Board of Pharmacy

INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Prescriber Compounding

Updated 8/14/2024

This guide is not intended for use by pharmacies engaged in drug compounding. For more information on pharmacy compounding requirements, visit: www.pharmacy.ohio.gov/compound

To review updates, please see the update history section at the end of this document.

This document is reference material for licensees and applicants. The document does not bind the Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant, or licensee.

What is a Terminal Distributor of Dangerous Drugs (TDDD) license?

A Terminal Distributor of Dangerous Drugs (TDDD) license allows a business entity to purchase, possess, administer, and/or distribute dangerous drugs at a specific location. A terminal distributor of dangerous drugs includes hospitals, pharmacies, EMS organizations, laboratories, nursing homes, and prescriber practices.

Distribution includes the administration of drugs on-site to patients as well as handing medications to patients to take away from the facility for later use (commonly known as personally furnishing).

Dangerous drugs are defined in the Ohio Revised Code as a drug the meets any of the following:

1. Requires a prescription;
2. Bears on the label a Federal Legend (Rx Only or Caution: Federal law prohibits dispensing without a prescription); or
3. Is intended for injection into the human body.

There are some exemptions to this licensure requirement for prescriber practices that purchase, possess, administer, and/or distribute dangerous drugs. These exemptions can be found by visiting: www.pharmacy.ohio.gov/prescriberTDDD

Drug Compounding by Prescriber Practices and TDDD Licensure

In general, the exemptions to Ohio's TDDD licensure requirements (www.pharmacy.ohio.gov/prescriberTDDD) do not apply if the prescriber practice is engaged in drug compounding.

Compounding is defined as the "preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance."

However, if a practice that possesses dangerous drugs is exempted from TDDD licensure (www.pharmacy.ohio.gov/PrescriberTDDD) there are some additional exemptions in the Board's prescriber drug compounding rules that would apply practices engaged in lower-risk compounding activities.

Therefore, any practice that is generally exempted from TDDD licensure (www.pharmacy.ohio.gov/PrescriberTDDD) that engages in the following lower-risk compounding activities is **NOT** required to obtain a TDDD license:

(1) The preparation of a device, as defined in Title 21 U.S. Code section 321, containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. **(Example, preparing Restylane per manufacturer's instructions.)**

(2) The preparation or reconstitution of non-hazardous*, conventionally manufactured sterile dangerous drug products for direct administration with no intervening steps in accordance with the manufacturer's labeling for preparation, administration and beyond-use dating. **(Example, preparing Botox injections).**

(3) The compounding, preparation, dilution or reconstitution of non-hazardous*, non-sterile dangerous drug preparations. **(Example, amoxicillin oral suspension that requires reconstitution)**.

(4) The possession of compounded drug preparations provided by an Ohio licensed outsourcing facility. **(NOTE: If a prescriber compounds any sterile drug received from an outsourcing facility, the prescriber office is subject to licensure as a TDDD).**

(5) The dilution of non-hazardous*, conventionally manufactured sterile dangerous drug products (e.g., diluting or mixing into a syringe to administer directly to the patient). **(Example, diluting Kenalog or buffering lidocaine at the time of administration. NOTE:**

Preparation of such medications in advance of administration requires licensure and compliance with the Board's compounding rules).

What is Considered a Non-Hazardous Drug?

Ohio rules define a hazardous drug for the purpose of compounding as any antineoplastic drug listed in **table one** on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

REMINDER: *If you are administering a hazardous drug from a single-use vial with no intervening steps, you are not engaged in drug compounding.*

SPECIAL NOTE FOR VETERINARIANS: The Board's compounding rules, and the requirements listed in this inspection guide, only apply to veterinarians that are engaged in hazardous drug compounding. Non-hazardous drug compounding for veterinary medicine is not regulated by the Board of Pharmacy. However, any compounding done in a veterinary clinic must comply with certain labeling requirements. For more information, please see page 32 of the Veterinary Clinic inspection guide (www.pharmacy.ohio.gov/vetinspect).

I am a prescriber practice that is licensed as a TDDD. Am I required to comply with the Board's drug compounding rules?

The Board has exempted the following **non-hazardous*** devices and drugs **prepared by prescriber practice licensed as a TDDD** from the general compounding requirements of Chapter 4729:7-3 of the Ohio Administrative Code:

(1) The preparation of a device, as defined in Title 21 U.S. Code section 321, containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the device. If no such beyond-use date exists, the dangerous drug product may only be used for up to six hours following preparation. These devices shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Unless administered immediately, the drug device described in this paragraph shall bear a label listing the name of the device (if not legible), date, and time prepared.

(2) The reconstitution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration, and the beyond-use dating indicated on the manufacturer's labeling. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond use date or timeframe exists, the dangerous drug product may only be used for up to six hours following preparation. These drug products shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(3) The preparation, reconstitution or dilution of a conventionally manufactured nonsterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond-use date exists, the dangerous drug product shall be assigned a beyond-use date in accordance with USP. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(4) The dilution of a conventionally manufactured sterile dangerous drug product (e.g., diluting or mixing into a syringe to administer directly to the patient). The drug product shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. The dangerous drug product may only be used for up to six hours following preparation. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug, date, and time prepared.

Ohio rules define a hazardous drug for the purpose of compounding as any antineoplastic drug listed in table one on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

REMINDER: This inspection guide is intended to be part of an overall inspection of a prescriber practice licensed as a terminal distributor of dangerous drugs. The practice is also required to comply with the requirements of that facility's license type, which includes one of the following:

- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Animal Shelters – 4729:5-15
- Laboratories – 4729:5-16
- Office-Based Opioid Treatment Facilities – 4729:5-18
- Clinic and Prescriber Offices – 4729:5-19
- Veterinary Clinics – 4729:5-20
- Opioid Treatment Programs – 4729:5-21
- Non-limited Facilities – 4729:5-22
- Limited Facilities – 4729:5-23

Inspection Authority

Pursuant to section 3719.13 of the Revised Code and rule 4729:5-3-03 of the Administrative Code, a location licensed by the State Board of Pharmacy as a terminal distributor of dangerous drugs is subject to an on-site inspection by the Board. An authorized Board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed by the Board.

Upon verification of the Board agent's credentials, the agent shall be permitted to enter the licensed entity.

Submission of an application for a license as a terminal distributor of dangerous drugs with the State Board of Pharmacy constitutes permission for entry and on-site inspection by an authorized Board agent.

After the completion of the inspection, the authorized Board agent will provide an inspection report for review and any corrective actions required. If the inspection report requires a written response, responses must be e-mailed within 30 days of the inspection to writtenresponse@pharmacy.ohio.gov.

Applicable Rules

The following provides a general list of rule chapters that apply to clinics and prescriber offices licensed as terminal distributor of dangerous drugs:

- **4729:7-1 – Compounding References**
    - 4729:7-1-01 – Compounding references.
- **4729:7-3 – Prescriber Compounding**
    - 4729:7-3-01 - Definitions - prescriber compounding.
    - 4729:7-3-02 - Exemptions.
    - 4729:7-3-03 - Non-hazardous drugs compounded by a prescriber.
    - 4729:7-3-04 - Immediate-use, sterile non-hazardous drugs compounded by a prescriber.
    - 4729:7-3-05 - Hazardous drugs compounded by a prescriber.
    - 4729:7-3-06 - Record keeping.
    - 4729:7-3-07 – Pharmacists conducting medication validation.

Health Insurance Portability and Accountability Act (HIPAA)

Upon inspection, Board staff may ask to review patient records to determine compliance with Ohio laws and rules. To address concerns regarding compliance with HIPAA, the Board has developed the following FAQ to assist licensees.

What is HIPAA?

- HIPAA is a federal privacy rule created to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.

Why does the HIPAA privacy rule not apply to the Ohio Board of Pharmacy?

- HIPAA applies to health plans, health clearinghouses, and to any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted standards under HIPAA, known as "covered entities" and to their business associates.
    - The Board of Pharmacy does not fit the definition of a covered entity because:
        1) The Board does not provide or pay for the cost of medical care;
        2) The Board is not a health care provider; and
        3) The Board does not process health information on behalf of other organizations (billing, community health management information systems, etc.).
- In addition, the Board is not considered a "business associate" because it does not perform activities on behalf of or provide services to a covered entity (as described in 1-3 above) that involves the use or disclosure of identifiable health information.
- Examples of a business associate include, but are not limited to, the following: third-party administrators that assist with claims processing or a consultant that performs utilization review for a hospital.

How can a Licensee be assured the Board will protect patient information?

- The Board's confidentiality statute, ORC 4729.23, provides that any information provided to the Board in the course of an investigation is confidential and is not a public record.
- In addition, there are exemptions in Ohio's Public Records law, that exempt medical records/patient information from being released in response to a public record request (ORC Section 149.43(A)(1)(a)).

For more information about the HIPAA Privacy Rule, visit: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

Positive Identification Guidance

"Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

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

(2) A magnetic card reader;

(3) A bar code reader;

(4) A biometric method;

(5) A proximity badge reader;

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

(7) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

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

NOTE: A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

REMINDER: Positive identification should be at the conclusion of a drug transaction. For electronic systems, positive identification required at log-in does not document the specific drug transaction and causes other security problems. For example, a nurse does not document the administration of a medication when they log in to an electronic drug record keeping system.

