



Ohio Administrative Code

Rule 4729-16-11 Hazardous Drugs Compounded by a Prescriber.

Effective: May 1, 2016

(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 twelve 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 twelve 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) and safety techniques

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



protection.

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

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

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

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

(a) Receipt

(b) Storage

(c) Transport

(d) Compounding

(e) Administration

(f) Deactivation or decontamination, cleaning, and disinfecting

(g) Spill control

(v) Chemotherapy gloves must be tested to ASTM standard D6978 (or its successor) and must be



powder-free. Gloves must be inspected for physical defects before use and must be changed every thirty minutes or when torn, punctured, or contaminated.

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

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

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

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

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

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

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



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

(5) Respiratory protection

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

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

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

(7) Personnel training

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

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



(ii) Proper use of PPE;

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

(iv) Spill management; and

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

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

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

(8) Facilities

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

(9) Receipt of hazardous drugs

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

(10) Storage of hazardous drugs

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



(b) Hazardous drugs shall be stored separately from other inventory.

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

(11) Decontamination, deactivation, cleaning and disinfection

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

(12) Spill control

(a) All personnel who may be required to clean-up a spill of hazardous drugs shall receive proper training in spill management and the use of PPE. Spills shall be contained and cleaned immediately only by qualified personnel with appropriate PPE. Qualified personnel must be available at all times in facilities handling hazardous drugs. Signs must be available for restricting access to the spill area. Spill kits containing all of the materials needed to clean hazardous drug spills shall be readily available in all areas where hazardous drugs are routinely handled. If hazardous drugs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator shall be available. All spill materials shall be disposed of as hazardous waste.

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

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

(15) Patient training

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

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

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

(c) Stability or incompatibilities of the medication.

(16) Quality assurance

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



- (i) Adequate training and continuing competency monitoring, including an initial skills assessment and examination as well as annual assessments, of compounding personnel in all of the following areas:
 - (a) Personal cleansing including proficiency of proper hand hygiene;
 - (b) Proper attire;
 - (c) Aseptic technique;
 - (d) Proper clean room conduct; and
 - (e) Clean room disinfecting procedures.
- (ii) Continued verification of compounding accuracy including physical inspection of end products.
- (iii) Continued verification of automated compounding devices.
- (iv) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected.
- (b) Instructors shall have the appropriate knowledge and experience necessary to conduct the training.
- (c) All clean rooms and other primary engineering devices shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency shall be maintained for at least three years.
- (17) Packaging and transport
 - (a) Compounding personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the hazardous drugs during transport.



Packaging materials must protect the hazardous drug from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport hazardous drugs. The entity shall have written standard operating procedures to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, mode of transport, and experience of the compounding personnel.

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

(C) Records of hazardous drug compounding shall be 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 prescribers 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).