INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Institutional Pharmacy and Facility

Updated 8/17/2023

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 State of Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant, or licensee.

Applicability

This guide applies only to locations licensed as terminal distributor of dangerous drugs that meet the following definition of an "institutional pharmacy" or "institutional facility" in rule 4729:5-9-01 of the Ohio Administrative Code:

> ***"Institutional pharmacy"*** *means a pharmacy that primarily provides inpatient pharmacy services to an institutional facility in accordance with this chapter.*
>
> ***"Institutional facility"*** *means any of the following:*
>
> *(1) A public hospital or hospital as defined in section 3701.01 or 5122.01 of the Revised Code.*
>
> *(2) A freestanding emergency department.*
>
> *(3) A freestanding inpatient rehabilitation facility or inpatient rehabilitation facility as defined in rule 3701-83-25 of the Administrative Code.*
>
> *(4) An ambulatory surgical facility as defined in rule 3701-83-15 of the Administrative Code.*
>
> *(5) A nursing home licensed under Chapter 3721. of the Revised Code;*
>
> *(6) An inpatient psychiatric service provider as defined in rule 5122-14-01 of the Administrative Code;*
>
> *(7) A facility that provides medically supervised detoxification services that meets the following requirements:*
>
> *(a) Patients are administered dangerous drugs to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of drugs or alcohol;*
>
> *(b) Patients are under the care of a licensed prescriber and are provided continuous onsite monitoring by nurses licensed in accordance with Chapter 4723 of the Revised Code;*
>
> *(c) If the period of detoxification is less than twenty-four hours, patients shall be transitioned to an inpatient, residential, or outpatient treatment program; and*
>
> *(d) The facility holds the appropriate license or certification by the Ohio department of mental health and addiction services.*
>
> *(8) A residential care facility licensed under Chapter 3721. of the Revised Code that provides skilled nursing care to its residents, including medication administration as authorized in Chapter 3701-16 of the Administrative Code, provided the facility meets the following requirements:*
>
> *(a) The administration of medication shall be in compliance with this Chapter and Chapter 3701-16 of the Administrative Code, including the requirement to maintain individual medication records and documentation of medication orders; and*

(b) The residential care facility maintains an executed contract or agreement with an institutional pharmacy for the provision of institutional pharmacy services. The executed contract or agreement shall be maintained in a readily retrievable manner.

(9) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(10) A juvenile correctional facility that is under the management and control of the department of youth services or a private entity with which the department of youth services has contracted for the institutional care; and

(11) Any other facility as determined by the board. ***[See below for additional facilities determined by the Board].***

Additional Institutional Facilities Determined by the Board:

In accordance with paragraph (A) of rule 4729:5-9-01 of the Administrative Code (effective 2/1/22), the State of Ohio Board of Pharmacy recognizes the following as institutional facilities for purposes of regulation under division 4729:5-9 of the Administrative Code:

- A facility providing services under contract with the department of developmental disabilities under section 5123.18 of the Revised Code.
- A facility providing **inpatient hospice care** operated by a hospice care program licensed under section 3712.04 of the Revised Code.
- A facility operated by a pediatric respite care program licensed under section 3712.041 of the Revised Code.

REMINDER: This inspection guide **does not apply** to **outpatient pharmacies** or any of the following license types that have their own corresponding chapter of the Ohio Administrative Code:

- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Emergency Medical Service Organizations – 4729:5-14
- 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 institutional pharmacies/facilities licensed as terminal distributor of dangerous drugs:

- **4729:5-1 – Definitions**
- **4729:5-2 – Licensing**
- **4729:5-3 – General Terminal Distributor Provisions**
    - 4729:5-3-01 - Disposal of controlled substances.
    - 4729:5-3-02 - Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.
    - 4729:5-3-03 - Inspections and corrective actions.
    - 4729:5-3-04 - Verification of licensure prior to sale or purchase.
    - 4729:5-3-05 - Confidentiality of patient records.
    - 4729:5-3-06 - Storage of adulterated drugs.
    - 4729:5-3-07 - Controlled substances inventory requirements.
    - 4729:5-3-08 - Sales of dangerous drugs on-line.
    - 4729:5-3-09 - Occasional sale and drug transfers.
    - 4729:5-3-10 - Employment of individuals with felony convictions.
    - 4729:5-3-11 - Transmission of outpatient prescriptions.
    - 4729:5-3-12 - Protocols and pre-printed orders for medication administration.
    - 4729:5-3-13 - Temporary removal of dangerous drugs from a licensed location.

- 4729:5-3-14 - General security requirements.
- 4729:5-3-16 - Returned drugs.
- 4729:5-3-17 - Automated pharmacy systems.
- 4729:5-3-19 - Naloxone for emergency use and distribution via automated mechanisms.

- **4729:5-4 – Disciplinary Actions**
  - 4729:5-4-01 - Disciplinary actions.
  - 4729:5-4-02 - Duty to Report. **(Rule is currently pending. When finalized, a corresponding section will be added to the guide).**

- **4729:5-9 – Institutional Pharmacies and Facilities**
  - 4729:5-9-01 – Definitions.
  - 4729:5-9-02 – Institutional pharmacies.
  - 4729:5-9-02.1 – Minimum standards for institutional pharmacies.
  - 4729:5-9-02.2 – Security, storage and control of dangerous drugs in an institutional pharmacy.
  - 4729:5-9-02.3 – Record keeping at an institutional pharmacy.
  - 4729:5-9-02.4 – Dispensing of controlled substances by an institutional pharmacy.
  - 4729:5-9-02.5 – Patient profiles.
  - 4729:5-9-02.6 – Pharmacist drug utilization review.
  - 4729:5-9-02.7 – Medication orders for inpatients and outpatient prescriptions.
  - 4729:5-9-02.8 – Labeling of prescriptions for patients.
  - 4729:5-9-02.9 – Licensure of outpatient institutional pharmacies.
  - 4729:5-9-02.10 – Temporary absence of a pharmacist in an institutional pharmacy.
  - 4729:5-9-02.11 – Dispensing customized patient medication packages by an institutional pharmacy.
  - 4729:5-9-02.12 – Drugs repackaged or relabeled by an institutional pharmacy.

- 4729:5-9-02.13 – Institutional central fill pharmacies.
- 4729:5-9-02.14 – Remote medication order processing.
- 4729:5-9-02.15 – Remote Order Entry - Technician
- 4729:5-9-03 – Institutional facilities.
- 4729:5-9-03.1 – Contingency drugs in an institutional facility and emergency access to an institutional pharmacy.
- 4729:5-9-03.2 – Security, storage and control of dangerous drugs in an institutional facility.
- 4729:5-9-03.3 – Record keeping in an institutional facility.
- 4729:5-9-03.4 – Automated drug storage systems in an institutional facility.
- 4729:5-9-03.5 – Hospital self-service employee prescription kiosks.
- 4729:5-9-03.6 – Point of care locations in an institutional facility.

REMINDER: The inspection guide also includes links to the pharmacist, intern, and technician-specific rules that are applicable to institutional pharmacies.

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 State of 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 pharmacist does not document the dispensing of a medication when they log in to an electronic drug record keeping system.

Required Notifications or Document Submissions

Links to instructions and forms can be found in the table below and can also be accessed on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx

State of Ohio Board of Pharmacy rules require the following notifications to the Board:

Notification/Submission Requirement	How to Submit
Change in Business Description *OAC 4729:5-2-03* Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted **within thirty days** of any change in the ownership, business or trade name, category, or address.	A change of business description must be completed online using Ohio's eLicense system. Instructions on submitting this information can be accessed **here**.
Discontinuation of Business *OAC 4729:5-2-04* A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the Board of Pharmacy. The notice shall be submitted, in a manner determined by the Board, **at least thirty days in advance** of the proposed date of discontinuing business, unless waived by the Board's Executive Director or the Director's Designee due to extraordinary circumstances beyond the licensee's control.	Requires submission of a **Written Notice of Discontinuing Business Form**.
Change of Responsible Person *OAC 4729:5-2-01* A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified **within ten days** of the effective date of the appointment of the new responsible person.	Requires submission of a **Change of Responsible Person Form**.
Request to Store Records Off-Site (Institutional Pharmacy ONLY) *OAC 4729:5-9-02.3* An institutional pharmacy located in this state intending to maintain records at a location other than the location licensed by the State Board of Pharmacy shall send a request in a manner determined by the Board. The Board will provide written or electronic notification to the inpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.	Requires submission of an **Request to Store Records Off-Site Form**.

Notification of Off-Site Records Storage (Institutional Facility ONLY) *OAC 4729:5-9-03.3* A terminal distributor intending to maintain records at a location other than the location licensed by the State Board of Pharmacy must notify the Board.	Requires submission of an **Off-Site Records Notification Form**.
Theft or Significant Loss of Dangerous Drugs and Drug Documents *OAC 4729:5-3-02* Licensees are required to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents.	For more information on this requirement, the Board developed this **guidance** document.
Notification of Installation or Modification to Physical Barrier or Alarm System (Institutional Pharmacy ONLY) *OAC 4729:5-9-02.2* An inpatient pharmacy must be able to be secured by either: 1. A physical barrier (i.e. barricade) with suitable locks approved by the Board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the Board of any installation or modification to a physical barrier prior to implementation. **-OR-** 2. An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the Board of any installation or modification to an alarm system prior to implementation. **IMPORTANT:** The alarm system notification requirement is not required if the pharmacy also uses a Board approved physical barrier. The alarm system shall be tested on a biannual basis (e.g. every 6 months). The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party.	Requires submission of a **Pharmacy Security Request Form**.
Hospital Self-Service Employee Prescription Kiosk – Installation Request *OAC 4729:5-9-03.5* Prior to the operation of a kiosk, the board shall receive a request for approval from the responsible person on the terminal distributor	Requires submission of a **Hospital Self-Service Employee Prescription Kiosk Installation Request Form**.

of dangerous drugs license. Upon notification, the Board shall conduct an inspection of the area where the kiosk shall be located and review system specifications to determine if it meets the requirements of this rule. **NOTE:** This requirement **<u>does not</u>** apply to kiosks that have previously been approved by the Board.	

Important Terms

- **"Automated drug storage system"** means a mechanical system used for the secure storage of dangerous drugs used as floor stock or contingency drugs outside of an institutional pharmacy that collects, controls, and maintains transaction information and records.

- **"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.

- **"Distributor of dangerous drugs"** or "drug distributor " means the following persons licensed in accordance with section 4729.52 of the Revised Code:

  (1) Wholesale distributors of dangerous drugs, including:

  (a) Brokers; and

  (b) Virtual wholesalers.

  (2) Manufacturers of dangerous drugs.

  (3) Outsourcing facilities.

  (4) Third-party logistics providers.

  (5) Repackagers of dangerous drugs.

- **"Inpatient"** means any person who receives drugs for use while within an institutional facility.

- **"Medications removed on override function"** or **"override medications"** means a dangerous drug that may be removed from floor stock or contingency drugs prior to

pharmacist review because the institutional facility's interdisciplinary committee has determined that the clinical status of the patient would be compromised by delay.

- **"Outpatient institutional pharmacy"** means a pharmacy located within or on the campus of an institutional facility that provides outpatient pharmacy services which is physically separate from, and not contiguous to, the area in which inpatient pharmacy services are provided.

- **"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.

- **"Point of care location"** means a location within an institutional facility that stores dangerous drugs and all the following apply:

  (1) The point of care location is licensed as a terminal distributor of dangerous drugs;

  (2) The dangerous drugs are not owned by the institutional facility where the point of care location is located;

  (3) The dangerous drugs stored are owned by another institutional facility licensed as a terminal distributor of dangerous drugs; and

  (4) The location may be used for the administration, personally furnishing, or dispensing of dangerous drugs, including controlled substances.

- **"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.

- **"Securely locked, substantially constructed cabinet or safe"** is a term used to define the standards by which controlled substances must be secured (see Security, Control, and Storage of Dangerous Drugs section). This is a term that is utilized by the State of Ohio Board of Pharmacy and the U.S. Drug Enforcement Administration (DEA). While there are no industry standards for this term, the Board has determined that such a security standard should meet the following requirements:

  1. The cabinet or safe shall be substantially constructed to generally resist entry by unauthorized persons.

  2. The cabinet or safe shall be able to be securely locked to prevent unauthorized access.

  3. The cabinet or safe shall be permanently constructed, attached to the building structure or fixtures, or be of such a size and weight that it would generally prevent the cabinet or safe from being physically removed from the premises.

NOTE: For controlled substances requiring temperature control, a licensee must ensure these drugs are stored in a securely locked, substantially constructed cabinet or safe. Some examples of include, but are not limited to, the following:

- A refrigerator or freezer secured with a lock; or
- A lockbox that is securely fastened to the refrigerator or freezer.

- **"Self-service employee prescription kiosk"** or **"kiosk"** means a self-service kiosk for the pickup of new or refill prescriptions only for hospital employees and their family members.