Important Terms

- **"Antineoplastic"** means a dangerous drug that blocks the formation of neoplasms. According to the Centers for Disease Control and Prevention, antineoplastic drugs are medications used to treat cancer. Antineoplastic drugs are also called anticancer, chemotherapy, chemo, cytotoxic, or hazardous drugs. These drugs come in many forms. Some are liquids that are injected into the patient and some are pills that patients take.

- **"Beyond-use date (BUD)"** or **"beyond-use dating"** means either the date or time after which a compounded drug preparation must not be used, or administration must not begin, and must be discarded. The beyond-use date is determined from the date/time that preparation of the compounded drug is initiated.

- **"Compounding"** means the preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance.

- **“Containment primary engineering control (C-PEC)”** means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when conducting sterile compounding.

- **“Dangerous drug”** means any of the following:

  (1) Any drug to which either of the following applies:

  (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

  (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

(4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

- **"Hazardous drug"** means any antineoplastic drug listed in table one on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

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

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

- **"Preparation"** means a drug compounded in a licensed pharmacy or other healthcare-related facility. Preparations may include the compounding of one or more drug products.

- **"Product"** means a drug in a commercially manufactured pharmaceutical dosage form that has been evaluated for safety and efficacy by the United States Food and Drug Administration. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

- **"Readily retrievable"** means that records maintained in accordance with this division shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the Board.

- **"Reconstitution"** means the process of adding a diluent to a powdered drug to prepare a solution or suspension.

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

- **"Sterile compounded drug"** means a dangerous drug preparation intended to be sterile.

Reminder on Enforcement of USP 797 and USP 795 Compounding Standards

The United States Pharmacopeia (USP) in June 2019 released several new and revised pharmacy compounding standards. Specifically, USP published the final revised version of general chapter <797> and <795>. Due to pending appeals, the effective date of the revised chapters is postponed until further notice.

To ensure compliance, licensees are reminded that the Board is conducting compliance inspections using the current version of USP 797 (last revised in 2008) and USP 795 (last revised in 2014) and not the revised version released in June 2019 that is currently on hold pending further review. Please be advised that any change in compounding enforcement standards will be communicated to licensees well in advance of implementation.

For more information about the USP revision process, visit the following links:

For USP 797: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-797-rb-notice-20200424.pdf

For USP 795: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-795-rb-notice-20200424.pdf

Free versions of the currently enforced USP compounding chapters can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw

Clarification on Dilution or Reconstitution of Allergen Extracts

Please be advised that rule 4729:7-3-03 requires adherence to the allergen extracts section of United States Pharmacopeia (USP) Chapter 797. This provision does not subject prescribers to the personnel, environmental, and storage requirements of USP 797 if certain criteria, listed in the chapter, are met. Therefore, allergen extracts may be prepared and used in accordance with the provisions of USP 797 and are not subject to a general six hour beyond use date.

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Prescriber Compounding - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code / BUD = Beyond-Use Date

Licensure Requirements

A prescriber clinic may be exempt from licensure as a terminal distributor if it is only conducting certain lower-risk drug compounding activities and does not meet any of the other criteria necessitating licensure as a terminal distributor of dangerous drugs (see: www.pharmacy.ohio.gov/prescriberTDDD). Board staff will review to determine if licensure is required using the criteria is this section.

Question	Description / Guidance	Law/Rule
Is the practice location compounding dangerous drugs exempt from licensure in accordance with rule 4729:7-3-02 of the Administrative Code?	Pursuant to section 4729.541 of the Revised Code all healthcare providers must obtain licensure from the Board of Pharmacy if engaged in the practice of drug compounding. However, rule 4729:7-3-02 further clarifies this provision by exempting the following from the Board's licensure requirements: (1) The preparation of a device, as defined in Title 21 U.S. Code section 321 (12/13/2016), containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. (2) The preparation or reconstitution of non-hazardous, conventionally manufactured sterile dangerous drug products for direct administration with no intervening steps in accordance with the manufacturer's labeling for preparation, administration and beyond-use dating.	ORC 4729.541 OAC 4729:7-3-02

	(3) The compounding, preparation, dilution or reconstitution of non-hazardous, nonsterile dangerous drug preparations. (4) The possession of compounded dangerous drug preparations provided by an outsourcing facility. (5) The dilution of non-hazardous, conventionally manufactured sterile dangerous drug products (e.g., diluting or mixing into a syringe to administer directly to the patient).	

Exempted Compounding Activities

*If a licensee is required to maintain a terminal distributor of dangerous drugs license because of more advanced compounding activities or meets other criteria for licensure (see: www.pharmacy.ohio.gov/prescriberTDDD), then the following **non-hazardous** lower-risk drug compounding activities are not subject to compounding requirements of Chapter 4729:7-3 of the Ohio Administrative Code:*

(1) The preparation of a device, as defined in Title 21 U.S. Code section 321 (12/13/2016), containing dangerous drugs strictly in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the device. If no such beyond-use date exists, the dangerous drug product may only be used for up to six hours following preparation. These devices shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Unless administered immediately, the drug device described in this paragraph shall bear a label listing the name of the device (if not legible), date, and time prepared.

(2) The reconstitution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration, and the beyond-use dating indicated on the manufacturer's labeling. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond use date or timeframe exists, the dangerous drug product may only be used for up to six hours following preparation. These drug products shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(3) The preparation, reconstitution or dilution of a conventionally manufactured nonsterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond-use dating. Manufacturer labeling that uses the phrase "should" when referring to a beyond-use date or timeframe for use shall be construed by the licensee as the required beyond-use date of the drug product. If no such beyond-use date exists, the dangerous drug product

shall be assigned a beyond-use date in accordance with USP. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible), date, and time prepared.

(4) The dilution of a conventionally manufactured sterile dangerous drug product (e.g., diluting or mixing into a syringe to administer directly to the patient). The drug product shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. The dangerous drug product may only be used for up to six hours following preparation. Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug, date, and time prepared.

This section includes the criteria that will be reviewed specifically related to the preparation of the drugs listed above.

REMINDER: These exemptions do not apply to hazardous drugs. A hazardous drug means any antineoplastic drug listed in table one on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

Question	Description / Guidance	Law/Rule
Do the beyond-use dates used for device preparation, sterile dangerous drug reconstitution, and/or non-sterile dangerous drug reconstitution exceed manufacturer recommendations or 6 hours if no manufacturer recommended beyond-use date is published?	Manufacturer labeling that uses the phrase "should" when referring to a beyond use date or timeframe for use shall be construed by the licensee as the required beyond-use date (BUD) of the device or drug product. If no such beyond-use date exists, the dangerous drug product may only be used for up to six hours following preparation. OAC 4729:7-3-02(B) allows a device containing a dangerous drug and/or sterile or non-sterile drugs for reconstitution to be assigned a BUD in accordance with manufacturer recommendations. The rule also states that if no such BUD is recommended by the manufacturer, the maximum BUD must comply with the following: ▪ For sterile products: Up to six hours.	OAC 4729:7-3-02

	▪ For non-sterile products: assigned a beyond-use date in accordance with USP <795> **NOTE:** A BUD for a 28-day multidose vial does not apply to drugs drawn into syringes and stored in advance of need (dilution) but applies to storage in the original package container only. The rule does not specify a container must be labeled with the BUD. Rather, it states the BUD must be in accordance with manufacturer labeling or the requirements of the rule. *Board staff will document how the facility keeps track of product BUDs if they are not noting it on the product. It would be acceptable for staff to know the BUD based of the date/time prepared, which is required to be on the container.*	
Are conventionally manufactured sterile dangerous drug products which are diluted or drawn into a syringe for direct patient administration administered within 6 hours of dilution/syringe draw?	A drug product which is diluted or drawn into a syringe for direct patient administration (with no intervening steps) may be drawn into that syringe not more than 6 hours prior to administration. Locations may pre-draw sterile dangerous drugs into syringes from manufacturer vials of drugs in solution or from reconstituted drug solutions and assign a 6-hour BUD to these products.	OAC 4729:7-3-02
If not immediately administered, are drug containing devices, reconstituted conventionally	Conventionally manufactured devices containing dangerous drugs, reconstituted sterile and/or non-sterile dangerous drug products, and/or conventionally manufactured sterile dangerous drug products which are diluted, mixed and drawn into a syringe for direct patient	OAC 4729:7-3-02

manufactured sterile or non-sterile drug products and any drug product which is diluted or drawn into a syringe for direct patient administration labeled with the drug name, and the date and time prepared?	administration, must be labeled with the drug name and the date and time the drug was drawn into the syringe. The BUD for conventionally manufactured devices containing dangerous drugs, reconstituted sterile or non-sterile drugs in their original manufacturer packaging must be in accordance with manufacturer recommendations, or 6 hours if there are no manufacturer recommendations. The BUD for conventionally manufactured sterile drug products diluted or drawn into syringes prior to patient administration may not exceed 6 hours from the time the medication is drawn into the syringe. **NOTE:** Each syringe must be labeled separately. Labeling a bag of multiple syringes is not permitted because it creates patient safety concerns. Any drug (sterile, non-sterile, drug device) which is reconstituted must contain the drug name and the date/time of reconstitution. If the drug product remains in the original manufacturer container, labeling only the date/time of reconstitution is appropriate provided the drug name is not obscured on the label.	
Is the preparation of all drug containing devices, reconstituted sterile conventionally manufactured drug	All drug containing devices, reconstituted conventionally manufactured sterile drug products, and conventionally manufactured sterile drug products which are diluted or drawn into a syringe for patient administration must be prepared using aseptic technique and processes must be in place to minimize the potential	OAC 4729:7-3-02

products, and the dilution or drawing of a drug product into a syringe for direct patient administration are prepared using aseptic technique and procedures which minimize potential contamination?	for contact with non-sterile surfaces. The introduction of particulate matter and/or biological fluids must be minimized. **IMPORTANT:** Aseptic conditions promote germ-free and sterile conditions, and include all the following: ✓ Using barriers to prevent the transfer of microorganisms from health care personnel and the environment to the patient. This may include gloves, gowns, masks, etc. ✓ Sterile instruments (syringes, equipment, devices) used for drug preparation. ✓ Antiseptic skin preparation for patient administration. ✓ Environmental controls: Keeping doors closed, minimizing traffic, limiting unnecessary people in compounding areas. ✓ Only sterile to sterile contact is allowed. Non-sterile to sterile contact must be avoided.	

