to compounded drugs intended for animal use by a licensed veterinarian.
- (B) For all non-sterile compounded products, 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 products, 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 veterinarian for the purpose of the direct administration to patients in the course of the veterinarian's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:
- (1) The pharmacy shall only provide compounded drug products 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 seven day supply of a compounded drug to a patient when, in their professional judgment, failure to provide the drug

would result in potential harm to the patient.

(F) The pharmacy shall not sell a compounded drug to another pharmacy or 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 product 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 product.

(9) The statement "Compounded Drug Product" or other similar statement.

(I) Compounded drug product 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), including all active ingredients;

(4) The drug strength(s);

(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 product 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.

(M) No pharmacy shall sell any amount of non-patient specific veterinarian administered compounds in excess of five percent of the total amount of drug products sold and/or dispensed from their pharmacy. The five percent limitation shall be calculated on an annual basis and shall reference the number of dosage units. For non-resident pharmacies, the total amount sold and/or dispensed shall reference the pharmacy's total business within this state.

Effective: 02/22/2016

Five Year Review (FYR) Dates: 02/22/2021

CERTIFIED ELECTRONICALLY

Certification

02/12/2016

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28, 4729.26
Rule Amplifies: 4729.55, 4729.01, 4729.54, 4729.541

4729-16-08

Drugs compounded by a nonresident pharmacy.

(A) For all non-sterile compounded drug products, the pharmacy shall comply with chapter <795> of the United States pharmacopeia, USP 38 - NF 33, or any official supplement thereto (09/01/2015).

(B) For all sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 - NF 33, or any official supplement thereto (09/01/2015).

(C) 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.

~~(A)~~(D) Except as provided in paragraph (C) of this rule, a 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)~~(E) 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 (A) and (B) 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 (A) and (B) of this rule ~~provided~~ by the national association of boards of pharmacy's verified pharmacy program as defined in rule 4729-16-01 of the Administrative Code;

(c) The most recent inspection report that is less than two years old that demonstrates compliance with paragraphs (A) and (B) of this rule

conducted by accreditation commission for health care inspection services (a.k.a. ACHC inspection services or AIS); or

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

~~(E)~~(F) 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)~~(G) 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)~~(H) 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)~~(I) Failure to report the required information in paragraph ~~(E)~~(H) 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)~~(J) This rule does not apply to a nuclear pharmacy that compounds radiopharmaceuticals pursuant to rule 4729-15-01 of the Administrative Code.

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CERTIFIED ELECTRONICALLY

Certification

02/05/2016

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Prior Effective Dates: 5/1/2015

4729-16-11

Hazardous Drugs Compounded by a Prescriber.

(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, 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 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:

(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 12 hours, a containment secondary engineering control in accordance with the United States Pharmacopeia Chapter <797> USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(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.

(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 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 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)

(a) 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. 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 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, 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 & 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 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> 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 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 healthcare 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:

(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 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).

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