Inspection Guide Table of Contents

Part I – Institutional Pharmacies: *Sections applicable to institutional pharmacies.*

***Part II – Institutional Facilities*:** *Sections applicable to institutional facilities.*

Part I - Institutional Pharmacy - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code

CFR = Code of Federal Regulations / USC = United States Code

*** = Notes a Substantive Change from Current Institutional Pharmacy & Facility Requirements (REMINDER: New Institutional Rules Effective 2/1/2022)**

Licensing, Responsible Person & DEA Registration – Institutional Pharmacy

Question	Description / Guidance	Law/Rule
Have there been any changes in the pharmacy's ownership, business name or trade name, category, or address without submitting a new application to the Board?	Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.	OAC 4729:5-2-03
Does the responsible person match what is indicated in eLicense?	A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified within ten days of the effective date of the appointment of the new responsible person. A change of responsible person form is available on the Board's website: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.	OAC 4729:5-2-01
Does the licensee have a valid registration issued by the Drug Enforcement Administration?	Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22 through 1301.26. The certificate of registration must be maintained at the registered location and kept available for official inspection. **NOTE:** Does not apply to pharmacies or facilities that apply for a Category II license as a terminal distributor of dangerous drugs.	21 CFR 1301.11

Does the institutional facility operate an outpatient institutional pharmacy?	An outpatient institutional pharmacy shall have a separate terminal distributor of dangerous drugs license in addition to the license for the institutional facility or pharmacy. An outpatient institutional pharmacy shall comply with the requirements of chapter 4729:5-5 of the Administrative Code. Board staff will inspect all outpatient institutional pharmacies using the outpatient pharmacy inspection guide: www.pharmacy.ohio.gov/OPinspect "Outpatient institutional pharmacy" means a pharmacy located within or on the campus of an institutional facility that provides outpatient pharmacy services which is physically separate from, and not contiguous to, the area in which inpatient pharmacy services are provided.	OAC 4729:5-9-02.9

Minimum Standards for Institutional Pharmacies

Question	Guidance	Law/Rule
Does the pharmacy have internet access to current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio?	All pharmacists working in a pharmacy must be able to access via the internet all the following resources: ▪ The board's website (www.pharmacy.ohio.gov); ▪ LAWriter® Ohio Laws and Rules (http://codes.ohio.gov/); ▪ The code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC); and ▪ The Code of Federal Regulations. Board staff will confirm the pharmacy can access the required online resources. ***Substantive Change: New rule requires internet access.**	OAC 4729:5-9-02.1
If the pharmacy engages in drug compounding, does it have access to all references listed in rule 4729:7-1-01 of the Administrative Code?	A pharmacy engaged in the compounding of dangerous drugs shall have access to all references listed in rule 4729:7-1-01 of the Administrative Code. This includes the following: For compounding hazardous drugs: ▪ 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. ▪ "United States Pharmacopeia Chapter <800>" or "USP <800>" means United States Pharmacopeia Chapter <800>, USP 43-NF 38, or any official supplement thereto. For non-sterile compounding: "United States Pharmacopeia Chapter <795>" or "USP <795>" means United States Pharmacopeia Chapter <795>, USP 43-NF 38, or any official supplement thereto.	OAC 4729:5-9-02.1 OAC 4729:7-1-01

	For sterile compounding: "United States Pharmacopeia Chapter <797>" or "USP <797>" means United States Pharmacopeia Chapter <797>, USP 43-NF 38, or any official supplement thereto. **NOTE:** Access can be physical copies of reference materials or access to online resources.	
Does the pharmacy have access to the telephone number of a poison control center?	All pharmacists working in a pharmacy shall have access to the telephone number of a poison control center. Board staff will confirm the pharmacy has access to the telephone number of a poison control center.	OAC 4729:5-9-02.1
Are all pharmacy staff wearing name tags/badges that include the employee's job title?	An employee of a pharmacy must be identified by a name tag that includes the employee's job title. For pharmacy technicians, the badge must specifically state the technician's registration status (i.e. certified, registered or technician trainee). **NOTE:** Attaching a "badge buddy" or other supplemental tag demonstrating an employee's job title satisfies this requirement. ***Substantive Change: New rule applies to all pharmacy staff regardless of whether the pharmacy staff is interfacing with the public.**	OAC 4729:5-9-02.1 OAC 4729:3-3-03 OAC 4729:3-3-04 OAC 4729:3-3-01
Are areas where drugs, equipment, and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?	All areas where drugs, equipment, and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition.	OAC 4729:5-9-02.1
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.	OAC 4729:5-9-02.1

Personnel

Question	Guidance	Law/Rule
Are staff working at the pharmacy properly licensed/registered with the Board?	No person who is not a pharmacist or a pharmacy intern under the personal supervision of a pharmacist shall compound or sell dangerous drugs or otherwise engage in the practice of pharmacy. No person who is not a pharmacist, pharmacy intern, registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee shall knowingly engage in any of the activities listed in section 4729.91 of the Revised Code in a location licensed as a terminal distributor of dangerous drugs or while performing the function of a terminal distributor, except that this division does not prevent a licensed health care professional from engaging in activities that are authorized by law as part of the licensed professional's practice.	ORC 4729.28 ORC 4729.95
Are technician trainees working within their applicable scope of practice?	A pharmacy technician trainee may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment: (1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent but shall not include verbal orders. (2) Entering information into and retrieving information from a database or patient profile. (3) Preparing and affixing labels. (4) Stocking dangerous drugs and retrieving those drugs from inventory. (5) Counting and pouring dangerous drugs into containers. (6) Placing dangerous drugs into containers prior to dispensing by a pharmacist.	OAC 4729:3-3-01

	(7) Non-sterile drug compounding in accordance with the required training in USP 795. (8) Sterile drug compounding in accordance with the required training in USP 797. (9) Packaging and selling a dangerous drug to a patient or patient representative. (10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. **NOTE:** For more information regarding technician duties, visit: www.pharmacy.ohio.gov/techFAQ	
Are there enough pharmacists supervising technician trainees?	A pharmacist is not permitted to supervise more than three pharmacy technician trainees, unless otherwise approved by the Board.	OAC 4729:3-3-01
Are registered pharmacy technicians working within their applicable scope of practice?	A registered pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities to the extent that the activities do not require the exercise of professional judgment: (1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent but shall not include verbal orders. (2) Requesting refill authorizations for dangerous drugs from a prescriber or prescriber's agent, so long as there is no change from the original prescription. (3) Entering information into and retrieving information from a database or patient profile. (4) Preparing and affixing labels. (5) Stocking dangerous drugs and retrieving those drugs from inventory.	OAC 4729:3-3-03

	(6) Counting and pouring dangerous drugs into containers. (7) Placing dangerous drugs into containers prior to dispensing by a pharmacist. (8) Non-sterile drug compounding in accordance with the required training in USP 795. (9) Packaging and selling a dangerous drug to a patient or patient representative. (10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. **NOTE:** For more information regarding technician duties, visit: www.pharmacy.ohio.gov/techFAQ	
Are certified pharmacy technicians working within their applicable scope of practice?	A certified pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment: (1) Accepting new written, faxed, or electronic prescription orders from a prescriber or a prescriber's agent. (2) Entering information into and retrieving information from a database or patient profile. (3) Preparing and affixing labels. (4) Stocking dangerous drugs and retrieving those drugs from inventory. (5) Counting and pouring dangerous drugs into containers. (6) Placing dangerous drugs into containers prior to dispensing by a pharmacist.	OAC 4729:3-3-04

	(7) Non-sterile drug compounding in accordance with the required training in USP 795. (8) Sterile drug compounding in accordance with the required training in USP 797. (9) Packaging and selling a dangerous drug to a patient or patient representative. (10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. (11) Stocking automated drug storage systems, floor stock, and crash carts at a location licensed as a terminal distributor of dangerous drugs. **NOTE:** A certified pharmacy technician may stock an automated drug dispensing unit and floor stock at a location licensed as a terminal distributor of dangerous drugs if a pharmacist is not physically present at the licensed location and all of the following apply: (a) A pharmacist is readily available to answer questions of the certified pharmacy technician. (b) A pharmacist is responsible for conducting routine verifications of the activities of the certified pharmacy technician to prevent the diversion of dangerous drugs. (c) A pharmacist is fully responsible for all activities conducted by the certified pharmacy technician at the licensed location. (12) Requesting refill authorizations for dangerous drugs from a prescriber or prescriber's agent, so long as there is no change from the original prescription. (13) Accepting new verbal prescription orders, including refill authorizations, for non-controlled drugs from a prescriber or a prescriber's agent pursuant to all of the following:	

	(a) The pharmacist on duty who is supervising the activity of the certified pharmacy technician will determine if the technician is competent to receive a verbal order. (b) The pharmacist on duty who is supervising the activity of the certified pharmacy technician is responsible for the accuracy of a prescription order received by a technician. (c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription order received by a certified pharmacy technician. (d) The certified pharmacy technician may not receive a prescription order for a controlled substance. (e) If applicable, the certified pharmacy technician receiving a prescription order must document the full name of the prescriber's agent. (f) The receiving certified pharmacy technician shall immediately reduce the prescription order to writing and shall review the prescription with the pharmacist on duty. (g) Prior to dispensing, positive identification of the receiving certified pharmacy technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the prescription. (h) The certified pharmacy technician and the pharmacist on duty must meet all other applicable rules for the receipt of new verbal prescription orders pursuant to agency 4729 of the Administrative Code. (14) Send or receive copies of non-controlled prescriptions pursuant to all of the following: (a) The pharmacist on duty who is supervising the activity of the certified pharmacy technician will determine if the technician is competent to send or receive a prescription copy.	

	(b) The pharmacist on duty who is supervising the activity of the certified pharmacy technician is responsible for the accuracy of a prescription copy that is sent or received by a technician. (c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription copy that is sent or received by a certified pharmacy technician. (d) The certified pharmacy technician may not send or receive a prescription copy for a controlled substance. (e) The pharmacist or certified pharmacy technician receiving a prescription copy from a certified pharmacy technician must document the full names of the sending technician and the technician's supervising pharmacist. The receiving technician shall immediately reduce the prescription copy to writing and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the certified pharmacy technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the copy. (f) The pharmacist or certified pharmacy technician sending a prescription copy to a certified technician must document the full names of the receiving technician and the technician's supervising pharmacist. (g) The certified technician and the pharmacist on duty must meet all other applicable rules for the transfer of a prescription copy pursuant agency 4729 of the Administrative Code. (15) Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment. (16) Performing diagnostic laboratory testing pursuant to rule 4729:3-3-05 of the Administrative Code.	

	NOTE: For more information regarding technician duties, visit: www.pharmacy.ohio.gov/techFAQ	
Are pharmacy interns working within their applicable scope of practice?	In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist: (1) The sale of schedule V controlled substances pursuant to agency 4729 of the Administrative Code. (2) The receipt of oral prescriptions pursuant to rule 4729:5-5-10 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code. (3) The transfer and receipt of a non-controlled prescription copy pursuant to rule 4729:5-5-11 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code. (4) The act of patient counseling pursuant to rule 4729:5-5-09 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code. (5) The administration of immunizations pursuant to section 4729.41 of the Revised Code and agency 4729:2-3-03 of the Administrative Code. (6) The documentation of informed consent to administer an immunization pursuant to section 4729.41 of the Revised Code. (7) The dispensing of naloxone pursuant to section 4729.44 of the Revised Code and other dangerous drugs as authorized under Chapter 4729. of the Revised Code. (8) Non-sterile compounding. (9) Sterile compounding.	OAC 4729:2-3-01

	(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. (11) Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment. (12) Performing diagnostic laboratory testing pursuant to rule 4729:2-3-05 of the Administrative Code. (13) Requesting refill authorizations for dangerous drugs that are not controlled substances from a prescriber or the prescriber's agent. (14) Notwithstanding the definition of direct supervision, a pharmacy intern may stock an automated drug dispensing unit and floor stock at a location licensed as a terminal distributor of dangerous drugs if a pharmacist is not physically present at the licensed location and all of the following apply: (a) A pharmacist is readily available to answer questions of the intern. (b) A pharmacist is responsible for conducting routine verifications of the activities of the intern to prevent the diversion of dangerous drugs. (c) A pharmacist is fully responsible for all activities conducted by the intern at the licensed location.	
Are there enough pharmacists supervising pharmacy interns?	The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty, unless otherwise approved by the Board. **IMPORTANT:** The number of pharmacy interns engaged in the administration of immunizations at any time is limited to not more than six for each pharmacist providing personal supervision.	OAC 4729:2-1-01

Are pharmacy support personnel working within their permitted scope?	Support personnel include any of the following: (1) An individual employed or performing contracted services at a location licensed as a terminal distributor of dangerous drugs, trained to perform clerical duties associated with the practice of pharmacy, including pricing, cashiering, drug purchasing, delivering, scheduling deliveries, answering non-professional telephone inquiries, transportation of dispensed medications within a hospital, documenting and processing third-party billing information for reimbursement, or any other activity as determined by the board. (2) An individual contracted by a terminal distributor of dangerous drugs to perform drug inventories. (3) Except for those responsible for the delivery of dangerous drugs, support personnel shall not have unsupervised access to dangerous drugs. (4) Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee. (5) Support personnel may have access to or retrieve information from patient records, including a database or patient profile to perform clerical duties associated with the practice of pharmacy. Support personnel shall not enter prescription information into a patient profile. (6) Support personnel may perform the following: (a) Transporting dangerous drugs from a loading dock, warehouse or other area that receives shipments from a licensed wholesaler or other person licensed in accordance with section 4729.52 of the Revised Code; and (b) Stocking and retrieving from inventory non-controlled dangerous drugs that are not dispensed by the pharmacy.	OAC 4729:3-1-01

	(7) The terminal distributor of dangerous drugs shall be responsible for ensuring all support personnel comply with state and federal requirements to ensure the confidentiality of patient health records. (8) Stocking of automated drug dispensing units and floor stock with intravenous fluids that are non-controlled dangerous drugs and are not dispensed by an institutional pharmacy.* (9) Overwrapping/placing in plastic dangerous drugs that have been compounded or dispensed (i.e. appropriately labeled) by a terminal distributor of dangerous drugs.* (10) Entering demographic and insurance information into a patient's profile.* *Additional responsibilities added via Board resolution.	