Immediate Use Sterile Non-Hazardous Drugs Compounded by a Prescriber

Question	Description / Guidance	Law/Rule
Does the prescriber location compound immediate-use, non-hazardous drugs?	Immediate use sterile compounding involves the simple transfer of not more than three commercially manufactured drug packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one package (e.g. bag, vial) of sterile infusion solution or administration container/device. **NOTE:** If a drug vial requires reconstitution, the product used to reconstitute counts as a commercially manufactured sterile drug. Therefore, two sterile drug powders each reconstituted, and then combined into an IV bag is not permitted for immediate use, it is medium risk compounding because there would be five commercially manufactured packages of sterile non-hazardous drugs used in the compound.	OAC 4729:7-3-04
Do compounding personnel adhere to appropriate aseptic technique including hand-hygiene and gloving prior to engaging in compounding activities?	Compounding personnel shall adhere to appropriate aseptic technique, including all the following: ✓ Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure and shall don gloves prior to engaging in compounding activities. ✓ Hand-hygiene includes the following: o Removing jewelry below the elbow and cleaning fingernails under warm water to remove debris.	OAC 4729:7-3-04

	○ Working from the fingertips to the elbows vigorously wash in circular motions for 30 seconds. ○ Rinsing completely without allowing the rinse water to run over your fingertips. ○ Drying hands with a lint-free wipe from fingertips to elbows. **NOTE:** Gloves do not need to be sterile for immediate use compounding.	
Except for buffered lidocaine products, does the compounding location assign a beyond-use date to each compounded product not greater than 6 hours following preparation of the drug?	Except for buffered lidocaine products, the beyond-use date for an immediate-use compounded drug preparation is no later than six hours following preparation of the drug.	OAC 4729:7-3-04
Does the compounding location assign a beyond-use date to each buffered lidocaine product not greater than 12 hours following preparation of the drug?	The beyond-use date for an immediate-use compounded drug preparations containing buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug.	OAC 4729:7-3-04

Does the compounding location compound preparations of buffered lidocaine containing antimicrobial preservatives in anticipation of need?	A prescriber may compound preparations of buffered lidocaine containing antimicrobial preservatives for anticipated needs where multiple non-patient specific doses are produced in a single activity. **NOTE:** Except for buffered lidocaine containing antimicrobial preservatives, no immediate-use compounded preparations may be prepared for anticipated needs.	OAC 4729:7-3-04
Does the compounding location compound immediate-use preparations that do not contain buffered lidocaine containing antimicrobial preservatives?	Except for buffered lidocaine containing antimicrobial preservatives, compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited.	OAC 4729:7-3-04
If not immediately administered, are finished compounded products properly labeled?	Unless administered immediately, the compounded drug preparation shall bear a label listing the following: ✓ Patient identification information, including the patient's first and last name. **NOTE:** Patient identification is not required for buffered lidocaine that is prepared for anticipatory needs. ✓ The name and quantity of each ingredient. ✓ The date and time prepared and the beyond use date. ✓ The name or initials of the person who prepared the compounded drug preparation.	OAC 4729:7-3-04

Are compounded preparations not administered prior to the beyond-use date promptly and properly destroyed?	If administration has not begun within the compounded drug preparations beyond-use date, the drug must be promptly, properly, and safely disposed. Prompt disposal may be immediate, or it may be at the end of the day. If drugs are not immediately destroyed, Board staff will confirm there is a system to remove the drugs from active work areas to prevent administration to patients.	OAC 4729:7-3-04
Are prescribers personally furnishing immediate-use compounded drug preparations?	Immediate-use compounded drug preparations are for administration only and ***must not be personally furnished by a prescriber***.	OAC 4729:7-3-04
Is the compounding location using new sterile needles for the administration of all immediate-use compounded drug preparations?	For an immediate-use compounded drug preparation administered via injection, a new sterile needle shall be used to administer the compounded drug preparations to the patient. **IMPORTANT:** The needle used for compounding must **NEVER** be the needle use for patient administration.	OAC 4729:7-3-04
Are immediate-use compounded drug preparations compounded more than 1-hour prior administration prepared in a designated clean medication area?	Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that meets the following requirements: ✓ The area is not adjacent to areas where potentially contaminated or hazardous items are placed. Board staff will inspect to ensure there is a designated compounding area that	OAC 4729:7-3-04

	is segregated from contaminants such as food, trash, biological waste containers, urine samples, etc. ✓ The area is limited to compounding personnel. Board staff will review the area to ensure that traffic from non-compounding staff is limited. ✓ The area must not be located in areas that have unsealed windows or doors that connect to the outside, high traffic areas, or areas adjacent to construction sites, warehouses or food preparation areas. ✓ The area is cleaned and disinfected before sterile compounding is performed. This does not mean once per day but rather prior to each time compounding occurs. o Board staff will ensure that cleaning of the designated area is conducted using a product that is a surfactant (i.e. containing soap). Licensees are encouraged to use health-care quality germicidal and sporicidal products. o Board staff will also ensure that the area is disinfected following cleaning. Licensees must use a residue-free disinfecting agent, such as sterile 70% isopropyl alcohol, which is allowed to dry before compounding begins. Using other concentrations of isopropyl alcohol (i.e. 99%) is not permitted because the ratio of water to alcohol plays a role in the ability of alcohol to penetrate cell walls and kill microorganisms.	

Are designated medication preparation areas limited to compounding personnel?	Areas designated for compounding should limited to personnel engaged in compounding. Board staff will examine the space surrounding the compounding area to determine if staff are constantly closely walking by or working on other tasks. A segregated compounding area limits traffic flow so that the area remains as free as possible from dust and microbial contaminants. The more people moving around, the more dirt and germs become airborne, which increases the chances of contaminating a compounded sterile product.	OAC 4729:7-3-04
Are segregated compounding areas located away from unsealed windows or doors that connect to the outdoors, high traffic areas, construction sites, warehouses, or food preparation areas?	Designated medication preparation areas must not be in areas that have unsealed windows or doors that connect to the outside, high traffic areas, or areas adjacent to construction sites, warehouses, or food preparation areas. Unsealed doors and windows which connect to the outside increase the chances of microbial contamination, including spores, mold, and yeast. High traffic areas, construction areas and warehouses also have increased dust, dirt and debris which become airborne particles. Such areas may contribute to sterile compounded product contamination and present a risk to patients. The FDA does not recommend eating any food left at room temperature for more than 2 hours. Bacteria grow rapidly on food between 40-140 F, nearly doubling every 20 minutes. If food is left in compounding areas the bacterial count of the area is greater and may contaminate compounded drugs.	OAC 4729:7-3-04

	The greater the time between compounding and administration of a sterile compounded product, the greater the risk of contamination from outside sources.	
Are cleaning and disinfection agents used to clean the segregated compounding area effective, compatible with surfaces cleaned, and formulated to prevent the deposit toxic residues?	Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% isopropyl alcohol, which is allowed to dry before compounding begins. Cleaning is a mechanical process enhanced by germicidal detergents to remove dirt, debris, biofilm, and microbes. Therefore, cleaning prepares a surface to be disinfected. Sterile alcohol or bleach **is not** considered a cleaning agent. Cleaning must be achieved using a product that is a surfactant (e.g. has soap in it). Facilities should, but are not required to, use health-care quality germicidal and sporicidal products for cleaning this area that can remain wet on the surface for the required amount of time indicated on the product's instructions. Board staff will review cleaning and disinfecting products and procedures to determine compliance.	OAC 4729:7-3-04

Is the segregated compounding area cleaned and disinfected prior to use?	Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% isopropyl alcohol, which is allowed to dry before compounding begins. **NOTE:** 70% is also required because the ratio of water to alcohol plays a role in the ability of alcohol to penetrate cell walls and kill microorganisms. Facilities are not permitted to use other concentrations.	OAC 4729:7-3-04
Has the facility's responsible person developed and implemented policies and procedures, including training, on immediate-use drug compounding?	The responsible person for the compounding location which compounds for immediate use must develop and implement policies and procedures appropriate for the compounding process. The responsible person must also ensure compounding personnel are trained, and competent to perform compounding duties. At a minimum, policies and procedures should address all the following: ▪ Proper hand hygiene (i.e. hand washing) ▪ Gloving ▪ Segregated compounding area designation ▪ Aseptic technique ▪ Cleaning and disinfecting procedures	OAC 4729:7-3-04

	▪ Compounding documentation/recordkeeping ▪ Assignment of appropriate BUDs	
Is the facility's responsible person ensuring the proper maintenance, cleanliness and use of all compounding equipment?	The responsible person for a facility compounding immediate-use sterile products is responsible for the maintenance, cleanliness and use of all equipment use for compounding. Board staff will review the following to determine compliance: ▪ Is the compounding area and equipment used in compounding clean, and in good working order? ▪ Is staff cleaning appropriately between compounding? ▪ If specialized equipment is used for compounding, are there records of repair or calibration of any equipment necessary for immediate use sterile compounding?	OAC 4729:7-3-04
Have the compounded drug processes been inspected and approved by the prescriber prior to patient administration?	For all compounded drugs prepared pursuant to this rule, a prescriber shall inspect and approve the compounding process. All processes used to compound drugs must be inspected and approved by the prescriber. Therefore, non-prescriber staff cannot develop the compounding process (master formula) without the prescribers check and approval. Board staff will verify that master formula has been approved by a prescriber prior to the compound being made.	OAC 4729:7-3-04

Are the compounded drug products verified (e.g., final check is performed)?	For all drugs prepared pursuant to this rule, a prescriber shall perform medication validation ("final check") prior to the medication being administered. Verification can be completed using any of the following methods: ✓ Verification by a prescriber or pharmacist; or ✓ **FOR ADMINISTRATION ONLY:** Verification by at least two nurses* approved by the responsible person; or ✓ **FOR ADMINISTRATION ONLY:** Verification by a nurse if the nurse* prepared the compounded drug. ***IMPORTANT:** Licensed practical nurses are **NOT** permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may prepare or reconstitute an antibiotic additive. As such, it is **NOT** within an LPN's scope of practice, and they cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive). **REMINDER:** Final checks/medication validation must be documented using positive identification.	OAC 4729:7-3-04 OAC 4729:7-3-06 OAC 4729:7-3-07
If compounding is verified by a nurse (RN), does the licensee comply with the medication validation	The rule provides two avenues for the verification of compounded drugs by registered nurses: 1) If a nurse* prepares a compounded drug product and directly administers it to a patient pursuant to a prescriber order, but	OAC 4729:7-3-04 OAC 4729:7-3-06

requirements prior to administration?	without the final check of the prescriber, the nurse who prepared the drug must comply with the verification requirements of the rule. 2) If an individual (nurse*, pharm tech, etc.) prepares a compounded drug product and gives it to a nurse to administer pursuant to a prescriber order, but without the final check of the prescriber, two nurses* must comply with the verification requirements of the rule. The verification requirements for nurse administration include all the following prior to the administration of the compounded drug: a. Verify the patient identification using two different patient identifiers (name + DOB, etc.) b. Confirm with the patient the treatment plan, drug route, and symptom management. c. Verify the drug name, strength, dosage form and quantity to be administered. d. Verify the route and rate (if applicable) of administration. e. Verify the expiration date/time of the compounded product prior to administration.	

	f. Review the appearance and physical integrity of the drug to be administered. g. Document in the compounding record verification was completed. h. Ensure a prescriber is on-site and immediately available. **REMINDER:** Rule 4729:7-3-06 requires the positive identification of the person or persons performing medication validation (in this case verification) prior to the compounded drug being administered. Therefore, the positive identification of the verifying nurse or nurses must be captured in the compounding record. ***IMPORTANT:** Licensed practical nurses are **NOT** permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may prepare or reconstitute an antibiotic additive. As such, it is **NOT** within an LPN's scope of practice, and they cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive).	

Record Keeping & Drug Disposal

IMPORTANT: *This section applies to all compounded drug preparations except those preparations that meet the exemptions in OAC 4729:7-3-02. This includes immediate use compounded products, and non-hazardous and hazardous sterile and non-sterile prescriber compounded preparations.*

Question	Description / Guidance	Law/Rule
Does the compounding location maintain records of all drug orders, including logs relating to the compounding of drugs which provide an exact duplicate of the original order or prescription?	All drug orders and records, including logs, relating to the compounding of drugs. Such drug orders and records may be retained by any process providing an exact duplicate of the original order or prescription. Board staff will review records for drug orders, these are most likely found in the patient chart, but can be recorded in any alternate location, if the order is complete. **REMINDER:** The order must be specific. Example: "Give Rocephin" is not a drug order. "Ceftriaxone 250mg IM" is a drug order.	OAC 4729:7-3-06
How does the facility maintain its compounding records?	Board staff will review to determine if records are maintained: 1) Via paper records; or 2) Via electronic methods (EHR, scanned paper records, etc.)	OAC 4729:7-3-06
If records are electronic, does the facility comply with the requirements for the electronic storage of drug compounding records?	Records maintained in an electronic format must meet the following: 1) Paper records maintained in an electronic format must be scanned in full color via technology designed to capture information and reproduce it in an electronic medium presentable	OAC 4729:7-3-06

	and usable to an end user. This means an exact, legible copy/scan of the paper record. 2) The electronic system storing records must contain security features such as unique usernames and passwords to prevent unauthorized access. (**NOTE:** This is not a requirement for positive ID, but a requirement that authorized persons can access data using a user/name password, and that unauthorized persons cannot access the records.) 3) The storage medium for electronic records must be backed up daily to protect against records loss. This can be a back-up to the cloud or a hard drive/server. 4) Records maintained electronically shall comply with the requirements of the rule (e.g. contain all required information and, when required, must capture positive identification). **NOTE:** Positive identification can be captured using scanned records, as a scanned copy of a signature meets the requirements.	
Do records of each drug compounded include the minimum information as required in rule?	Records of each drug compounded shall, at a minimum, include all the following: 1) The full name of the patient, unless buffed lidocaine is compounded in advance [see paragraph (G)(2) of rule 4729:7-3-04 of the Administrative Code] 2) The name, strength, and dosage form of the compounded drug;	OAC 4729:7-3-06 OAC 4729:7-3-02 OAC 4729:7-3-04

	3) The name and quantity of each ingredient (including all ingredients such as diluent, drug, etc.); 4) If a controlled substance, the disposition of unused drug(s) and amount; 5) The date and time of preparation; 6) The beyond-use date of the compounded drug; 7) The positive identification of the personnel responsible for compounding the drug; 8) The positive identification of **<u>either</u>** of the following: a. The person or persons performing medication validation prior to the compounded drug being administered; or b. The prescriber personally furnishing the compounded drug.	
Does the licensee dispose of non-controlled compounded drugs using a method that prevents the possession or use of the drugs by unauthorized persons?	Methods of disposal of non-controlled dangerous drugs must prevent the possession or use of the drugs by unauthorized persons.	OAC 4729:5-3-06
Does the licensee maintain complete and accurate	Records of disposal of compounded dangerous drugs from inventory, other than controlled substances, shall contain the name, strength,	OAC 4729:7-3-06

records of the disposal of non-controlled dangerous drugs?	dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal. **NOTE:** This does not apply to wastage from administration. For non-controlled drugs, such documentation is not required. All records must be maintained for a period of three years.	
Does the licensee dispose of controlled substances on-site using a method that renders the drug non-retrievable?	Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request. "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or	OAC 4729:5-3-01

	controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes. **NOTE:** Per the Drug Enforcement Administration, flushing (i.e. drain or toilet) does not meet the definition of non-retrievable. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable.	
Does the licensee use a reverse distributor for the disposal of controlled substances?	If yes, Board staff will document the name of the reverse distributor.	
Does the licensee maintain complete and accurate records of the disposal of controlled substances?	A licensee must use a DEA Form 41 to document the disposal of controlled substances. **NOTE:** Use of the DEA Form 41 does not apply to the disposal of an unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply. If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification on the DEA Form 41 of two licensed healthcare professionals (nurses, physicians, pharmacists, etc.) conducting and witnessing the	OAC 4729:5-3-01 OAC 4729:7-3-06

	disposal, one of whom shall be the responsible person or the responsible person's designee. A veterinarian may use an animal aide in lieu of one of the licensed or registered healthcare professionals required to conduct and witness the disposal of controlled substances from inventory. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	
Does the licensee maintain complete and accurate records of the disposal of unused portions of controlled substances resulting from patient administration?	Records must include the name of the drug, the quantity disposed, the date and manner of disposal, and the positive identification of two licensed healthcare professionals (nurses, physicians, etc.) conducting and witnessing the disposal. Documentation may be maintained in the patient record (i.e. with administration record). The disposal method does not have to render the unused portion of the drug non-retrievable. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	OAC 4729:5-3-01 OAC 4729:7-3-06
Does the licensee maintain all required records on-site for a period of three years in	All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.	OAC 4729:7-3-06

a readily retrievable manner?	If stored off-site, Board staff will document the off-site location and confirm the licensee submitted proper notification to the Board.	