Positive Identification – Institutional Pharmacy

Substantive Change: Effective 2/1/2023, all pharmacy record keeping systems must capture the positive identification of the medication order or prescription information entered into the pharmacy's record keeping system. This requires positive identification of pharmacists, interns and technicians that are entering medication order or prescription information into a pharmacy's record keeping system. [OAC 4729:5-9-02.3 (A)(1)]

Question	Guidance	Law/Rule
Has the institutional pharmacy's computerized record keeping system changed since the last inspection?	If a computerized drug record keeping system is being utilized, the method(s) of achieving positive identification must be approved, in a manner determined by the Board, prior to implementation or any subsequent modification.	OAC 4729:5-9-02.3
Does the record keeping system capture the positive identification of the pharmacist verifying the prescription information entered into the record keeping system?	All pharmacy record keeping systems must capture the positive identification of the pharmacist entering order information into the system. **NOTE:** Unlike the substantive change listed above, this requirement is effective on 7/1/2021.	OAC 4729:5-9-02.3
Does the record keeping system capture the positive identification of the pharmacist conducting a drug utilization review?	All pharmacy record keeping systems must capture the positive identification of the pharmacist conducting the drug utilization review. **NOTE:** This may be captured as a standalone action or as part of either: 1. The prescription verification process; or 2. The dispensing process.	OAC 4729:5-9-02.3
Does the record keeping system capture the positive identification of the dispensing pharmacist?	All pharmacy record keeping systems must capture the positive identification of the dispensing pharmacist. Specifically, this requires the following: ▪ When a pharmacist dispenses a drug pursuant to an original order, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.	OAC 4729:5-9-02.3

	▪ When a pharmacist dispenses a drug pursuant to an authorized refill of an order, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.	
Does the record keeping system capture the positive identification of the individual transcribing an order received by telephone, facsimile, or recording device?	All pharmacy record keeping systems must capture the positive identification of the individual (pharmacist, pharmacy intern, or certified technician) transcribing an order received by telephone, facsimile, or recording device. **NOTE:** Prior to dispensing, the positive identification of the receiving certified pharmacy technician or pharmacy intern and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the prescription.	OAC 4729:5-9-02.3
Does the record keeping system capture the positive identification of the individual making any changes or annotations to a prescription?	All pharmacy record keeping systems shall be able to capture the positive identification of any individual responsible for any changes or annotations made to a prescription or medication order.	OAC 4729:5-9-02.3
Does the pharmacy capture positive identification using a hard copy printout of each day's prescription data?	**IMPORTANT:** This provision only applies if a pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to electronically document positive identification. If yes, the printout must include the following data: (1) Date of dispensing; (2) Order number; (3) Patient name; (4) Name, strength, and quantity of drug dispensed; (5) Identification of the pharmacist or pharmacy personnel responsible for any activity requiring positive identification; (6) Identification of the pharmacy; and (7) Identification of controlled substances. The printout must be verified, dated, and signed by each individual responsible for any activity requiring positive identification. The	OAC 4729:5-9-01 OAC 4729:5-9-02.3

	printout must be verified and manually signed by the individual within a reasonable time frame to ensure the accuracy of the record. The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.	
If using a hard copy printout of each day's prescription data, does the pharmacy store this data electronically?	**IMPORTANT:** This provision only applies if a pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to electronically document positive identification. If yes, the signed, scanned printouts must comply with the following: (1) All paper records maintained electronically shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user; (2) All computerized record keeping systems, including systems used to store scanned paper records, shall have daily back-up functionality to protect against record loss; and (3) Contain security features to prevent unauthorized access to the records.	OAC 4729:5-9-02.3

Dispensing Records and Patient Profiles – Institutional Pharmacies

Question	Guidance	Law/Rule
Does the pharmacy maintain dispensing records containing the required information?	Records of drugs dispensed shall including all the following: (1) The name, strength, dosage form, route of administration, and quantity of drugs dispensed; (2) The date of dispensing; (3) The name of the inpatient to whom, or for whose use, the drug was dispensed; and (4) The positive identification of the individuals involved in the dispensing as required by rule 4729:5-9-02.3 (see previous section).	OAC 4729:5-9-02.3
Does the pharmacy maintain dispensing records for the required timeframe?	Record keeping systems shall provide immediate retrieval via digital display and hard copy printout or other mutually agreeable transfer medium of information for all prescriptions, or medication orders, dispensed within the previous twelve months, and shall provide in a manner that is readily retrievable information on all prescriptions dispensed beyond the previous twelve months but within the previous three years.	OAC 4729:5-9-02.3
Does the pharmacy maintain patient profiles containing the required information?	Patient profiles consist of both a patient data record and a drug therapy record. A patient data record shall contain all the following information: (1) Full name of the patient for whom the drug is intended. (2) Patient's date of birth. (3) Patient's gender, if provided. (4) A list of current patient-specific data consisting of at least the following, if made known to the pharmacist or agent of the pharmacist: (a) Drug related allergies;	OAC 4729:5-9-02.5

	(b) Previous drug reactions; (c) History of or active chronic conditions or disease states; and (d) Other drugs, including nonprescription drugs, devices and nutritional supplements used on a routine basis. (5) The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug. A patient's drug therapy record shall contain all the following information for all prescriptions dispensed by the pharmacy within the last twelve months: (1) The original medication order. (2) Date and time of issuance of the medication order by the prescriber. (3) Full name of the prescriber. (4) The prescriber's credential (MD/DO, NP, PA, etc.). (5) Directions for use. (6) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug or device dispensed. (7) The strength, dosage form, route of administration, and quantity of the drug or device dispensed. **REMINDER:** All institutional pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received medications from that pharmacy.	
Does the licensee maintain the patient profile for a	The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This	OAC 4729:5-9-02.5

period of not less than one year from the date of the last entry in the profile record?	record may be a hard copy or maintained as a part of computerized system.	

Medication Orders & Outpatient Prescriptions

IMPORTANT: *A prescription or medication order, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law [OAC 4729:5-9-02.7 (I)].*

Question	Guidance	Law/Rule
Do medication orders contain all the required information?	All medication orders for drugs for inpatients shall include the following: (1) Name of patient; (2) Name, strength, and dosage form of drug; (3) Directions for use, including route of administration; (4) Date prescribed; (5) The ordering prescriber's positive identification; and (6) If applicable, the positive identification of the authorized individual transmitting the order on behalf of the prescriber. **NOTE:** This requirement applies to all forms of orders (electronic, verbal/oral, and hardcopy, including traditional paper and fax).	OAC 4729:5-9-02.7
Does the institutional pharmacy have a stop order policy or other method of assuring that drug orders or not continued inappropriately?	An institutional pharmacy shall develop and maintain written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient. Examples of stop order policies include, but are not limited to, the following: ▪ Routine monitoring of patient's drug therapy by a pharmacist; ▪ Routine monitoring of the patient's drug therapy by the patient's physician/prescriber in accordance with facility policies and procedures;	OAC 4729:5-9-02.7

	▪ A facility-approved, drug class-specific, automatic stop order policy covering those drug orders not specifying a number of doses or duration of therapy.	
Does the facility restrict access to the electronic system used to transmit medication orders to personnel authorized by the facility's policies and procedures?	Medication orders for inpatients of an institutional facility transmitted to a pharmacy by use of an electronic drug record keeping system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to personnel authorized in accordance with written policies and procedures of the institutional facility.	OAC 4729:5-9-02.7
If an inpatient order is transmitted electronically by authorized personnel on behalf of a prescriber, does the electronic system capture the positive identification of the prescriber that issued the order?	If the authorized personnel entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order within a reasonable period of time which shall be made readily retrievable. **NOTE:** The prescriber must verify the order using positive identification in accordance with institutional policy or no later than 30 days from the initiation of the order, whichever is first.	OAC 4729:5-9-02.7
If an inpatient order is transmitted orally by authorized personnel on behalf of a prescriber, does the facility capture the positive identification of the prescriber that issued the order?	Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized in accordance with written policies and procedures of the institutional facility. Such orders shall be transcribed by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility. Authorized personnel at an institutional facility may transcribe an oral order of a prescriber, including those received telephonically, in accordance with rules 3701-16-09 or 3701-17-13 of the Administrative Code and transmit the written transcription to the pharmacy by facsimile machine or electronic prescription transmission system in accordance with written policies and procedures of the institutional facility. The transcribed order shall	OAC 4729:5-9-02.7

	include the positive identification of the authorized facility personnel who transcribed and transmitted the order to the pharmacy. **NOTE:** The facility must ensure the prescriber verifies the order using positive identification in accordance with institutional policy or no later than 30 days from the initiation of the order, whichever is first.	
Do pharmacy interns comply with the requirements for receiving oral orders for non-controlled substances?	Oral orders for non-controlled substances issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacy intern by personnel authorized by, and in accordance with, written policies and procedures of the facility if the pharmacist on duty who is personally supervising the activity of the intern determines that the intern is competent to perform this function. The intern shall immediately transcribe the order (may be written or entered directly into an electronic system), document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent and shall review the order with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the oral order. **REMINDER:** The rule requires the pharmacist on duty to be responsible for the accuracy of the prescription and to be immediately available to answer questions or discuss the prescription with the prescriber or the prescriber's agent.	OAC 4729:5-9-02.7
Do certified pharmacy technicians comply with the requirements for receiving oral orders for non-controlled substances?	The certified pharmacy technician shall immediately transcribe the order (may be written or entered directly into an electronic system), document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent and shall review the order with the pharmacist on duty. Prior to dispensing, positive identification of the certified technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the oral order. **REMINDER:** The rule requires the pharmacist on duty to be responsible for the accuracy of the prescription and to be	OAC 4729:5-9-02.7 OAC 4729:3-3-04

	immediately available to answer questions or discuss the prescription with the prescriber or the prescriber's agent.	
Does the institutional pharmacy maintain non-controlled hard copy medication orders electronically in compliance with the requirements in rule?	All non-controlled hard copy medication orders, including facsimiles, may be electronically maintained, provided that the system creates and maintains electronic records in accordance with the following: (1) All hard copy medication orders for non-controlled dangerous drugs may be electronically filed and then destroyed after one hundred and eighty days from the date of creation or receipt. Disposal of the hard copy shall use a secure method of destruction to ensure privacy and confidentiality of the contents. (2) All hard copy medication orders electronically filed in accordance with this rule shall be scanned front and back in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user. Prior to scanning, the written or faxed order shall be clearly notated to indicate it has been received by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription. (3) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted. (4) The electronic form shows the exact and legible image of the original hard copy medication order. **NOTE:** Per the rule, all hard copy orders filed electronically in accordance with this rule shall be deemed the original prescription. **REMINDER:** Electronic prescriptions transmitted by facsimile may be stored electronically if the system maintains the original prescription for three years.	OAC 4729:5-9-02.7

Does the institutional pharmacy dispense outpatient prescriptions?	Drugs may be dispensed for outpatients by an institutional pharmacy pursuant to an original prescription of a prescriber in accordance with rule 4729:5-5-15 of the Administrative Code. All outpatient prescriptions dispensed by an institutional pharmacy shall comply with the following outpatient pharmacy requirements: (1) Labeling requirements in accordance with rule 4729:5-5-06 of the Administrative Code [see page 62 of outpatient pharmacy guide]; (2) Record keeping requirements in accordance with rule 4729:5-5-04 of the Administrative Code [see page 34 of outpatient pharmacy guide]; (3) Patient counseling requirements pursuant to rule 4729:5-5-09 of the Administrative Code [see page 64 of outpatient pharmacy guide]; (4) Prescription filing requirements pursuant to rule 4729:5-5-03 of the Administrative Code [see page 28 of outpatient pharmacy guide]; (5) Manner of processing requirements pursuant to rule 4729:5-5-10 of the Administrative Code [see page 65 of outpatient pharmacy guide]; (6) Serial numbering requirements pursuant to rule 4729:5-5-13 of the Administrative Code [see page 39 of outpatient pharmacy guide]; (7) Pick-up station requirements pursuant to rule 4729:5-5-14 of the Administrative Code [see page 98 of outpatient pharmacy guide]; (8) Patient profile requirements pursuant to rule 4729:5-5-07 of the Administrative Code [see page 34 of outpatient pharmacy guide]; (9) Reporting of all drugs pursuant to division 4729:8 of the Administrative Code*; and	OAC 4729:5-9-02.7 OAC 4729:5-5

	(10) Prospective drug utilization review requirements pursuant to rule 4729:5-5-08 of the Administrative Code [see page 88 of outpatient pharmacy guide]. **NOTE:** These requirements apply to medications started during in-patient use and provided to the patient upon discharge. *Drugs dispensed on an inpatient basis that are provided upon discharge are not required to be reported to OARRS. New prescriptions dispensed for the purposes of discharge (i.e., outpatient prescriptions) are still required to be reported to OARRS.	

Contingency Drugs and Emergency Access to an Institutional Pharmacy – Institutional Pharmacy

"Contingency drugs" are a supply of non-patient specific dangerous drugs which may be required to meet the therapeutic needs of patients or staff when either apply: (1) The institutional facility's on-site pharmacy is closed or otherwise unavailable to provide pharmacy services; (2) The institutional facility does not have an on-site pharmacy.

Question	Guidance	Law/Rule
Does the on-site pharmacy have a policy whereby a licensed pharmacist shall be made available when the institutional pharmacy is closed?	An institutional facility with an on-site pharmacy, including institutional facilities under a campus license, shall develop and implement a policy whereby a licensed pharmacist shall be made available for emergencies when the institutional pharmacy is closed. The pharmacist may be made available via telephone or other form of electronic communication.	OAC 4729:5-9-03.1
Does the pharmacy maintain prescription and records of controlled substance dispensing for emergency kits provided to nursing homes or residential care facilities?	A pharmacy providing emergency kits for use by a nursing home or residential care facility pursuant to rule 4729:5-9-03.1 of the Administrative Code must receive a valid outpatient prescription issued in accordance with rule 4729:5-5-15 of the Administrative Code prior to the administration of the initial **controlled substance dose** contained in the kit. The pharmacy providing the emergency kit shall be responsible for generating and maintaining a record of the dispensing of the **initial controlled substance dose** obtained from the kit in compliance with the record keeping requirements set forth in rule 4729:5-9-02.3 of the Administrative Code.	OAC 4729:5-9-02.7 OAC 4729:5-9-03.1
Does the pharmacy have policies and procedures for emergency access to an on-site institutional pharmacy in the event of an urgent medical need?	If a dangerous drug is not available from the contingency drug stock and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from an on-site institutional pharmacy pursuant to written policies and procedures adopted by the terminal distributor of dangerous drugs. The policies and procedures shall: (1) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy.	OAC 4729:5-9-03.1

	(2) Ensure a minimum of two employees of the institutional facility, one of whom shall be a prescriber or nurse to accompany and witness the activity of each other when accessing the pharmacy. (3) Provide a written or electronic record documenting emergency access to the pharmacy. Such record shall include the names, titles, and positive identification of all institutional personnel accessing the pharmacy, date and time of access, the name and quantity of drugs obtained, the name of the patient, and the name of the ordering prescriber. Such records shall be maintained for three years and made readily retrievable. (4) The written or electronic record of each access to the institutional pharmacy when it is closed and a pharmacist is not present shall be filed no later than the next business day with the institutional facility's responsible person or the responsible person's designee and maintained by the institutional pharmacy for three years.	
Does the pharmacy have policies and procedures for emergency access to an on-site institutional pharmacy in the event of a fire, flood, natural disaster, or other exigent circumstance?	An institutional pharmacy may be accessed in the event of a fire, flood, natural disaster, or other exigent circumstance pursuant to written policies and procedures adopted by the terminal distributor of dangerous drugs. The policies and procedures shall: (1) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy. (2) Ensure a minimum of two employees of the institutional facility, one of whom shall be a prescriber or nurse licensed pursuant to Chapter 4723. of the Revised Code, to accompany and witness the activity of each other when accessing the pharmacy. (3) Provide a written or electronic record documenting emergency access to the pharmacy. Such record shall include the names, titles, and positive identification of all institutional personnel accessing the pharmacy, and the date and time of access. If dangerous drugs are removed from the pharmacy, the name and quantity of drugs removed, the name of the patient (if applicable), and the name of the ordering prescriber (if applicable). Such records shall be maintained for three years and made readily retrievable.	OAC 4729:5-9-03.1

	(4) The written or electronic record of each access to the institutional pharmacy shall be filed no later than the next business day with the institutional facility's responsible person or the responsible person's designee and maintained by the institutional pharmacy for three years.	