Non-Hazardous Drugs Compounded by a Prescriber

REMINDER: *"Hazardous drug" means any antineoplastic drug listed in table one on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.*

Free versions of the currently enforced USP compounding chapters can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw

Question	Description / Guidance	Law/Rule
Did the licensee develop and implement appropriate sterile compounding procedures?	The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for developing and implementing appropriate compounding procedures. Such standard operating procedures (SOPs) must be designed to ensure the quality of the environment in which a CSP is prepared. Licensees are strongly advised to review and adopt the suggested SOPs as outlined in USP 797. **NOTE: See below for SOP requirements for non-sterile compounding.** Board staff will review procedures to ensure compliance.	OAC 4729:7-3-03
Did the licensee develop and implement appropriate non-sterile compounding procedures?	The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for developing and implementing appropriate compounding procedures. All significant procedures performed in the compounding area should be covered by written standard operating procedures (SOPs). Procedures should be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded	OAC 4729:7-3-03

	preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding. Board staff will review procedures to ensure compliance.	
Does the compounding location ensure documented training and competency of compounding personnel?	The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for documenting training and competencies of compounding personal. According to USP, training competencies must be documented for compliance and must occur annually. Additionally, there must be a didactic and observed skills assessment training for sterile and non-sterile compounding. **Training documentation for compliance with USP 797 must include:** 1) Personnel training and evaluation of aseptic manipulation skills; 2) Training for gowning/gloving/garbing 3) Gloved fingertip testing; 4) Media fill testing; 5) Training on cleaning and disinfecting the sterile compounding area;	OAC 4729:7-3-03

	6) Training for any specialized equipment or devices used in compounding; 7) Patient/caregiver training (if applicable); and 8) Review of USP 797. **Training documentation for compliance with USP 795 must include:** 1) Training specific to the type of compounding conducted; 2) Review of USP 795; 3) Equipment training; 4) Evaluation of packaging, storage and dispensing non-sterile compounds. Board staff will review documentation to ensure compliance.	
Are there processes in place to ensure environmental control of compounding areas?	The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for ensuring environmental control of the compounding areas. Compounding locations which do not meet the exemptions of OAC 4729:7-3-02 or OAC 4729:7-3-04 are required to follow USP 797 (sterile, non-hazardous) and USP 795 (non-sterile, non-hazardous).	OAC 4729:7-3-03

	For USP 795: Compounding facilities must have adequate space that is specifically designated for compounding. The space must provide for the orderly placement of equipment and materials to prevent mix-ups. The compounding area should be well-lit, and heating and ventilation systems must be controlled to avoid decomposition and contamination of chemicals used in compounding. This may include temperature and humidity monitoring for certain components. All components, equipment and containers must be stored off the floor. **For USP 797:** Primary and secondary engineering controls must undergo environmental monitoring every 6 months, including viable air and surface sampling.	
Have the compounded drug processes been inspected and approved by the prescriber prior to patient administration?	For all compounded drugs prepared pursuant to this rule, a prescriber shall inspect and approve the compounding process. All processes used to compound drugs must be inspected and approved by the prescriber. Therefore, non-prescriber staff cannot develop the compounding process (master formula) without the prescribers check and approval. Board staff will verify that master formula has been approved by a prescriber prior to the compound being made.	OAC 4729:7-3-03
Are the compounded drug products verified (e.g., final check is performed)?	For all drugs prepared pursuant to this rule, a prescriber shall perform medication validation ("final check") prior to the medication being administered. Verification can be completed using any of the following methods:	OAC 4729:7-3-03 OAC 4729:7-3-06 OAC 4729:7-3-07

	✓ Verification by a prescriber or pharmacist; or ✓ **FOR ADMINISTRATION ONLY:** Verification by at least two nurses* approved by the responsible person; or ✓ **FOR ADMINISTRATION ONLY:** Verification by a nurse if the nurse* prepared the compounded drug. ***IMPORTANT:** Licensed practical nurses are **NOT** permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may prepare or reconstitute an antibiotic additive. As such, it is **NOT** within their scope of practice and an LPN cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive). **REMINDER:** Final checks/medication validation must be documented using positive identification.	
If compounding is verified by a nurse (RN), does the licensee comply with the medication validation requirements prior to administration?	The rule provides two avenues for the verification of compounded drugs by registered nurses: 1) If a nurse* prepares a compounded drug product and directly administers it to a patient pursuant to a prescriber order, but without the final check of the prescriber, the nurse who prepared the drug must comply with the verification requirements of the rule. 2) If an individual (nurse*, pharm tech, etc.) prepares a compounded drug product and gives it to a nurse to administer pursuant to a prescriber order, but without the final check of the prescriber, two	OAC 4729:7-3-03 OAC 4729:7-3-06

	nurses* must comply with the verification requirements of the rule. The verification requirements for nurse administration include all the following prior to the administration of the compounded drug: a. Verify the patient identification using two different patient identifiers (name + DOB, etc.) b. Confirm with the patient the treatment plan, drug route, and symptom management. c. Verify the drug name, strength, dosage form and quantity to be administered. d. Verify the route and rate (if applicable) of administration. e. Verify the expiration date/time of the compounded product prior to administration. f. Review the appearance and physical integrity of the drug to be administered. g. Document in the compounding record verification was completed. h. Ensure a prescriber is on-site and immediately available.	

	REMINDER: Rule 4729:7-3-06 requires the positive identification of the person or persons performing medication validation (in this case verification) prior to the compounded drug being administered. Therefore, the positive identification of the verifying nurse or nurses must be captured in the compounding record. ***IMPORTANT:** Licensed practical nurses are **NOT** permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may prepare or reconstitute an antibiotic additive. As such, it is **NOT** within their scope of practice and an LPN cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive).	
Does the licensee engage in anticipatory compounding?	Except for buffered lidocaine antimicrobial containing compounds intended for immediate-use, a prescriber may not compound drug preparations unless a specific need exists. Multiple non-patient specific doses may not be produced in a single activity (batching).	OAC 4729:7-3-03
Does the licensee properly report compounded drugs containing controlled substances, gabapentin, or naltrexone that are personally furnished to the Ohio Automated Rx Reporting System (OARRS)?	A prescriber shall comply with the drug database reporting requirements for personally furnishing drugs pursuant to section 4729.79 of the Revised Code. Pursuant to section 4729.75 of the Revised Code, the required information for all controlled substances in schedule II, III, IV, and V and all dangerous drugs containing gabapentin or naltrexone dispensed pursuant to an outpatient prescription, personally	OAC 4729:7-3-03 OAC 4729:8-2-01

	furnished by a prescriber, or sold at wholesale to a terminal distributor of dangerous drugs must be submitted to OARRS pursuant to sections 4729.77, 4729.78 and 4729.79 of the Revised Code and this division of the Administrative Code. For more information on submitting data to OARRS, **click here**.	
Are all non-hazardous, non-sterile compounded drug preparations, which do not meet the exemptions in OAC 4729:7-3-02, prepared in accordance with USP 795?	Except for veterinarians [see paragraph (L) of OAC 4729:7-3-03], all non-hazardous, non-sterile compounded drug preparations shall be prepared in accordance with United States Pharmacopeia Chapter <795>. **IMPORTANT:** The United States Pharmacopeia (USP) in June 2019 released several new and revised pharmacy compounding standards. Specifically, USP published the final revised version of general chapter <797> and <795>. Due to pending appeals, the effective date of the revised chapters is postponed until further notice. To ensure compliance, licensees are reminded that the Board is conducting compliance inspections using the current version of USP 797 (last revised in 2008) and USP 795 (last revised in 2014) and not the revised version released in June 2019 that is currently on hold pending further review. Please be advised that any changes to the version of USP used to enforce this chapter will require a rule change and updates will be reflected in this inspection guide.	OAC 4729:7-3-03 OAC 4729:7-1-01
Are all non-hazardous, sterile compounded drug preparations, which do not meet the exemptions in OAC	Except for sterile compounded products prepared for immediate-use as provided in paragraph (C) of rule 4729:7-3-03, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States Pharmacopeia Chapter <797>.	OAC 4729:7-3-03 OAC 4729:7-1-01

4729:7-3-02 and do not qualify as immediate-use, prepared in accordance with USP 797?	**IMPORTANT:** The United States Pharmacopeia (USP) in June 2019 released several new and revised pharmacy compounding standards. Specifically, USP published the final revised version of general chapter <797> and <795>. Due to pending appeals, the effective date of the revised chapters is postponed until further notice. To ensure compliance, licensees are reminded that the Board is conducting compliance inspections using the current version of USP 797 (last revised in 2008) and USP 795 (last revised in 2014) and not the revised version released in June 2019 that is currently on hold pending further review. Please be advised that any changes to the version of USP used to enforce this chapter will require a rule change and updates will be reflected in this inspection guide.	