Records of Drug Distribution – Institutional Pharmacies Only

This section only applies to records maintained by an institutional pharmacy. General record keeping provisions for institutional facilities can be found on page 124 of this guide.

Question	Guidance	Law/Rule
Does the institutional pharmacy maintain records for the distribution of non-patient specific dangerous drugs to other areas of the institutional facility for administration or use?	An institutional pharmacy shall maintain records for the distribution of non-patient specific dangerous drugs to other areas of the institutional facility for administration or use, which shall include all the following: (1) The name, strength, dosage form, and amount of drug distributed; (2) The area receiving the drug; and (3) The date distributed.	OAC 4729:5-9-02.3
Does the institutional pharmacy document the positive identification of the pharmacist checking the dangerous drugs prior to distribution?	An institutional pharmacy shall maintain records for the distribution of non-patient specific dangerous drugs to other areas of the institutional facility for administration or use, which shall include all the following: (1) The positive identification of the pharmacist checking the dangerous drugs prior to distribution. Such documentation shall be maintained for a period of three years in a manner that is readily retrievable. **REMINDER:** This provision is not applicable if the institutional pharmacy complies with certain requirements listed in rule. See next question in this section.	OAC 4729:5-9-02.3
Does the institutional pharmacy meet the requirements to exempt documentation of the positive identification of the pharmacist checking the dangerous drugs prior to distribution?	A pharmacist shall not be required to perform a check of dangerous drugs prior to distribution if all the following apply: (1) The drugs are stored or will be stored in an automated drug storage system that utilizes barcode system to track and correctly identify drugs stored within the system.	OAC 4729:5-9-02.3

	(2) A pharmacist has conducted an initial check of every barcode to ensure they have been assigned correctly to the appropriate drug. The initial check shall be documented using positive identification and maintained for a period of three years in a manner that is readily retrievable. (3) The pharmacy develops and implements a policy that includes all the following: (i) Verification by a pharmacist, documented using positive identification, prior to any changes to barcodes, additions to the formulary, or modification of a drug's national drug code (NDC). Any change shall be documented using positive identification and maintained for a period of three years in a manner that is readily retrievable. (ii) Requiring a pharmacist to document using positive identification the addition of auxiliary barcodes to drugs. Such documentation shall be maintained for a period of three years in a manner that is readily retrievable. (iii) A process to immediately alert the pharmacy of an error resulting from an incorrect barcode or a barcode override to ensure the accuracy of the system. (iv) Prohibits a pharmacy technician or pharmacy intern from moving or modifying any barcodes inside the system. Any modifications may only be done by a pharmacist and shall be documented using positive identification. Such documentation shall be maintained for a period of three years in a manner that is readily retrievable.	
Do records of non-controlled drug distribution document the identification of facility personnel?	For non-controlled dangerous drugs: The records must capture the identification of the facility personnel receiving the drug or authorized personnel stocking the automated drug storage system. **REMINDER:** Positive identification is only required for controlled drugs (see next question in this section).	OAC 4729:5-9-02.3
Do records of controlled drug distribution document	For controlled substance dangerous drugs: The records must capture the positive identification of the facility personnel receiving the drug	OAC 4729:5-9-02.3

the identification of facility personnel?	or authorized personnel stocking the automated drug storage system.	

General Record Keeping Requirements – Institutional Pharmacy

This section only applies to records maintained by an institutional pharmacy. General record keeping provisions for institutional facilities can be found on page 124 of this guide.

Question	Guidance	Law/Rule
Does the pharmacy's record keeping system contain security features to prevent unauthorized access to the records?	All institutional pharmacy records required in accordance with this chapter shall be maintained under appropriate supervision and control to restrict unauthorized access. This access may include a username and password, security question, pin, fingerprint, etc.	OAC 4729:5-9-02.3
Does the pharmacy's record keeping system contain back-up functionality to protect against record loss?	All computerized records shall contain daily back-up functionality to protect against record loss. Pharmacies must be able to provide documentation demonstrating back-up functionality.	OAC 4729:5-9-02.3
Does the licensee maintain all DEA Forms 222 for a period of three years?	All required records must be uniformly maintained for a period of three years. **NOTE:** 21 CFR 1305.17 requires executed DEA Forms 222 must be maintained separately from all other records of the registrant. Ohio regulations require these records to be retained for at least three years.	OAC 4729:5-9-02.3 ORC 3719.07
Does the licensee maintain records at an off-site location?	If yes, did the pharmacy submit and receive approval to store required records off-site? An institutional pharmacy located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy shall send a request in a manner determined by the Board. The Board will provide written or electronic notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the Board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.	OAC 4729:5-9-02.3

	The off-site records approval request form can be accessed here: www.pharmacy.ohio.gov/offsite.	
Does the institutional pharmacy provide medications to be distributed by a hospital self-service kiosk?	A dispensing pharmacy shall maintain an appropriate recordkeeping system that will provide accountability for proper receipt of all prescriptions provided to a patient or employee representative of the patient via a self-service kiosk. "Self-service employee prescription kiosk" or "kiosk" means a self-service kiosk for the pickup of new or refill prescriptions only for hospital employees and their family members. For more information see the Hospital Self-Service Employee Prescription Kiosks section of the inspection guide.	OAC 4729:5-9-03.5

Drug Purchases and Online Sales – Institutional Pharmacy

Question	Guidance	Law/Rule
Does the licensee maintain complete and accurate records of drugs purchased?	Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. Records must be maintained for a period of three years.	OAC 4729:5-9-02.3
Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?	Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale (including samples), the terminal distributor shall query the board's online roster (elicense.ohio.gov) to confirm any of the following: (1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code (i.e., wholesaler, manufacturer, repackager, outsourcing facility or 3PL); or (2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code (i.e., pharmacies or other terminal distributors). If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.	OAC 4729:5-3-04
Does the licensee sell or offer to sell dangerous drugs on its website?	If yes, Board staff will confirm that the licensee is using a pharmacy or service that maintains accreditation as a Verified Internet Pharmacy Practice Site (VIPPS) from the National Association of Boards of Pharmacy. A list of VIPPS-Accredited sites can be accessed here: https://nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/	OAC 4729:5-3-08

	NOTE: This requirement does not apply to a licensee using online services to distribute naloxone pursuant to a physician protocol.	

Drug Transfers or Occasional Wholesale Sales – Institutional Pharmacy

REMINDER: *Any drug transfers, including intracompany transfers, or occasional sales of controlled substances and gabapentin must be reported to OARRS as a wholesale transaction. Wholesale sales must be reported at least monthly.*

More information on reporting wholesale transactions can be accessed here: www.pharmacy.ohio.gov/wholesalereport

Question	Guidance	Rule/Law
Does the licensee comply with the record keeping requirements for intracompany transfers or occasional wholesale sales?	If yes, records of transfers to other terminal distributors of dangerous drugs, including sales conducted in accordance with rule 4729:5-3-09 of the Administrative Code, shall contain the name, strength, dosage form, and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred and the date of transfer. Board staff will review a sample of records to determine compliance. **REMINDER:** • A licensee must verify appropriate Ohio licensure prior to engaging in a drug transfer or occasional wholesale per OAC 4729:5-3-04. **NOTE:** There are some licensure exemptions - see this guidance for more information: www.pharmacy.ohio.gov/verify. • Licensure verification **DOES NOT** apply to sales or transfers to entities outside of the state. While Ohio does not have a prohibition on shipping drugs into another state, the licensee must comply with the requirements of the state where it is selling or transferring dangerous drugs.	OAC 4729:5-9-02.3 OAC 4729:5-3-09
Does the licensee exceed the annual limits on occasional wholesale sales?	For occasional sales, the dosage units of all dangerous drugs distributed by the pharmacy shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year. **NOTE:** There are no limits on intracompany transfers. An intracompany transfer includes any of the following:	OAC 4729:5-3-09

	(1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control. (2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.	

Security, Control, and Storage of Dangerous Drugs and Records – Institutional Pharmacy

Question	Guidance	Law/Rule
Is a licensed pharmacist the only person with access to keys or other methods for accessing the pharmacy?	Only a licensed pharmacist may have access to keys, alarm codes, or other methods of gaining access to the pharmacy when the pharmacy is closed. Keys to the pharmacy maintained on-site that are not in the possession of a licensed pharmacist shall be secured to prevent unauthorized access. All combinations or access codes, including alarm codes, shall be changed upon termination of employment of an employee having knowledge of the combination or access code. **NOTE:** This does not apply to the following: 1) Areas used for on-site records storage (see next question of this section) 2) Urgent medical needs in the event contingency drugs are unavailable (see page 43); or 3) Emergency access in the event of a natural disaster (see page 44).	OAC 4729:5-9-02.2
Are on-site areas used to store drug records outside of the pharmacy secured by a physical barrier with suitable locks to detect unauthorized entry?	Any designated area located outside an institutional pharmacy at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of D.E.A. controlled substance order forms, records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to this chapter of the Administrative Code, shall be secured by an physical barrier with suitable locks to detect unauthorized entry.	OAC 4729:5-9-02.2
Is a pharmacist providing supervision of the dangerous drugs, D.E.A. controlled substance order forms, all records relating to the distribution of	A pharmacist shall provide supervision of dangerous drugs, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs within the institutional pharmacy. Supervision means a pharmacist must be physically present at the licensed location and responsible for the security of the pharmacy and supervision of pharmacy personnel. **NOTE:** A pharmacist may	OAC 4729:5-9-02.2

dangerous drugs in the pharmacy?	leave a pharmacy that is currently operational (but must stay on-site) to use the bathroom and eat meals. **REMINDER:** Supervision by a pharmacist is not required if the institutional pharmacy permits the temporary absence of a pharmacist in accordance with OAC 4729:5-9-02.10 (see page 96).	
Can the pharmacy be secured by a physical barrier or alarm system?	Except during the temporary absence of a pharmacist (see page 96), whenever a pharmacist cannot meet the supervision requirements, the pharmacy must be secured by either: 1. A physical barrier (i.e. barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the Board of any installation or modification to a physical barrier prior to implementation. **-OR-** 2. An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the Board of any installation or modification to an alarm system prior to implementation. **IMPORTANT:** The alarm system notification requirement is not required if the pharmacy also uses a Board approved physical barrier.	OAC 4729:5-9-02.2
Are all schedule II controlled substances stored in a securely locked,	All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous drugs. The cabinet or safe shall remain locked and secured when not in use.	OAC 4729:5-9-02.2

substantially constructed cabinet or safe?	Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs. ***Substantive Change: Pharmacies are no longer permitted to disperse schedule II controlled substances throughout the pharmacy's non-controlled pharmaceuticals. Schedule III - V may still be dispersed among the pharmacy's non-controlled pharmaceuticals.**	
Does the licensee comply with the security requirements for storing thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine?	Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.	21 CFR 1301.75
Does the pharmacy have a policy in place to prevent hypodermics from theft or acquisition by any unauthorized person?	An institutional pharmacy shall develop and implement policies to prevent hypodermics from theft or acquisition from the pharmacy by any unauthorized person. **NOTE:** There is a similar requirement for institutional facilities.	OAC 4729:5-9-02.2 ORC 3719.172

Temperature Monitoring – Institutional Pharmacy

Substantive Change: New rule includes minimum requirements for temperature monitoring and temperature excursions.

Question	Guidance	Law/Rule
Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?	The pharmacy must maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained: (1) Temperature logs with, at a minimum, daily observations; or (2) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion. Records of temperature control monitoring for refrigerators and freezers used for the storage of drugs must include any of the following: (1) For temperature logs, either: (a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or (b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded. (2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion. **REMINDER:** Temperature records must be maintained for a period of three years.	OAC 4729:5-9-02.2 OAC 4729:5-9-02.3
Does the pharmacy have a policy to respond to any out-of-range individual temperature readings or	The pharmacy must develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.	OAC 4729:5-9-02.2

excursions to ensure the integrity of stored drugs?	The policy must be made available for review upon inspection and should describe, at a minimum, all the following: ▪ The actions to be taken in the event of temperature excursions outside the labelled storage conditions. ▪ The process for appropriately investigating, documenting, and assessing temperature excursions outside the labelled storage conditions to ensure the integrity of the drug stock (for example, stability data or technical justification).	
Are refrigerators and/or freezers used for the storage of drugs free of food or beverage products?	The pharmacy is required to develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs. The policy must be made available for review upon inspection and all refrigerators and freezers used for drug storage will be examined to ensure compliance. The policy may permit the storage of foods and beverages used for medication administration (i.e., for medication pass or med pass). **NOTE:** Facilities may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures. The bottle should be labeled to identify that the water is for temperature regulation only.	OAC 4729:5-9-02.2

Theft or Significant Loss of Drugs and Drug Documents – Institutional Pharmacy

Question	Guidance	Law/Rule
Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?	A licensee is required to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or significant loss to the Board using the online portal within thirty days following the discovery of such theft or significant loss. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02
Has the licensee experienced any theft or loss of uncompleted prescription blank(s), written prescription order(s) not yet dispensed, or D.E.A. controlled substance order forms in the past twenty-four months?	A licensee is required to report, immediately upon discovery, to the Board any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or loss to the Board using the online portal within thirty days following the discovery of such theft or loss. **NOTE:** Unlike dangerous drugs, drug documents do not have a significant loss threshold. Therefore, all losses (in addition to thefts) must be reported to the Board. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02

Controlled Substance Inventory – Institutional Pharmacy

Question	Guidance	Law/Rule
Does the licensee conduct an annual inventory of controlled substances?	All Category III licensees must complete an annual inventory **even if drugs are not on-site** (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory. Each inventory must contain a complete and accurate record of all controlled substances on hand the date the inventory is conducted. This includes controlled substances stored in automated dispensing systems, automated drug storage systems, and emergency kits. The inventory must have the names of the controlled substances, each finished form, the number of units, and/or the number of commercial containers of each finished form. If listed in Schedules I or II, make an exact count or measure of the contents. If listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case the licensee must make an exact count of the contents. **NOTE:** The annual inventory may be taken on any date which is within thirteen months of the previous inventory date. Board staff will review records to determine compliance.	OAC 4729:5-3-07
How does the licensee monitor its inventory of controlled substances?	Board staff will review and document how the licensee monitors its inventory of controlled substances (e.g. daily count, perpetual inventory, etc.).	

Drug Disposal – Institutional Pharmacy

This section does not apply to pharmacies operating drug take back programs. See "Drug Collection Receptacles" section.

Question	Guidance	Rule/Law
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 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. **REMINDER:** The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method by any person legally authorized under Chapters 3719. and 4729. of the Revised Code and this division of the Administrative Code to possess controlled substance dangerous drugs. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable. A record of such destruction shall be	OAC 4729:5-3-01 21 CFR 1304

	made in accordance with 21 C.F.R. 1304 and shall be maintained for a minimum of three years from the date of destruction and made readily retrievable to the Board of Pharmacy upon request. 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:** The 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 of two licensed or registered healthcare professionals (including interns, pharmacy technicians, and technician trainees) conducting and witnessing the disposal, one of whom shall be a pharmacist. 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 4729:5-9-02.3
Does the licensee dispose of non-controlled 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. **NOTE:** This does not require a licensee to dispose of non-controlled drugs in the same manner as controlled substances (i.e. non-retrievable). However, the method utilized should reasonably ensure that no one would be able to utilize the medication following disposal.	OAC 4729:5-3-06

Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs?	Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed or registered health care professional (may include interns, pharmacy technicians, and technician trainees) 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.	OAC 4729:5-9-02.3

Drug Collection Receptacles – Institutional Pharmacy

REMINDER: *A pharmacy the offers to collect non-controlled substances only must still comply with the federal requirements [See OAC 4729:10-1-02(B)].*

Question	Guidance	Rule/Law
Does the facility operate a drug take back program (i.e. collection receptacle)?	If yes, Board staff will review documentation to confirm the licensee has modified its Drug Enforcement Administration registration to become an "authorized collector." Modification to a DEA registration may also be confirmed online: www.pharmacy.ohio.gov/collectors. 21 CFR 1317.40 requires a pharmacy that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with 21 CFR 1301.51. **NOTE:** Authorized hospitals/clinics with an on-site pharmacy and retail pharmacies may maintain collection receptacles at long-term care facilities. Clinics that have a dispensing room that is not operated by a pharmacist are not considered entities with an on-site pharmacy.	21 CFR 1317.40 [as required by OAC 4729:10-1-02 (A)]
Is the receptacle located in compliance with DEA regulations?	**For Hospitals ONLY:** A collection receptacle must be located in an area regularly monitored by employees and shall not be located in the proximity of any area where emergency or urgent care is provided. **For Long-Term Care Facilities ONLY:** A collection receptacle must be located in a secured area regularly monitored by long-term care facility employees.	21 CFR 1317.75 [as required by OAC 4729:10-1-02 (A)]
Does the collection receptacle meet the required design specifications?	A controlled substance collection receptacle shall meet the following design specifications: (1) Be securely fastened to a permanent structure so that it cannot be removed. (2) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner.	21 CFR 1317.40 [as required by OAC 4729:10-1-02 (A)] OAC 4729:10-1-02

	(3) The outer container shall include a small opening that allows contents to be added to the inner liner but does not allow removal of the inner liner's contents. The small opening in the outer container of the collection receptacle must be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed). (4) The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances. The signage must also indicate that the following are not acceptable: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). (5) The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.	
Are sealed inner liners containing drugs collected by a pharmacy stored in a manner consistent with the security requirements for Schedule II controlled substances?	21 CFR 1317.05 requires all inner liners and contents to be securely stored at the collector's registered location in a manner consistent with rules for Schedule II controlled substances until prompt destruction can occur. 21 CFR 1301.75 states that sealed inner liners shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access. **IMPORTANT:** Sealed inner liners may only be stored at the long-term care facility for *up to three business days* in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer.	21 CFR 1317.05 [as required by OAC 4729:10-1-02 (A)]

Drug Samples – Institutional Pharmacies

Question	Guidance	Rule/Law
Does the pharmacy have sample drugs as part its inventory?	Except for charitable pharmacies, an institutional pharmacy is not permitted to dispense sample drugs. "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code. **NOTE:** Pharmacies are permitted to dispense complimentary supplies of dangerous drugs. "Complimentary supply" also known as "starter packs," "initial dose packs," "starter stocks," "replacement programs," or any other similar supply means a drug or pharmaceutical preparation that is distributed without charge by licensed drug distributors to pharmacies licensed as terminal distributors of dangerous drugs or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug. **REMINDER:** Rule 4729:6-3-08 does not permit a pharmacist who is authorized to manage drug therapy under a consult agreement from ordering, dispensing or personally furnishing a sample within a pharmacy licensed as a terminal distributor of dangerous drugs. This provision does not apply to charitable pharmacies. Board staff will review drug inventory to check for samples.	OAC 4729:6-3-08

Dispensing of Controlled Substances – Institutional Pharmacy

Question	Guidance	Rule/Law
Does the pharmacy dispense controlled substances in packaging the meets the requirements of the rule?	All controlled substances dispensed in quantities exceeding a seventy-two-hour supply shall be packaged in tamper-evident, unit-of-use containers except when unit-of-use packaging is not available including, but not limited to, multi-dose liquids and injectables. **NOTE:** This provision **does not** apply to controlled substances where the manufacturer's instructions prohibit repackaging of the drug.	OAC 4729:5-9-02.4

Labeling – Institutional Pharmacy

Question	Guidance	Rule/Law
Are inpatient orders dispensed by the pharmacy properly labeled?	The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include: (1) The non-proprietary or proprietary name of the drug; (2) Dosage form and route of administration; (3) The strength and volume, where applicable, of the drug; (4) The control number and expiration date; (5) National drug code, universal product code, or formulary code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label; (6) Identification of the manufacturer, packer, or distributor, or, if the repackager is the dispensing pharmacy, identification of the repackager shall be by name or by the final seven digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label; and (7) Special storage conditions, if required. **IMPORTANT:** At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label. **REMINDER:** For medications dispensed in blister cards, the label may be applied to the blister card directly. ***See next question for labeling requirements for admixtures of parenteral solutions.***	OAC 4729:5-9-02.8
Are admixtures of parenteral solutions properly labeled?	Prior to dispensing, any admixtures of parenteral solutions shall bear a distinctive label indicating:	OAC 4729:5-9-02.8

	(1) The patient's full name; (2) The name and amount of the parenteral solution; (3) The name and amount of the drug(s) added; (4) The expiration date or beyond-use date; (5) The name and address of the institutional pharmacy; and (6) Cautionary statements, if required.	
Does the institutional pharmacy utilize supplemental labels that contain a barcode or QR code for the purpose of identifying a drug that complies with the requirements of the rule?	Supplemental labels created by a pharmacy that contain a barcode or QR code for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for: (1) Association of the barcode to the drug product; (2) Association of the label to the drug product.	OAC 4729:5-9-02.8
Are drugs dispensed for self-administration by inpatients or dispensed for outpatient use labeled in accordance with OAC 4729:5-5-06?	No drug may be dispensed by outpatient prescription unless a label is affixed to the container in which such drug is dispensed, and such label includes: (1) The name or "doing business as" (DBA) name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license; (2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals; (3) The full name of the prescriber or the first initial of the prescriber's first name and the full last name of the prescriber; (4) Directions for use of the drug; (5) The date of dispensing;	OAC 4729:5-9-02.8 → 4729:5-5-06

	(6) Any cautions which may be required by federal or state law; (7) The serial number of the prescription; (8) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission and such request is documented; and (9) The quantity of drug dispensed. **NOTE:** The term "affix" means the prescription label must be attached or fastened to the drug's container. However, a label meeting the requirements of the rule may be placed on the packaging of a commercially manufactured dangerous drug product. ***Substantive Change:** ▪ **Sets uniform requirements for animal prescription labeling (see #2 above).** ▪ **Permits labels to be affixed to the packaging of commercially manufactured dangerous drug (ex: asthma inhaler packaging rather than the inhaler itself). This does not prohibit a pharmacy or institutional facility from implementing a policy requiring labels to be affixed directly to the drug container itself.**	

Pharmacist Drug Utilization Review & OARRS – Institutional Pharmacy

IMPORTANT: *Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about safe and appropriate use and the legitimacy of a medication order. A pharmacist shall not dispense a dangerous drug from a medication order or prescription of doubtful, questionable, or suspicious origin [OAC 4729:5-9-02.6 (D)].*

Question	Guidance	Rule/Law
Is a pharmacist conducting a prospective drug utilization review for all drugs dispensed	With some exceptions (see below), prior to dispensing any initial medication order or medication order change, a pharmacist shall conduct a prospective drug utilization review of the patient profile for the purpose of identifying the following: (1) Over-utilization or under-utilization of medications dispensed in the institutional facility; (2) Therapeutic duplication; (3) Drug-disease state contraindications; (4) Drug-drug interactions; (5) Incorrect drug dosage; (6) Drug-allergy interactions; (7) Abuse/misuse; (8) Inappropriate duration of drug treatment; and (9) Food-nutritional supplements-drug interactions. **REMINDER:** Upon identifying any issue listed above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include, but shall not be limited to, the following: (1) Requesting and reviewing an OARRS report or another state's prescription drug monitoring report;	OAC 4729:5-9-02.6

	(2) Consulting with the prescriber; or (3) Counseling the patient. **EXCEPTIONS:** The requirement to conduct a prospective drug utilization review **does not** apply to drugs personally furnished or administered from floor stock, contingency drugs, or an automated drug storage system in either of the following circumstances: (1) A prescriber controls the ordering, preparing, and administering of the drug; or (2) Delay would harm the patient.	
Is a pharmacist conducting a retrospective review of medication orders in accordance with the rule? ***The requirement to conduct a retrospective review has been temporarily suspended by Board resolution (click here). The Board will provide additional information and guidance when the provision is enforceable.**	A pharmacist shall conduct a retrospective review of medication orders within a reasonable amount time and make a determination about the safe and appropriate use and the legitimacy of the order in either of the following circumstances: (1) Any drug removed from the pharmacy or contingency stock in accordance with rule 4729:5-9-03.01 of the Administrative Code; and (2) The use of override medications. **NOTE: The prescriber must verify the order using positive identification in accordance with institutional policy or within 30 days from the date of issuance, whichever comes first.** **REMINDER:** Override medication means a dangerous drug that may be removed from floor stock or contingency drugs prior to pharmacist review because the institutional facility's interdisciplinary committee has determined that the clinical status of the patient would be compromised by delay.	OAC 4729:5-9-02.6
Does the institutional pharmacy/facility have policies and procedures to require pharmacists to report the unsafe or	An institutional pharmacy/facility shall develop and implement policies and procedures to require pharmacists to report unsafe or inappropriate prescribing or dosing by prescribers to the appropriate oversight committee.	OAC 4729:5-9-02.6

inappropriate prescribing or dosing by prescribers to the appropriate oversight committee?		
Are any of the pharmacists using delegates to request OARRS reports?	Delegates are required to have their own OARRS accounts. A delegate is not permitted to use the username and login for a pharmacist or another delegate. **NOTE:** Support personnel shall not serve as a pharmacist's delegate pursuant to section 4729.80 of the Revised Code.	OAC 4729.80 OAC 4729:3-1-01

Return to Stock – Institutional Pharmacy

IMPORTANT: *Drugs dispensed for patients, which have not been dispensed or personally furnished directly to the ultimate user, that require further manipulation prior to administration may be re-dispensed by a pharmacy [OAC 4729:5-3-16 (A)(4)].*

Question	Guidance	Rule/Law
Does the institutional pharmacy return dispensed drugs to stock shelves?	No drug that has been dispensed pursuant to a prescription or personally furnished by a prescriber and has left the physical premises of the terminal distributor of dangerous drugs shall be returned to the terminal distributor or dispensed or personally furnished again, except as follows: (1) Drugs dispensed for inpatients or personally furnished to inpatients provided that: (a) The drugs are packaged in unopened, single-dose or tamper-evident containers; and (b) The drugs have not been in the possession of the ultimate user. (2) Drugs dispensed for inpatients in accordance with rule 4729:5-9-02.11 of the Administrative Code (see Customized Patient Medication Packaging section).	OAC 4729:5-3-16

Customized Patient Medication Packaging (Adherence Packaging) – Institutional Pharmacy

Question	Guidance	Rule/Law
Does the pharmacy dispense customized patient medication packages (sometimes referred to as adherence packaging)?	In lieu of dispensing two or more dangerous drugs in separate containers, a pharmacist practicing at an institutional pharmacy may dispense a customized patient medication package. A customized patient medication package is a package for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms.	OAC 4729:5-9-02.11
Do the customized medication packages dispensed by the pharmacy comply meet the requirements of the rule?	Customized medication packages must comply with the following requirements: (1) The package is designed, or each container is labeled, to indicate the day and time or period of time when the contents within each container are to be taken by the patient. (2) The number of drugs placed in each container cannot exceed the capability of the container to prevent damage to the dosage forms. (3) The quantity of the package dispensed may not be more than a thirty-one-day supply. (4) The containers of a package are sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.	OAC 4729:5-9-02.11
Are the customized medication packages appropriately labeled?	The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required in accordance with the institutional pharmacy labeling requirements (see Labeling section), including the use of accessory labels. When a customized medication packaging is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container or package with an affixed label containing the following information: (1) Identification of the dispensing pharmacy; (2) The patient's full name;	OAC 4729:5-9-02.11

	(3) The date of dispensing; (4) The non-proprietary and/or proprietary name of the drug; (5) National drug code, universal product code, or formulary code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label; (6) The strength of the drug; (7) The pharmacy's expiration date or beyond-use date, which shall not exceed the expiration date on the manufacturer's container or six months from the date the drug was originally packaged, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or six months from the date the drug was originally repackaged, whichever date is earlier. **REMINDER:** All drugs dispensed to inpatients for self-administration or dispensed for outpatient use shall also be labeled in accordance with 4729:5-5-06 of the Administrative Code.	
Does the pharmacy comply with the return to stock requirements for customized medication packaging?	Dangerous drugs which have been dispensed in a customized patient medication package may only be returned to stock or re-dispensed in accordance with all the following: (1) The drugs have not been in the possession of the ultimate user; and (2) The drugs have not been placed in the same container with another dangerous drug (i.e. did not come into direct contact with a different drug within the same container).	OAC 4729:5-9-02.11
Does the pharmacy maintain and implement the required policies and procedures on the exclusion of drugs from customized packages?	Any pharmacy dispensing customized patient medication packages in accordance with this rule must implement policies and procedures that will exclude drugs having any of the following characteristics from such packaging:	OAC 4729:5-9-02.11

	(1) The U.S.P. monograph or official labeling requires dispensing in the original container, unless there is documentation from the manufacturer stating otherwise; (2) The drugs or dosage forms are incompatible with packaging components or each other; (3) The drugs are therapeutically incompatible when administered simultaneously; and (4) The drugs require special packaging.	