Hazardous Drugs Compounded by a Prescriber

REMINDER: *"Hazardous drug" means any antineoplastic drug listed in table one on the National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.*

Free versions of the currently enforced USP compounding chapters can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw

Question	Description / Guidance	Law/Rule
Does the licensee maintain a policy and procedure manual for the compounding, safe handling, personally furnishing, and administration of hazardous drugs?	Rule 4729:7-3-05 requires the following policy and procedures to be maintained by a licensee conducting hazardous drug compounding: 1) 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. [Paragraph (B)(1)(a)] 2) The facility shall establish written procedures for decontamination, deactivation, cleaning, and disinfection (for sterile compounding areas). [Paragraph (B)(11)] 3) The entity shall have written standard operating procedures to describe appropriate shipping containers and insulating materials, based on information from product specifications,	OAC 4729:7-3-05

	vendors, mode of transport, and experience of the compounding personnel. [Paragraph (B)(17)] Board staff will review all available manuals for compliance with the rule.	
Is the licensee's policy and procedure manual reviewed regularly by the responsible person?	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 Board has established a policy that regular review shall be no less than every two years. Reviews should include documented dates of review and the name and signature or initials of the reviewer. **NOTE:** The responsible person may delegate the review of the policy and procedures manual to another licensed healthcare provider supervising the compounding process. The licensee must include documentation of this delegation signed by the responsible person. Board staff will review all available manuals to ensure regular review by the responsible person or the responsible person's designee.	OAC 4729:7-3-05
Are hazardous sterile drugs compounded in a containment primary engineering control that provides ISO 5 class air or better, using a high-	Facilities must compound hazardous drugs in a biological safety cabinet (BSC) or a compounding aseptic containment isolator (CACI). Class II or class III biological safety cabinets type A2, B1 and B2 are acceptable.	OAC 4729:7-3-05

efficiency particulate air filter (HEPA), which is vented to the outside?	The BSC or CACI must have a HEPA filter that is vented to the outside (no air is permitted to be pulled back into the facility from heating/AC, windows, doors, etc.). Fans must be placed downstream of the HEPA filter, so contaminated ducts are maintained under negative pressure. **IMPORTANT:** As negative pressure is necessary to minimize the spread of contamination and to provide total contamination control where hazardous compounding is conducted, Board staff will be inspecting for negative pressure monitoring to ensure compliance with this requirement. **NOTE:** Locations not meeting compliance with the requirement for external ventilation may request an extension from the Board if the location is unable to make structural modifications due to an existing building lease agreement. Requests must be submitted in writing to compliance@pharmacy.ohio.gov.	
Are hazardous non-sterile drugs compounded in an externally vented primary engineering control (PEC) or a redundant HEPA filtered series?	Nonsterile hazardous drugs must 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. **NOTE:** Primary engineering controls (PECs) used **only** for non-sterile compounding do not need to be unidirectional.	OAC 4729:7-3-05

Does the licensee engage in occasional non-sterile hazardous drug compounding in the sterile hazardous drug compounding primary engineering device (C-PEC)?	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. **NOTE:** Occasional is not defined in rule. Board staff will examine records of compounding to determine if compounding is used more than occasionally.	OAC 4729:7-3-05
Are primary engineering controls (PECs) used for compounding hazardous drugs (sterile and non-sterile) with a beyond-use date that does not exceed 12 hours located in a containment segregated compounding area (C-SCA) that meets the requirements of the rule?	PECs used for hazardous drug compounding shall be located in a containment secondary engineering control (C-SEC). For nonsterile compounded hazardous drugs and sterile hazardous compounded drugs with a beyond use date that does not exceed twelve hours, an unclassified containment segregated compounding area (C-SCA) that is isolated from other areas and designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area is acceptable. The segregated compounding area must 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. If the 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.	OAC 4729:7-3-05

	A sink or wash station must be available for hand washing as well as for emergency access to water for removal of hazardous substances from eyes and skin.	
Are sterile hazardous compounded drugs assigned a beyond-use date exceeding 12 hours compounded in a primary engineering control located in a secondary engineering control that meets the requirements of USP <800>?	Sterile hazardous compounded drugs with a beyond use date that exceeds twelve hours, must be compounded in a containment secondary engineering control that meets the requirements of USP 800. USP 800 requires: 1) Externally vented primary engineering control (PEC) which maintains ISO class 5 air or better (Class II or III BSC or CACI). 2) The PEC must be located in a SEC which is an ISO 7 negative pressure (0.01 to 0.03 inches of water column relative to all adjacent areas) externally vented buffer room which maintains a minimum of 30 ACPH of HEPA filtered air. 3) The SEC must be adjacent to an ISO 7 anteroom that must maintain a minimum of 30 ACPH of HEPA filtered air, and a positive pressure of 0.02 inches water column relative to all adjacent unclassified areas. 4) A hand washing sink must be placed in the ISO 7 anteroom at least 1 meter from the entrance to the HD buffer room.	OAC 4729:7-3-05

Does the licensee ensure the primary and secondary engineering controls used for compounding sterile and non-sterile hazardous drugs <u>ARE NOT</u> used for non-hazardous drug compounding?	A primary engineering control (PEC) and secondary engineering control (SEC) used for the preparation of hazardous drugs shall not be used for the preparation of a non-hazardous drug. Compounding locations must have separate designated areas for compounding hazardous and non-hazardous drugs.	OAC 4729:7-3-05
Does the licensee maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products?	The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.	OAC 4729:7-3-05
Does the licensee maintain sufficient, current reference materials related to sterile products to meet the needs of the facility staff?	The facility shall have sufficient, current reference materials related to sterile products to meet the needs of the facility staff. At a minimum, Board staff will review to ensure access to the compounding references listed in OAC 4729:7-1-01, which include the following: 1. "The national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings" means publication number 2016-161 or any official supplement thereto (3/10/2020).	OAC 4729:7-3-05

	2. "United States Pharmacopeia Chapter " or "USP " means United States Pharmacopeia Chapter, USP 43-NF 38, or any official supplement thereto (3/10/2020). 3. "United States Pharmacopeia Chapter " or "USP " means United States Pharmacopeia Chapter, USP 43-NF 38, or any official supplement thereto (3/10/2020). 4. "United States Pharmacopeia Chapter " or "USP " means United States Pharmacopeia Chapter, USP 43-NF 38, or any official supplement thereto (3/10/2020). **NOTE:** Demonstrating online access to these resources satisfies the requirements of the rule.	
Is environmental wipe sampling conducted routinely to detect hazardous drug surface residue?	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. Surface wipe sampling should include the interior of the C-PEC and equipment contained in it, staging or work areas near the C-PEC, areas adjacent to C-PECs (e.g., floors directly under staging and dispensing area) and patient administration areas. **NOTE:** Environmental wipe sampling is not required but recommended as a best practice.	OAC 4729:7-3-05
If measurable contamination is found during wipe	If any measurable contamination is found during surface wipe sampling the responsible person shall identify, document, and	OAC 4729:7-3-05

sampling, does the responsible person identify, document, and contain the cause of contamination by performing a thorough deactivation, decontamination, and cleaning?	contain the cause of contamination. The compounding location must perform thorough deactivation (using an appropriate deactivating agent), decontamination, and cleaning. The facility shall also consider reevaluating work practices, re-training personnel, and improving engineering controls as needed to prevent further contamination. **NOTE:** This is required if the licensee performs wipe sampling.	
Do compounding personnel wear all required personal protective equipment when compounding sterile and non-sterile hazardous drugs?	Personal protective equipment for compounding includes: 1) Chemotherapy gloves (must be sterile for sterile compounding). **NOTE:** 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. 2) Disposable gown. **NOTE:** 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	OAC 4729:7-3-05

	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. 3) Head, hair, and shoe covers (or dedicated shoes). 4) 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). ***Double gloving is recommended (not required) for all activities involving hazardous drugs, and the outer glove must extend over the cuff of the gown.***	
Are personnel handling and administering hazardous drugs don chemotherapy gloves and gowns?	Chemotherapy gloves are required for handling and administering hazardous drugs. Personnel should (e.g. recommended but not required) use double gloving for all activities involving hazardous drugs making sure that the outer glove extends over the cuff of the gown. **NOTE:** 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.	OAC 4729:7-3-05

	Disposable gowns are required handling and administering injectable antineoplastic hazardous drugs. 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.	
Does the facility have policies and procedures that describe the appropriate personal protective equipment (PPE) to be worn for handling hazardous drugs during receipt, storage, transport, compounding, administration, deactivation or decontamination, cleaning and disinfecting, and spill control?	The facility's policy and procedure manual must describe the appropriate PPE to be worn. The facility must develop policies and procedures for PPE based on the risk exposure and activities performed. Appropriate PPE must be worn handling hazardous drugs during the following: receipt, storage, transport, compounding, administration, deactivation or decontamination, cleaning, and disinfecting, and spill control. Appropriate PPE shall be used when unpacking hazardous drugs from their shipping containers. *Board staff will review policies to determine compliance.*	OAC 4729:7-3-05

Are all personnel handling hazardous drugs or hazardous drug waste washing hands with soap and water before donning protective gloves, and immediately after removal.	All personnel handling hazardous drugs or hazardous drug waste shall wash hands with soap and water before donning protective gloves and immediately after removal. *Board staff will review relevant policies and may observe staff activity to determine compliance.*	OAC 4729:7-3-05
Are eye and face protection worn when there is a risk of spills or splashes of hazardous drugs or hazardous drug waste materials?	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. Eyeglasses 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.	OAC 4729:7-3-05
At the completion of compounding, are hazardous drug preparations sealed in plastic bags prior to transport out of the primary engineering control (PEC)?	When a hazardous drug preparation is completed, personnel shall seal the final product in a plastic bag or other sealed container for transport before taking it out of the C-PEC. *Board staff will review relevant policies and may observe staff activity to determine compliance.*	OAC 4729:7-3-05