Repackaging of Drugs – Institutional Pharmacy

Question	Guidance	Rule/Law
Does the pharmacy engage in the repackaging of drugs?	"Repackaging" means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging. Repackaging does not include any of the following activities: 1. Repackaging drug products for use in animals; 2. Repackaging non-dangerous drug products (e.g. OTC); 3. Radiopharmaceuticals as defined in chapter 4729:5-6 of the Administrative Code; 4. Repackaging conducted by outsourcing facilities or repackagers licensed in accordance with section 4729.52 of the Revised Code; 5. Removing a drug product from the original container at the point of care (e.g., patient's bedside) for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient); 6. Upon receipt of a valid patient-specific prescription or medication order, a licensed pharmacy removing from one container the quantity of non-sterile drug products (e.g., oral dosage forms) necessary to fill the prescription and placing it in a different container to dispense directly to the patient; and 7. Investigational new drugs being studied under an investigational new drug application.	OAC 4729:5-9-02.12
Are repackaged sterile drug products assigned beyond-use dates in	Unless otherwise specified in the individual monograph or in the absence of stability data to the contrary, the beyond-use date shall be not later than the expiration date on the manufacturer's container	OAC 4729:5-9-02.12

compliance with the requirements of the rule?	or one-year from the date the drug is repackaged, whichever is earlier. Sterile compounded drug preparations shall comply with United States pharmacopeia chapter as referenced in rule 4729:7-1-01 of the Administrative Code.	
Are repackaged drugs properly labeled?	Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following: ▪ Name of drug, strength, and dosage form; ▪ National drug code or universal product code, if applicable, which may be embedded in a bar code or quick response (QR) code on the label; ▪ The identification of the repackager by name or by the final seven digits of the terminal distributor of dangerous drugs license number; ▪ Pharmacy control number; and ▪ The beyond-use date of the repackaged drug.	OAC 4729:5-9-02.12
Does the licensee maintain the required records for repackaged drugs?	A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept in a readily retrievable manner for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include the following: (1) Name of drug, strength, dosage form, and quantity; (2) National drug code (NDC) or universal product code (UPC), if applicable, which may be embedded in a bar code or quick response (QR) code on the label; (3) Manufacturer's or distributor's control number; (4) Manufacturer's or distributor's name, if a generic drug is used, or if not using NDC or UPC; (5) Pharmacy control number; (6) Manufacturer's or distributor's expiration date; (7) The pharmacy's beyond-use date; (8) The positive identification of the individual responsible for the repackaging of the drug; and	OAC 4729:5-9-02.12

	(9) The positive identification of the pharmacist conducting the final verification of the repackaged drug to confirm the accuracy of the drug and conformity to the requirements of this rule prior to dispensing or distribution. Board staff will review records to determine compliance.	
Does the licensee use supplemental labels containing a bar code or QR code?	A pharmacy that uses supplemental labels that contain a bar code or QR code for the purpose of identifying a repackaged drug shall capture the positive identification of the pharmacist responsible for the following: (1) Association of the bar code to the drug product; and (2) Association of the label to the drug product. Board staff will review records to determine compliance.	OAC 4729:5-9-02.12

Drug Compounding – Institutional Pharmacy

Question	Guidance	Rule/Law
Is the licensee engaged in either sterile or non-sterile drug compounding on site?	If engaged in drug compounding, the licensee may be subject to an additional inspection by a Board Specialist (i.e. pharmacist). For more information on pharmacy compounding, visit: www.pharmacy.ohio.gov/compounding.	OAC 4729:7-2

Expired/Adulterated Drugs – Institutional Pharmacy

IMPORTANT: *See Drug Disposal section on page 62 for record keeping requirements related to disposal.*

Question	Guidance	Rule/Law
Are multi-dose vials properly labeled?	Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.	OAC 4729:5-9-02.2
Are there expired/adulterated drugs present in the licensee's active drug stock?	Board staff will conduct a check for expired drugs/adulterated drugs, including, but not limited to, the following: ▪ Expired drugs in common stock areas. ▪ Multidose vials that have been opened/punctured and exceed twenty-eight days from the date of puncture, unless otherwise specified by the manufacturer. ▪ Adulterated drugs in common stock areas (partial vials of single-dose injectable drugs). If the vial says single use and it is not stored in an ISO 5 space (must be labeled with a BUD of 6 hours), and it has been punctured/used, it must be discarded and may not be used again.	OAC 4729:5-3-06
Are expired/adulterated drugs appropriately segregated from the licensee's active drug stock?	Expired/adulterated drugs must be stored separately from active drug stock in a manner that prohibits access by unauthorized persons. Expired/adulterated drugs must be segregated from the active drug stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored in common stock areas but segregated in a manner that is clear to all who see it that the drugs may not be used. All expired/adulterated drugs must be stored within the pharmacy or a secured area at the licensed location.	OAC 4729:5-3-06

Are expired/adulterated drugs stored no longer than one year from the date of expiration/adulteration?	Expired/adulterated drugs shall be stored no longer than one year from the date of expiration/adulteration by those holding a terminal distributor of dangerous drugs license. Board staff will review expired/adulterated drugs to confirm.	OAC 4729:5-3-06

Immunization Administration – Institutional Pharmacy

IMPORTANT: *A pharmacist or pharmacy intern, under the direct supervision of a pharmacist, may administer vaccinations in accordance with Ohio laws and rules or the process established by the U.S. Department of Health and Human Services. For more information visit: www.pharmacy.ohio.gov/COVIDvaccine*

For more information on immunization administration, visit: www.pharmacy.ohio.gov/immunize.

Question	Guidance	Rule/Law
Does the pharmacy offer immunizations?	A pharmacist or pharmacy intern, under the direct supervision of a pharmacist, may administer the following immunizations: (1) In the case of an individual who is seven years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following: (a) Influenza; (b) COVID-19; (c) Any other disease, but only pursuant to a prescription. (2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19. ***Substantive Change: New law/rule allows for administration of COVID-19 immunization.**	ORC 4729.41 OAC 4729:1-3-02 OAC 4729:2-3-03
Does the pharmacy have a physician-established protocol for immunization administration?	A physician-established protocol for the administration of immunizations shall include the following: (1) For each immunization offered by the pharmacy, the protocol shall contain all of the following: (a) Name and strength; (b) Precautions and contraindications; (c) Intended audience or patient population; (d) Dosage; (e) Administration schedules; (f) Routes of administration; and (g) Injection sites.	ORC 4729.41 OAC 4729:1-3-02

	(2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation. (3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks. (4) A method to notify an individual's physician or the applicable board of health within thirty days after administering an immunization, except for influenza immunizations administered to individuals eighteen years of age and older. (5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations. Board staff will review protocol to determine compliance.	
Is the physician-established protocol renewed on a biennial basis?	All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis. (1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs. (2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.	OAC 4729:1-3-02
Does the pharmacy maintain records of immunization administration?	Records shall be maintained for three years and made readily retrievable for all immunizations administered in accordance with section 4729.41 of the Revised Code and rules 4729:1-3-02 and 4729:2-3-03 of the Administrative Code and shall include the following information:	OAC 4729:5-5-04

	(1) Full name and address of the patient; (2) Patient's date of birth or age; (3) Patient's applicable allergy information; (4) Date of administration; (5) Name, strength, and dose of the immunization administered; (6) Lot number and expiration date of the immunization; (7) Route of administration; (8) Location of the injection site; (9) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist; (10) Identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer the immunization.	
Does the pharmacy notify an individual's family physician or the board of health of the health district in which the individual resides?	For each immunization administered to an individual by a pharmacist or pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist or pharmacy intern shall notify the individual's primary care provider or, if the individual has no provider, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification: (1) Electronic mail; (2) Interoperable electronic medical records system; (3) Facsimile; (4) Electronic prescribing system; (5) Electronic pharmacy record system; (6) Documented verbal communication; or (7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.	ORC 4729.41 OAC 4729:1-3-02 OAC 4729:2-3-03
Do pharmacists or pharmacy interns administering immunizations maintain	A pharmacist/pharmacy intern shall maintain proof of successful completion of a training course on file at the location(s) where the pharmacist/intern administers immunizations.	OAC 4729:1-3-02 OAC 4729:2-3-03

proof of successful completion of an immunization training course?	**NOTE:** The course must be conducted by an Accreditation Council for Pharmacy Education (ACPE) accredited provider and must be five hours in length. Board staff will review documentation and document the training courses completed.	
Does the pharmacist or pharmacy intern administering immunizations maintain certification to perform basic life-support procedures?	A pharmacist/pharmacy intern shall maintain proof of maintenance of certification to perform basic life-support procedures on file at the location(s) where the pharmacist/intern administers immunizations. A pharmacist/pharmacy intern administering immunizations shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American Red Cross, American Heart Association or other training course approved by the Board. **NOTE:** The Board, by resolution, recognizes that CPR/AED or Basic Life Support certification provided by American Safety and Health Institute (ASHI) meets the basic-life support training requirements pursuant to sections 4729.41 and 4729.45 of the Revised Code. For more information on basic life-support requirements during COVID-19, please review the following guidance: www.pharmacy.ohio.gov/COVIDvaccine www.pharmacy.ohio.gov/TechAdmin	OAC 4729:1-3-02 OAC 4729:2-3-03

Drug Administration (Non-Immunization) – Institutional Pharmacy

Question	Guidance	Rule/Law
Does the pharmacy offer the administration of other drugs (i.e. non-immunizations) via injection?	Other drugs include any of the following: (1) An addiction treatment drug administered in a long-acting or extended-release form. **NOTE: Effective 8/16/2023, the Board has updated its enforcement guidance to permit the administration of controlled substances used to treat addiction in a long-acting or extended-release form.** (2) An antipsychotic drug administered in a long-acting or extended-release form. (3) Hydroxyprogesterone caproate for pregnant women. (4) Medroxyprogesterone acetate for non-pregnant women. (5) Cobalamin, to include: cyanocobalamin, hydroxocobalamin or any other vitamin B12 injection approved by the United States Food and Drug Administration.	ORC 4729.45 OAC 4729:1-3-03
Does the pharmacy have a physician-established protocol for drug administration?	A physician-established protocol for the administration of dangerous drugs in accordance with section 4729.45 of the Revised Code shall include the following: (1) For the dangerous drugs administered: (a) Name and strength; (b) Precautions and contraindications; (c) Intended audience or patient population; (d) Dosage; (e) Administration schedules; (f) Routes of administration; (g) Injection sites; and (h) The type of tests that may be ordered for the administration of an opioid antagonist. (2) The length of time the pharmacist must observe an individual for adverse effects, which shall be based on standards of care established by the physician. The location of the observation shall be	OAC 4729:1-3-03

	in the general vicinity of the administering pharmacist to allow for on-going evaluation. (3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks. (4) The locations that a pharmacist shall engage in the administration of dangerous drugs to ensure the privacy and dignity of the patient. (5) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to a drug administered by the pharmacist. Board staff will review protocol to determine compliance.	
Is the physician-established protocol renewed on a biennial basis?	All physician-established protocols shall be signed and dated by the physician prior to implementation and shall be readily available to the administering pharmacist. The protocol shall be renewed by the physician on a biennial basis. Board staff will review protocol to determine compliance.	OAC 4729:1-3-03
Does the pharmacist obtain written permission prior to the administration of each drug?	Each time a pharmacist administers a drug, the pharmacist shall comply with all the following: (1) For each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain written permission from the individual. (2) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain written permission from the individual's parent or other person having care or charge of the individual. (3) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the	OAC 4729:1-3-03

	pharmacist shall obtain written permission from the person authorized to make such decisions on the individual's behalf. (4) Permission obtained in accordance with this paragraph shall also include notification of the patient's right to request a private area.	
Does the pharmacist obtain and review test results prior to the administration of an opioid antagonist?	A pharmacist administering an opioid antagonist shall obtain and evaluate test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered: (1) The initial dose of the drug; and (2) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered. **REMINDER:** A pharmacist may obtain the test results from either: ▪ The prescribing physician or the physician's agent; or ▪ By ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered.	OAC 4729:1-3-03
Does the pharmacy maintain records of drug administration?	Records shall be maintained for three years and made readily retrievable for all dangerous drugs administered in accordance with section 4729.45 of the Revised Code and rule 4729:1-3-03 of the Administrative Code and shall include the following information: (1) Full name and address of the patient; (2) Patient's date of birth or age; (3) Patient's applicable allergy information; (4) Date of administration; (5) Name, strength, and dose of the drug administered; (6) Lot number and expiration date of the drug;	OAC 4729:5-5-04