Is hazardous drug waste collected inside the primary engineering control sealed in a container (plastic bag) and wiped prior to removal from the PEC and depositing into waste containers?	When a hazardous drug preparation is completed, personnel shall seal and wipe all waste containers inside the C-PEC before removing them from the cabinet. When hazardous drugs are compounded in the primary engineering control, all waste is deemed hazardous waste. Hazardous waste must be collected inside a plastic bag at the end of compounding. The plastic bag must be wiped down/decontaminated with an appropriate decontamination agent prior to being removed from the PEC and placed in a hazardous waste receptacle for disposal. *Board staff will review relevant policies and may observe staff activity to determine compliance.*	OAC 4729:7-3-05
When dosage forms allow, are all hazardous drugs administered using a closed-system transfer devices or other protective techniques?	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. Closed system transfer devices (CSTD) are drug transfer devices that mechanically prohibit the transfer of environmental contaminants into a system and the escape of hazardous drugs or drug vapor concentrations outside the system. Each CSTD will have its own studies/representative guidelines regarding what drugs are or are not compatible.	OAC 4729:7-3-05

	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.	
During spill clean-up or when there is a significant risk of inhalation exposure to hazardous drug particles, do personnel wear appropriately fitted national institute for occupational safety approved N95 or equivalent 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. N95 respirators are not always needed for compounding and handling of hazardous drugs but are required to be worn when there is a spill, or when there is a risk of inhalation of hazardous drug particles. N95 respirators must be fit tested. Fit testing requirements are through OSHA. Testing is required annually and can be conducted by a contracted company or by the employer. N95 respirators with exhalation valves must not be used when sterile conditions must be maintained. N95 respirators are FDA-cleared as single-use disposable devices, and should be discarded if they are damaged, soiled, or if breathing becomes difficult. *Board staff will review training records to determine is proper fit testing has been completed and to ensure proper access to N95 respirators.*	OAC 4729:7-3-05

Is personal protective equipment worn during hazardous drug handling disposed of in appropriate waste containers and in accordance with local, state, and federal regulations?	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.	OAC 4729:7-3-05
Are personnel who handle hazardous drugs trained based on their job functions?	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. **NOTE:** If a person does not complete any of the above tasks as a part of their job duties, they do not need to complete training in that area. If the person does not perform the task as a part of their normal job duties but may need to perform those job duties on occasion (employee call-off/vacation, etc.) then they must be trained in that area.	OAC 4729:7-3-05

Does employee training include all the required topics set forth in rule?	All training and competency assessment must be documented. The training must include at least the following: 1) Review of the entity's policies and procedures related to handling of hazardous drugs; 2) Proper use of PPE; 3) Proper use of equipment and devices (e.g., engineering controls); and 4) Spill management. Additionally, compounding personnel of reproductive capability shall also confirm in writing that they understand the risks of handling hazardous drugs. *Board staff will review training records to determine compliance.*	OAC 4729:7-3-05
Are compounding personnel reminded to undergo medical examinations annually?	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. **NOTE:** The recommendation for annual exams is required. The annual exam itself is not a requirement of the rule.	OAC 4729:7-3-05

	There is no specific requirement that this recommendation be documented in writing, but it is a best practice for documentation and meeting the requirement of the rule.	
Are personnel who are handle hazardous drugs reassessed every 12 months, and when significant changes in processes and/or standard operating procedures occur?	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. *Board staff will review employee training files to ensure training has been repeated annually or when a new hazardous drug or new equipment is used or a new or significant change in process or standard operating procedure occurs.*	OAC 4729:7-3-05
Are areas where hazardous drugs are unpacked, stored, and prepared restricted to authorized staff and notated by signage?	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.	OAC 4729:7-3-05
Are hazardous drugs stored separately from other inventory in a manner that prevents spills, breakage,	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. Hazardous drugs shall be stored separately from other inventory. Hazardous drugs shall be stored in a manner to prevent contamination and personnel exposure.	OAC 4729:7-3-05

contamination, and personnel exposure?	**NOTE:** This should be a separate room, cupboard, or shelf that contains hazardous drugs only. There should be some type of lip on the edge of shelving to prevent drugs from falling off, or drugs may be stored in baskets/bins.	
Are areas where hazardous drugs are handled and all reusable equipment and devices are routinely deactivated, decontaminated and cleaned?	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). **NOTE:** At a minimum, high-touch surfaces (counter tops/trays/work areas) must be deactivated, decontaminated, cleaned daily. Other low-touch surfaces should be deactivated, decontaminated, cleaned at least monthly (shelves/storage areas). The PEC must be deactivated, decontaminated, cleaned, and disinfected daily when compounding, between compounds, and if a spill occurs.	OAC 4729:7-3-05

	If the location is using a CACI, the deck under the unit must be deactivated, decontaminated, cleaned, and sterilized at least monthly. *The rule does not specify documentation of cleaning, however Board staff will be reviewing documentation to validate cleaning has occurred at the minimum requirements, using the correct agents, for the correct dwell times.* Some additional considerations when it comes to selecting the correct products: ▪ **Cleaning:** Some cleaning agents work for deactivating, decontamination and/or cleaning but the dwell times may vary. Review each cleaning agent package information to validate if the agent is correct for the task. ▪ **Deactivation:** EPA registered oxidizing agents are used for decontamination. o Deactivation must occur in the PEC between compounding different HDs, daily when compounding, and any time there is a spill. o Deactivation must be completed using appropriate deactivating agent for the type of hazardous drugs compounded.	

	○ Decontamination includes thoroughly wetting the surface and allowing it to dry over time. Each decontamination agent will list on the package what it is effective for, and how long the agent needs to sit on the surface wet, for it to be effective. Check the package and compare to the location's policy and procedures. ○ The location should not use a spray bottle to apply decontaminating agents. Spray bottles may spread contamination of hazardous drug residues. Wipes or low-lint towels may be saturated and applied to the surface. ▪ **Decontamination:** Occurs after deactivation of HDs. Decontamination occurs by inactivating, neutralizing or physically removing HD residues from non-disposable surfaces and transferring them to absorbent materials. ○ Decontamination must occur in the PEC between compounding different HDs, daily when compounding, and any time there is a spill. ○ Decontamination must include an appropriate agent which may include alcohol, water, peroxide, or sodium hypochlorite.	
Is equipment used to perform deactivation,	Equipment used to perform deactivation, cleaning, and disinfection shall not be used in areas where hazardous drugs are not handled.	OAC 4729:7-3-05

disinfection and cleaning maintained only in areas where hazardous drugs are handled?	**NOTE:** Such equipment is likely to contain hazardous drug residues, which can be spread to other areas of the facility during re-use. For this reason, reusable cleaning tools must be used only in areas where hazardous drugs are handled.	
Are spills contained and cleaned immediately by qualified personnel with appropriate personal protective equipment?	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. Board staff will ensure that personnel properly trained in spill management are present when hazardous drugs are being handled.	OAC 4729:7-3-05
Are spill kits located in areas where hazardous drugs are prepared or administered and contain all materials needed to clean a hazardous spill, including signs restricting access to spill areas?	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 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 spill kit and respirator shall be available. All spill materials shall be disposed of as hazardous waste.	OAC 4729:7-3-05

	IMPORTANT: Spill kits can be purchased commercially or assembled by the organization. Spill kits should contain all the following: 1) Absorbent powder 2) Absorbent pads 3) Chemosorb pads 4) Chemo-bio wipes 5) Antiseptic towels 6) Hazardous waste chemo drug liners 7) Safety goggles/face shields 8) N95 respirator masks 9) Shoe covers 10) Hair and beard covers 11) Chemo gowns and gloves 12) Scrapers/scoopers	

	13) Hazardous drug waste and exposure forms for recordkeeping 14) Caution signs **NOTE:** A commercially purchased kit will state how much volume it is able to contain (1000ml, etc.). Facilities should review this to determine if the kit can contain the largest possible spill at the location.	
Are personnel who are potentially exposed to hazardous drugs during a spill or spill cleanup, or persons who experience direct skin or eye contact with a hazardous drug immediately evaluated by a healthcare professional?	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. **NOTE:** Licensees must have a policy requiring immediate medical evaluation for unintended hazardous drug exposure.	OAC 4729:7-3-05
Does the facility have an eyewash station and/or other emergency or safety precautions readily available?	An eyewash station and other emergency or safety precautions that meet applicable laws and regulations must be readily available.	OAC 4729:7-3-05
Is hazardous drug waste disposed of in compliance with federal, state, and local regulations?	Disposal of all hazardous drug waste (including unused and unusable hazardous drugs) must comply with all applicable federal, state, and local regulations.	OAC 4729:7-3-05