	(7) Route of administration; (8) Location of the injection site; (9) Documentation of test results required prior to the administration of an opioid antagonist in accordance with rule 4729:1-3-03 of the Administrative Code; (10) Required physician notification pursuant to rule 4729:1-3-03 of the Administrative Code; (11) Positive identification of the administering pharmacist; and (12) Identification of the person who provides permission to administer the dangerous drug pursuant to rule 4729:1-3-03 of the Administrative Code (either the individual or parent/guardian if under 18). **NOTE:** Records of administration may be maintained electronically (i.e. scanned) in accordance with the following: (1) All information shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user; (2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted; (3) Contains security features to prevent unauthorized access to the records; (4) Contains daily back-up functionality to protect against record loss.	
Does the pharmacy notify an individual's physician who prescribed the drug	A pharmacist administering dangerous drugs pursuant to section 4729.45 of the Revised Code must notify the physician who prescribed the drug within seven days that the drug has been	OAC 4729:1-3-03

within seven days of administration?	administered to the individual. Notification of the physician shall be conducted using one of the following methods that is capable of confirming delivery of the required notification: (1) Electronic mail; (2) Interoperable electronic medical records system; (3) Facsimile; (4) Electronic prescribing system; (5) Electronic pharmacy record system; (6) Documented verbal communication; or (7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.	
Does the pharmacist administering dangerous drugs maintain proof of successful completion of a required training course?	A pharmacist shall maintain proof of successful completion of a training course on file at the location(s) where the pharmacist administers dangerous drugs. **NOTE:** The course must be conducted by an accreditation council for pharmacy education (ACPE) accredited provider. Board staff will review documentation and document the training courses completed.	OAC 4729:1-3-03
Does the pharmacist administering dangerous drugs maintain certification to perform basic life-support procedures?	A pharmacist shall maintain proof of maintenance of certification to perform basic life-support procedures on file at the location(s) where the pharmacist administers dangerous drugs. A pharmacist administering dangerous drugs shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American Red Cross, American Heart Association or other training course approved by the Board. **NOTE:** The Board, by resolution, recognizes that CPR/AED or Basic Life Support certification provided by American Safety and Health Institute (ASHI) meets the basic-life support training requirements pursuant to sections 4729.41 and 4729.45 of the Revised Code.	OAC 4729:1-3-03

Diagnostic Laboratory Testing – Institutional Pharmacy

Question	Guidance	Rule/Law
Does the pharmacy perform laboratory testing?	A pharmacist, pharmacy intern, or certified pharmacy technician* may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met: (1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States Department of Health and Human Services (HHS), as a clinical laboratory through the CLIA; (2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and (3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs ensures and documents that all pharmacists conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner. ORC 4729.42 permits a pharmacist to order and administer diagnostic tests for COVID-19 and tests for COVID-19 antibodies. Additionally, this section of the Ohio Revised Code also authorizes a pharmacy intern and certified pharmacy technician to administer diagnostic tests for COVID-19 and tests for COVID-19 antibodies.	OAC 4729:1-3-01 OAC 4729:2-3-05 OAC 4729:3-3-05 ORC 4729.42

Temporary Absence of a Pharmacist in an Institutional Pharmacy – Institutional Pharmacy

Question	Description / Guidance	Law/Rule
Does the institutional facility permit the temporary absence of a pharmacist from the pharmacy?	A pharmacist practicing within an institutional facility may temporarily leave the pharmacy to engage in the practice of pharmacy within the institutional facility without closing the pharmacy and removing staff from the pharmacy if the practicing pharmacist can ensure there are adequate security measures and policies to maintain the security of the drug stock in the pharmacist's absence. If permitted, the institutional facility shall have written policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist. The policies and procedures shall include the authorized duties of pharmacy staff, the pharmacist's responsibilities for checking all work performed by staff, and the pharmacist's responsibility for maintaining the security and control of the drug stock. **IMPORTANT:** The rule is intended to address the absence of a pharmacist from a pharmacy that is operating. It does not permit non-pharmacist personnel to have unsupervised access to drug stock when an institutional pharmacy is closed. For example, a pharmacy technician cannot open a pharmacy or obtain drugs from an institutional pharmacy that is currently closed.	OAC 4729:5-9-02.10

Drug Repository Program – Institutional Pharmacy

Section 3715.87 of the Revised Code permits a licensed terminal distributor of dangerous drugs (TDDD) to operate a drug repository program. A drug repository program is a program that receives eligible donated drugs to provide to patients who have no reasonable financial means to pay for the drug or who are patients of a nonprofit clinic. For additional information on drug repository programs, visit: www.pharmacy.ohio.gov/repository

Question	Guidance	Rule/Law
Does this facility operate a drug repository program?	If yes, Board staff should verify the licensee meets the eligibility requirements. **NOTE:** Only a pharmacy, hospital, or nonprofit clinic may elect to participate in a drug repository program. "Nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons as defined in section 2305.234 of the Revised Code. "Nonprofit clinic" does not include a hospital as defined in section 3727.01 of the Revised Code, a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit. "Hospital" means an institution classified as a hospital under section 3701.07 of the Revised Code in which are provided to inpatients diagnostic, medical, surgical, obstetrical, psychiatric, or rehabilitation care for a continuous period longer than twenty-four hours or a hospital operated by a health maintenance organization. "Hospital" does not include a facility licensed under Chapter 3721. of the Revised Code, a health care facility operated by the department of mental health and addiction services or the department of developmental disabilities, a health maintenance organization that does not operate a hospital, the office of any private licensed health care professional, whether organized for individual or group practice, or a clinic that provides ambulatory patient services and where patients are not regularly admitted as inpatients. "Hospital" also does not include an institution for the sick that is operated exclusively for patients who use spiritual means for healing and for whom the acceptance of medical care is inconsistent with their religious beliefs, accredited by a national accrediting organization,	ORC 3715.871

	exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986, 100 Stat. 2085, 26 U.S.C.A. 1, as amended, and providing twenty-four hour nursing care pursuant to the exemption in division (E) of section 4723.32 of the Revised Code from the licensing requirements of Chapter 4723. of the Revised Code.	
FOR NON-ORALLY ADMINISTERED CANCER DRUGS: Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**GENERAL REQUIREMENTS (DOES NOT APPLY TO ORALLY ADMINISTERED CANCER DRUGS):** ▪ The drugs are in their original sealed and tamper-evident unit dose packaging. ▪ The packaging must be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. ▪ If the drugs were packaged by a pharmacy, the name of the pharmacy and any other pharmacy identifiers must be removed from the packaging prior to dispensing or personally furnishing to a recipient patient. This may be accomplished by removing the drug from the pharmacy packaging or by removing the name from the outside packaging of a multiple dose, unit dose packaging system. ▪ The drugs have been in the possession of a licensed healthcare professional, terminal distributor of dangerous drugs, or drug distributor and not in the possession of the ultimate user. ▪ The drugs must have an expiration date of six months or greater. ▪ The packaging must list the expiration date of the drug. ▪ The drugs must not have any physical signs of tampering or adulteration.	OAC 4729:5-10-04

	▪ The drug packaging must not have any physical signs of tampering. ▪ All confidential patient information must have been removed from the drug packaging. ▪ The drugs are not samples. ▪ The drugs are not controlled substances, except that controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction may be donated to a repository program.	
FOR ORALLY ADMINISTERED CANCER DRUGS: Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**REQUIREMENTS FOR ORALLY ADMINISTERED CANCER DRUGS:** ▪ The drugs do not have to be in an original sealed and tamper-evident unit dose packaging and may have been in possession of the ultimate user. ▪ The drugs must have an expiration date of six months or greater. ▪ The packaging must list the expiration date of the drug. ▪ The drugs must not have any physical signs of tampering or adulteration. **NOTE:** "Orally administered cancer drug" means either of the following: (1) An orally administered dangerous drug that is used to treat cancer or its side effects; or (2) An orally administered dangerous drug that is used to treat the side effects of a dangerous drug used to treat cancer.	OAC 4729:5-10-04
Does the repository program have standards and procedures to	The repository program shall develop and implement standards and procedures to determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing.	OAC 4729:5-10-04

determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing?	Board staff will review documentation containing standards and procedures. **NOTE:** This is a requirement for all drugs donated to the repository program.	
Are drugs donated by eligible persons?	The following may donate a dangerous drug, pursuant to the eligibility requirements of rule 4729:5-10-04 of the Administrative Code, to a pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program: (1) A licensed terminal distributor of dangerous drugs. (2) A licensed drug distributor (3) A person who was legally dispensed or personally furnished a dangerous drug pursuant to a patient-specific drug order. Except for orally administered cancer drugs, a person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through a terminal distributor of dangerous drugs. **NOTE:** A person who resides in an institutional facility and was legally dispensed a dangerous drug pursuant to a patient-specific order may elect to sign and date a donor form prior to donating a drug, which shall state "from this day forward I wish to donate all my remaining unused drugs that are eligible, pursuant to rule 4729:5-10-04 of the Administrative Code, to a drug repository program." Board staff will review documentation to verify donated drugs are coming from eligible persons.	OAC 4729:5-10-03
Are donor forms and records maintained in accordance with applicable rules?	Each donor must sign a form stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The donor form must be completed prior to any donation and include at least the following:	OAC 4729:5-10-06

	(1) The name of the person that was originally dispensed the drugs or the name of the terminal distributor of dangerous drugs or drug distributor that owns the drugs. (2) The signature of the donor, which may include the person designated by durable power of attorney, a guardian, an individual responsible for the care and wellbeing of a patient, or the signature of the responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor. (3) The date the form was signed. **NOTE:** A licensee may opt to have a patient sign a donor form in advance of receiving treatment in the event the patient discontinues treatment. Additionally, the following donor information must be documented on the donor form or an alternate record. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph. (1) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#). (2) The strength of the drug donated. (3) The quantity of the drug donated. (4) The date the drug was donated.	
Do the recipient forms comply with the requirements of Ohio law?	Prior to receiving donated drugs from a drug repository program, each recipient must sign a form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code. ORC 3715.872 (B) states: For matters related to donating, giving, accepting, or dispensing drugs under the drug repository program, all of the following apply:	OAC 4729:5-10-06

	(1) Any person, including a pharmacy, drug manufacturer, or health care facility, or any government entity that donates or gives drugs to the drug repository program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property. (2) A pharmacy, hospital, or nonprofit clinic that accepts or dispenses drugs under the program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct. (3) A health care professional who accepts or dispenses drugs under the program on behalf of a pharmacy, hospital, or nonprofit clinic, and the pharmacy, hospital, or nonprofit clinic that employs or otherwise uses the services of the health care professional, shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the health care professional, pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct. (4) The state board of pharmacy and the director of health shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the board or director constitutes willful and wanton misconduct.	
Does the repository charge a handling fee that complies with the limit set forth in rule?	A pharmacy, hospital, or nonprofit clinic may charge the recipient of a donated drug a handling fee up to twenty dollars to cover restocking and dispensing costs. If a drug repository program chooses to charge a handling fee, then the fees collected in any given year shall not exceed the program's total restocking and dispensing costs for that given year.	OAC 4729:5-10-07
Are all applicable records maintained in accordance with rule 4729:5-10-07?	Donor forms must be maintained for a minimum of three years in a readily retrievable manner by a terminal distributor of dangerous drugs, a distributor of dangerous drugs, or an institutional facility.	OAC 4729:5-10-07

	Recipient forms must be maintained for a minimum of three years in a readily retrievable manner by a pharmacy, hospital, or nonprofit clinic. Except for a licensee that donates to its own repository program, copies of invoices from the donor location must be maintained for a minimum of three years in a readily retrievable manner. The invoice must contain the following information: (1) The name and address of the donor location. (2) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#). (3) The strength of the drug. (4) The quantity of the drug. (5) The date the drug was sent to the pharmacy, hospital, or nonprofit clinic. (6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic. Records of personally furnishing and administration are maintained in accordance with OAC 4729:5-11-04. Board staff will review records to verify compliance.	

Temporary Removal of Drugs – Institutional Pharmacy

Question	Description / Guidance	Law/Rule
Does the licensee engage in the temporary off-site storage of dangerous drugs?	This may occur in the following three scenarios: 1. A licensed health professional authorized to prescribe drugs may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. **NOTE:** This would only apply to pharmacists who are practicing under a consult agreement. 2. A person authorized to personally furnish or dispense naloxone in accordance with a physician approved protocol The Board approved a resolution allowing indefinite off-site storage of naloxone at non-licensed locations. 3. A licensed health care professional (pharmacist or pharmacy intern), in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients.	OAC 4729:5-3-13
Are drugs removed from the terminal distributor returned within 24-hours?	The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the Board. The Board has approved the following extensions to this provision: 1. Naloxone to be personally furnished in accordance with a physician approved protocol. The Board approved a resolution allowing indefinite off-site storage of naloxone at non-licensed locations. 2. Dangerous drugs used by dental anesthesiologists. *All dangerous drugs temporarily removed from a licensed terminal distributor of dangerous drugs by a dental*	OAC 4729:5-3-13

	anesthesiologist to treat current or prospective patients shall be returned to the licensed terminal distributor of dangerous drugs no later than seventy-two hours. (R-2017-382)	
Does the person temporarily removing drugs from a licensed location maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the licensed location?	The person temporarily removing drugs from a licensed location shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. "Direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.	OAC 4729:5-3-13
If direct supervision is not provided, are the drugs that are temporarily removed securely stored at temperatures and conditions which will ensure the integrity of the drugs?	If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/ NF and/or the manufacturer's or distributor's labeling. Securely stored means that the drugs are secured in a manner that prevents unauthorized access. This may include the following: a locked drawer, filing cabinet, locked room, safe, lock box, or any other method that can be locked to prevent unauthorized access.	OAC 4729:5-3-13

Pharmacist Consult Agreements – Institutional Pharmacy

Question	Guidance	Law/Rule
Does the consult agreement contain all the required information?	**NOTE:** "Practitioner" includes all of the following: (1) Physicians (MD/DO); (2) Physician assistants, if entering into a consult agreement is authorized by one or more supervising physicians; (3) Clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), or certified nurse practitioners (CNPs), if entering into a consult agreement is authorized by one or more collaborating physicians. **NOTE:** This does not include CRNAs. A consult agreement must contain all the following: (1) Identification of the Ohio-licensed practitioners(s) and pharmacist(s) authorized to enter into the agreement. This may include: (a) Individual names of practitioners and pharmacists; (b) Provider or pharmacist practice groups; or (c) Identification based on institutional credentialing or privileging. (2) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid. (3) A description of the drugs or drug categories managed as part of the agreement. (4) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement. (5) A description of the types of diagnostic tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate to	ORC 4729.39 OAC 4729:1-6-02

	the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement. (6) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification. (7) A description of how communication between a managing pharmacist and practitioner acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement. The agreement may include a requirement that a managing pharmacist send a consult report to each consulting practitioner. (8) A provision that allows a practitioner to override a decision made by the managing pharmacist when appropriate. (9) A quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement. (10) A description of a continuous quality improvement (CQI) program used to evaluate the effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement. (11) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria. (12) An effective date and expiration date. (13) The agreement shall be signed by the primary practitioners, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:	

	(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs. Board staff will ask the licensee to review current agreements to determine compliance.	
Is a pharmacist able to manage controlled substances as part of a consult agreement?	If yes, a pharmacist shall be required to maintain a valid controlled substance prescriber registration issued by the State Board of Pharmacy by submitting an application and a valid consult agreement (that includes all the requirements listed in OAC 4729:1-6-02), in a manner determined by the board, authorizing the pharmacist to prescribe controlled substances. Additionally, a pharmacist managing controlled substances shall also obtain and maintain a valid registration with the U.S. Drug Enforcement Administration (D.E.A.). For more information on obtaining a controlled substance registration, visit: www.pharmacy.ohio.gov/consult **REMINDER:** Per federal law, a pharmacist may not prescribe controlled substances for the treatment of opioid use disorder.	OAC 4729:1-6-02

Automated Pharmacy Systems – Institutional Pharmacy

"Automated pharmacy system" means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records.