	REMINDERS: ▪ Hazardous waste includes sharps, PPE, disposable cleaning wipes, patient gowns, gauze and any other disposable item which has or may have come into contact with hazardous drugs. ▪ Hazardous waste may not be disposed of in general trash. ▪ Hazardous waste must be disposed of in yellow-bins or other RCRA trash receptacles.	
Are personnel who perform routine custodial waste removal and cleaning in hazardous drug handling areas are appropriately trained?	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. Administration areas in prescriber offices and cancer centers will contain hazardous drug waste. Custodial waste removal service employees must be trained in proper hazardous waste removal. This may include PPE training and garb availability for these employees. *Board staff will ensure that cleaning personnel are appropriately trained.*	OAC 4729:7-3-05
Are syringes and needles used in the course of hazardous drug preparation <u>not</u> clipped or crushed prior	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.	OAC 4729:7-3-05

to placement in hazardous waste containers?	**IMPORTANT:** Clipping/crushing increases the risk of spreading HD contamination.	
Do facility cleaning personnel wear appropriate personal protective equipment if they handle linens, feces or urine from patients who have received hazardous drugs with in the last 48 hours?	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.	OAC 4729:7-3-05
When possible, does a licensed healthcare provider discuss with the patient or caregiver the hazardous drug received?	When possible, a licensed health care provider shall be involved in discussing with each patient receiving a hazardous compounded drug, or the caregiver of such individual, the following matters: 1) Drug dosage form, route of administration, duration of therapy; 2) Special directions and/or precautions for administration; and 3) Stability and/or incompatibilities of the medication. **NOTE:** The rule specifies licensed health care provider, which can be a prescriber (MD/DO, APRN, PA) or a nurse (RN/LPN).	OAC 4729:7-3-05
Does the facility maintain a written quality assurance program that addresses adequate training and	The quality assurance program for training must be in writing and include both an initial skills assessment and examination, as well as annual assessments.	OAC 4729:7-3-05

continued competency for compounding staff?	Assessments included in the training quality assurance program must include all the following: 1) Personal cleansing, including proficiency in hand hygiene; 2) Proper attire (PPE and attire under and around PPE, i.e. jewelry, fuzzy sweaters, etc.); 3) Aseptic technique; 4) Proper cleanroom conduct; and 5) Cleanroom disinfecting procedures.	
Does the facility maintain a written quality assurance program that addresses verification of compounding processes?	There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug preparations, and facilities. At a minimum, there shall be written quality assurance programs developed that address: 1) Continued verification of compounding accuracy, including physical inspection of end products; 2) Continued verification of automated compounding devices; and 3) Review of end-product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected.	OAC 4729:7-3-05

Does the facility ensure that all clean rooms and other primary engineering devices have environmental monitoring performed at least every six months to certify operational efficiency?	All clean rooms and other primary engineering devices shall have environmental monitoring performed at least every six months to certify operational efficiency. Records certifying operational efficiency shall be maintained for at least three years and shall be readily retrievable. Operational efficiency and environmental monitoring must include, but is not limited to, the following tests under dynamic conditions: ▪ Certification and recertification of PEC and classified areas: airflow testing, HEPA filter integrity testing, total particle count testing, dynamic airflow smoke pattern test ▪ Total airborne particle sampling of all classified areas during dynamic operating conditions ▪ Microbiological air and surface monitoring: viable impact volumetric airborne particulate sampling and surface sampling in all classified areas Board staff will review certification records to determine compliance with the rule.	OAC 4729:7-3-05
Does the facility have a quality assurance plan if operational efficiency of the clean room and other primary engineering controls fail?	There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Board staff will review quality assurance plan to determine compliance.	OAC 4729:7-3-05

Do the packaging materials used during drug transport maintain the physical integrity, stability and sterility of hazardous drugs?	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. **NOTE:** Transport includes moving HDs within a healthcare setting. Material selection must be based on information from product specifications, vendors, method of transportation, and compounder experience.	OAC 4729:7-3-05
Are hazardous drugs requiring transport labeled, stored, and handled in accordance with federal, state, and local regulations?	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.	OAC 4729:7-3-05
Are hazardous drugs compounded and personally furnished by a prescriber meet the labeling	A hazardous compounded drug that is personally furnished by a prescriber must be labeled according to rule 4729:5-19-02 of the Administrative Code and must include the appropriate beyond-use date, in accordance with United States Pharmacopeia Chapters or	OAC 4729:7-3-05

requirements specified in rule?	and complete list of ingredients. The statement "Hazardous Compounded Drug" shall also be displayed prominently on the label. **IMPORTANT:** Compounded hazardous drug labeling must include the following: 1) Name and address of the prescriber; 2) Name of the patient for whom the drug is intended; 3) Name and strength of the drug (complete list of all ingredients for hazardous compounded drug); 4) Directions for use; 5) Date furnished; 6) Beyond-use date; and 7) Display “Hazardous Compounded Drug” prominently on the label.	
Does the facility engage in anticipatory hazardous drug compounding?	A prescriber shall not compound hazardous drugs in anticipation of prescriptions based on routine prescribing patterns. **IMPORTANT:** ▪ All hazardous drug compounds must be patient specific.	OAC 4729:7-3-05

	▪ If a patient is unable to receive a compounded hazardous drug, the provider may authorize the administration of that dose to another patient, provided the compound has not exceeded its BUD, and it was appropriately labeled after compounding, and never left the custody/control/proper storage of the compounding facility.	
Are the compounded drug products verified (e.g., final check is performed)?	For all drugs prepared pursuant to this rule, a prescriber shall perform medication validation ("final check") prior to the medication being administered. Verification can be completed using any of the following methods: ✓ Verification by a prescriber or pharmacist; or ✓ **FOR ADMINISTRATION ONLY:** Verification by at least two nurses* approved by the responsible person; or ✓ **FOR ADMINISTRATION ONLY:** Verification by a nurse if the nurse* prepared the compounded drug. ***IMPORTANT:** Licensed practical nurses are **NOT** permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may prepare or reconstitute an antibiotic additive. As such, it is **NOT** within their scope of practice and an LPN cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive).	OAC 4729:7-3-05 OAC 4729:7-3-06 OAC 4729:7-3-07

	REMINDER: Final checks/medication validation must be documented using positive identification.	
If compounding is verified by a nurse (RN), does the licensee comply with the medication validation requirements prior to administration?	The rule provides two avenues for the verification of compounded drugs by registered nurses: 1) If a nurse* prepares a compounded drug product and directly administers it to a patient pursuant to a prescriber order, but without the final check of the prescriber, the nurse who prepared the drug must comply with the verification requirements of the rule. 2) If an individual (nurse*, pharm tech, etc.) prepares a compounded drug product and gives it to a nurse to administer pursuant to a prescriber order, but without the final check of the prescriber, two nurses* must comply with the verification requirements of the rule. The verification requirements for nurse administration include all the following prior to the administration of the compounded drug: a. Verify the patient identification using two different patient identifiers (name + DOB, etc.) b. Confirm with the patient the treatment plan, drug route, and symptom management.	OAC 4729:7-3-05 OAC 4729:7-3-06

	c. Verify the drug name, strength, dosage form and quantity to be administered. d. Verify the route and rate (if applicable) of administration. e. Verify the expiration date/time of the compounded product prior to administration. f. Review the appearance and physical integrity of the drug to be administered. g. Document in the compounding record verification was completed. h. Ensure a prescriber is on-site and immediately available. i. Extravasation management procedures are defined. j. Antidote order sets and antidotes are accessible. **REMINDER:** Rule 4729:7-3-06 requires the positive identification of the person or persons performing medication validation (in this case verification) prior to the compounded drug being administered. Therefore, the positive identification of the verifying nurse or nurses must be captured in the compounding record. ***IMPORTANT:** Licensed practical nurses are **NOT** permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may	

	prepare or reconstitute an antibiotic additive. As such, it is **NOT** within their scope of practice and an LPN cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive).	
For all non-sterile hazardous drug preparations, does the prescriber comply with USP 795?	For non-sterile hazardous compounded drugs, the prescriber shall also comply with United States Pharmacopeia Chapter 795. **NOTE:** A free version of USP 795 can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw	OAC 4729:7-3-05
For all sterile hazardous drug preparations with beyond-use dates greater than 12 hours, does the prescriber comply with USP 797?	Sterile hazardous compounded drugs prepared with beyond-use dates greater than 12 hours, shall comply the requirements set forth in United States Pharmacopeia Chapter 797. **NOTE:** A free version of USP 797 can be downloaded by visiting: https://go.usp.org/l/323321/2020-03-09/3125jw	OAC 4729:7-3-05

Prescriber Compounding - Update History

Update Date	Section Update	Update
4/6/2021	Immediate Use Sterile Non-Hazardous Drugs Compounded by a Prescriber (see Page 24) Non-Hazardous Drugs Compounded by a Prescriber (see Page 34) Hazardous Drugs Compounded by a Prescriber (see Pages 57 - 58)	Permits a pharmacist to assist in the verification of compounded products prior to administration to a patient. See updated sections for additional details.
7/29/2021	Introduction Section (Page 11)	Adds the following clarification about allergen extracts: *Please be advised that rule 4729:7-3-03 requires adherence to the allergen extracts section of United States Pharmacopeia (USP) Chapter 797. This provision does not subject prescribers to the personnel, environmental, and storage requirements of USP 797 if certain criteria, listed in the chapter, are met. Therefore, allergen extracts may be prepared and used in accordance with the provisions of USP 797 and are not subject to a general six hour beyond use date* .
1/26/2024 **2/6/2024**	Immediate Use Sterile Non-Hazardous Drugs Compounded by a Prescriber (see Pages 24 - 25)	Clarifies that licensed practical nurses are NOT permitted to engage in the preparation of compounded drugs (see ORC 4723.18[C][5]) for intravenous therapy, except that an LPN may

	Non-Hazardous Drugs Compounded by a Prescriber (see Pages 34 - 35) Hazardous Drugs Compounded by a Prescriber (see Pages 57 - 58)	prepare or reconstitute an antibiotic additive. As such, it is NOT within their scope of practice and an LPN cannot engage in the verification of a compounded drug that is to be administered intravenously (except for the reconstitution of an antibiotic additive).