"Automated pharmacy system" does not include an "automated drug storage system" utilized by institutional facilities pursuant to Chapter 4729:5-9 of the Administrative Code or other locations licensed as terminal distributors of dangerous drugs.

"Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

> *In the case of an automated pharmacy system that dispenses dangerous drugs without the final association by a pharmacist, the system shall capture the positive identification of the pharmacist authorizing the patient-specific prescription in the system prior to its dispensation.*
>
> *Nothing in this paragraph shall prohibit an automated pharmacy system from being utilized to restock an automated drug storage system utilized by institutional facilities pursuant to Chapter 4729:5-9 of the Administrative Code or other locations licensed as terminal distributors of dangerous drugs.*

"Tamper evident" means a package, storage container or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

REMINDER: An automated pharmacy system shall be approved by the Board prior to its implementation by the terminal distributor of dangerous drugs. For more information on the approval process, visit: www.pharmacy.ohio.gov/APSapprove

Question	Guidance	Law/Rule
Is the automated pharmacy system located on the premises of a terminal distributor of dangerous drugs?	An automated pharmacy system shall be located on the premises of a licensed terminal distributor of dangerous drugs.	OAC 4729:5-3-17
Does the licensee maintain the required documentation for all automated pharmacy systems?	A terminal distributor of dangerous drugs operating an automated pharmacy system shall maintain the following documentation on-site in a readily retrievable manner: (1) The manufacturer's name and model;	OAC 4729:5-3-17

	(2) A description of how the automated pharmacy system is used; and (3) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction.	
FOR AUTOMATED PHARMACY SYSTEMS THAT DO NOT REQUIRE THE PHARMACIST TO CONDUCT THE FINAL ASSOCIATION OF THE DRUG AS PART OF THE DISPENSING PROCESS: Does the licensee have a quality assurance program to determine continued appropriate use of the automated pharmacy system?	**FOR AUTOMATED PHARMACY SYSTEMS THAT DO NOT REQUIRE A PHARMACIST TO CONDUCT THE FINAL ASSOCIATION OF THE DRUG AS PART OF THE DISPENSING PROCESS:** ▪ The terminal distributor of dangerous drugs shall implement a quality assurance program to determine continued appropriate use of the automated pharmacy system. ▪ The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed or ordered. ▪ At a minimum, the quality assurance program shall consist of a review of at least five percent of all dispensed prescriptions over the daily operational hours of the automated pharmacy system. REMINDER: As part of the Board's approval process, the responsible person shall compile metrics, using a form developed by the Board, documenting the performance of the system during this period. Unless otherwise approved by the Board, the accuracy metrics during the forty-five day pharmacy review period shall be no less than ninety-nine and nine hundred eighty-five thousandths (99.985) percent. ***For more information on the approval process, visit: www.pharmacy.ohio.gov/APSapprove***	OAC 4729:5-3-17
FOR AUTOMATED PHARMACY SYSTEMS THAT	**FOR AUTOMATED PHARMACY SYSTEMS THAT DO NOT REQUIRE A PHARMACIST TO CONDUCT THE FINAL**	OAC 4729:5-3-17

DO NOT REQUIRE THE PHARMACIST TO CONDUCT THE FINAL ASSOCIATION OF THE DRUG AS PART OF THE DISPENSING PROCESS: Does the licensee have documentation of the selection of an incorrect drug by an automated pharmacy system?	**ASSOCIATION OF THE DRUG AS PART OF THE DISPENSING PROCESS:** If the system selects an incorrect drug, the terminal distributor shall immediately institute a one-hundred percent pharmacist verification of all drugs dispensed. The one-hundred percent verification procedure shall continue until such time as the terminal distributor can document that the cause of the error has been determined and addressed and that the system is no longer making errors.	
Are automated pharmacy systems under the appropriate supervision of a pharmacist?	Except for an automated pharmacy system in a long-term care facility, a pharmacist shall be physically present at the terminal distributor of dangerous drugs to provide supervision of the automated pharmacy system.	OAC 4729:5-3-17
Are automated pharmacy systems stocked by appropriate personnel?	A registered or certified pharmacy technician, pharmacy technician trainee, pharmacy intern, or nurse licensed in accordance with chapter 4723. of the Revised Code may stock an automated pharmacy system provided that: (1) The container, canister, or other dangerous drug storage device being stocked by the technician, trainee, intern, or nurse is tamper-evident and is verified by a pharmacist and documented using positive identification. **NOTE:** Pharmacist verification requirements listed in #1 above do not apply if all the following are met: (a) Verification is being conducted by a registered or certified pharmacy technician, pharmacy intern, or nurse; and (b) The container, canister, or other dangerous drug storage device being stocked is properly identified by bar code or other such secondary information system, which has been verified by a pharmacist to ensure the proper drug is being placed into and recognized as the correct drug by the system.	OAC 4729:5-3-17

	(2) The licensee utilizes a bar code, electronic verification, or similar verification process that includes an initial quality assurance validation by a pharmacist followed by a quarterly quality assurance review by a pharmacist. (3) The positive identification of the individual stocking the system is documented. (4) A pharmacist is fully responsible for all activities conducted by the technician, trainee, intern, or nurse. (5) A pharmacist must be immediately available to answer questions or discuss the stocking of an automated pharmacy system. (6) A registered pharmacy technician or pharmacy technician trainee shall be acting under the personal supervision of a pharmacist (e.g., only certified pharmacy technicians and nurses may stock an automated pharmacy system located in a long-term care facility).	
Does the automated pharmacy system meet the security requirements of the rule?	The automated pharmacy system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and include safeguards to detect the diversion of dangerous drugs. This shall include the use of tamper-evident containers, canisters, or other storage devices for use in long-term care facilities.	OAC 4729:5-3-17
FOR LONG-TERM CARE FACILITIES ONLY: Does the automated pharmacy system comply with 21 CFR 1301.27?	Per 21 CFR 1301.27: (1) A retail pharmacy may install and operate automated dispensing systems, as defined in §1300.01 of this chapter, at long term care facilities, under the requirements of §1301.17. No person other than a registered retail pharmacy may install and operate an automated dispensing system at a long-term care facility. (2) Retail pharmacies installing and operating automated dispensing systems at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated dispensing systems are located. If more than one registered retail pharmacy operates automated dispensing systems	OAC 4729:5-3-17 → 21 CFR 1301.27

	at the same long term care facility, each retail pharmacy must maintain a registration at the long term care facility. (3) A registered retail pharmacy applying for a separate registration to operate an automated dispensing system for the dispensing of controlled substances at a long term care facility is exempt from application fees for any such additional registrations.	
Does the system maintain all records of drug distribution in accordance with OAC 4729:5-9-02.3?	The records kept by the automated pharmacy system shall comply with the applicable record keeping requirements of division 4729:5 of the Administrative Code and shall also capture all events involving the contents of the automated pharmacy system. For institutional pharmacies, the rule requires compliance with the provisions in OAC 4729:5-9-02.3. **REMINDER:** All records maintained in accordance with this rule, including documentation of quality assurance metrics, shall be readily retrievable and maintained for period of three years.	OAC 4729:5-3-17

Institutional Central Fill Pharmacies – Originating Pharmacy

This section applies to originating institutional pharmacies located in Ohio. *As a reminder:*

- *"Originating pharmacy" means an institutional pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill medication order.*

- *"Central fill pharmacy" means institutional pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a medication order. An institutional central fill pharmacy may be used to replenish automated drug storage systems and automated pharmacy systems. An institutional central fill may also compound patient-specific orders in accordance with OAC 4729:7-2.* ***IMPORTANT: Central fill pharmacies must comply with all applicable institutional pharmacy requirements.***

Question	Guidance	Law/Rule
If not owned by the same owner as the central fill pharmacy, does the originating pharmacy have a written contract with the central fill pharmacy?	The central fill pharmacy shall either have the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law, rules and regulations. Licensees must ensure that the central fill pharmacy is appropriately licensed as a terminal distributor of dangerous drugs.	OAC 4729:5-9-02.13
Does the central fill pharmacy have access to the required files to dispense or process medication orders/prescriptions?	The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.	OAC 4729:5-9-02.13
Does the originating pharmacy comply with the patient profile requirements prior to sending a prescription to the central pharmacy?	The originating pharmacy shall comply with the minimum required information for a patient profile pursuant to rule 4729:5-9-02.5 of the Administrative Code prior to sending a medication order to the central fill pharmacy.	OAC 4729:5-9-02.13

Do prescription labels contain the required information?	The prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. If applicable, the date on which the medication order was dispensed shall be the date on which the central fill pharmacy filled the order.	OAC 4729:5-9-02.13
Does the originating pharmacy maintain all original medication orders?	The originating pharmacy shall maintain the original of all medication orders received for purposes of filing and record keeping as required by state and federal law, rules, and regulations.	OAC 4729:5-9-02.13
Does the originating pharmacy have a quality assurance program?	The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems, and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.	OAC 4729:5-9-02.13

Institutional Central Fill Pharmacies – Central Fill Pharmacy

This section applies to in-state institutional central fill pharmacies that service originating pharmacies located in Ohio. For more information about non-resident central fill pharmacies (e.g., out-of-state), the Board developed the following non-resident pharmacy inspection guide: www.pharmacy.ohio.gov/NRPinspect.

As a reminder:

- *"Originating pharmacy" means an institutional pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill medication order.*

- *"Central fill pharmacy" means an institutional pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a medication order. A central fill pharmacy may be used to replenish automated drug storage systems and automated pharmacy systems. An institutional central fill may also compound patient-specific orders in accordance with OAC 4729:7-2.* ***IMPORTANT: Central fill pharmacies must comply with all applicable institutional pharmacy requirements.***

Question	Guidance	Law/Rule
If not owned by the same owner as the originating pharmacy, does the central fill pharmacy have a written contract with the originating pharmacy?	The central fill pharmacy shall either have the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law, rules and regulations. Licensees must ensure that the originating pharmacy is appropriately licensed as a terminal distributor of dangerous drugs.	OAC 4729:5-9-02.13
Does the central fill pharmacy maintain a record of all originating pharmacies?	The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and, if applicable, drug enforcement administration registration number, for which it processes a request for the filling or refilling of a medication order received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.	OAC 4729:5-9-02.13
Does the central fill pharmacy have access to the required files to dispense or process	The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient	OAC 4729:5-9-02.13

medication orders/prescriptions?	information necessary or required to dispense or process the medication order.	
Does the central fill pharmacy have a quality assurance program?	The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems, and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.	OAC 4729:5-9-02.13
Do prescription labels contain the required information?	The prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. If applicable, the date on which the medication order was dispensed shall be the date on which the central fill pharmacy filled the order.	OAC 4729:5-9-02.13

Part II - Institutional Facility - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code

CFR = Code of Federal Regulations / USC = United States Code

*** = Notes a Substantive Change from Current Institutional Pharmacy & Facility Requirements (REMINDER: New Institutional Rules Effective 7/1/2021)**

Licensing, Responsible Person & DEA Registration – Institutional Facility

Question	Description / Guidance	Law/Rule
Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?	Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.	OAC 4729:5-2-03
Does the responsible person match what is indicated in eLicense?	A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified within ten days of the effective date of the appointment of the new responsible person. A change of responsible person form is available on the Board's website: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.	OAC 4729:5-2-01
Does the licensee have a valid registration issued by the Drug Enforcement Administration?	Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22 through 1301.26. The certificate of registration must be maintained at the registered location and kept available for official inspection. **NOTE:** Does not apply to pharmacies or facilities that apply for a Category II license as a terminal distributor of dangerous drugs.	21 CFR 1301.11

Contingency Drugs – Institutional Facility

"Contingency drugs" are a supply of non-patient specific dangerous drugs which may be required to meet the therapeutic needs of patients or staff when either apply: (1) The institutional facility's on-site pharmacy is closed or otherwise unavailable to provide pharmacy services; (2) The institutional facility does not have an on-site pharmacy.

REMINDER: Per OAC 4729:5-9-03.2 (F), access to controlled substances shall be restricted to health care professionals authorized pursuant to the Revised Code to administer controlled substances as part of the professional's scope of practice.

Question	Guidance	Law/Rule
If an institutional pharmacy serves as the license holder for the institutional facility (e.g., pharmacy servicing an institution), does the facility maintain an executed contract or agreement outlining services provided and responsibilities of each party?	An institutional pharmacy may serve as the license holder for an institutional facility if the institutional pharmacy and institutional facility maintain an executed contract or agreement outlining the services to be provided and the responsibilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state law, rules, and regulations. The executed contract or agreement shall be maintained in a readily retrievable manner.	OAC 4729:5-9-03.1
Does the facility designate personnel authorized to access the contingency stock?	The entity holding the terminal distributor of dangerous drugs license for an institutional facility's contingency stock shall designate personnel who are authorized to access to the contingency drug supply. Licensees should be able to demonstrate this by providing policies and procedures on contingency drug access.	OAC 4729:5-9-03.1
Does the facility have a process to determine the drugs that are to be included in the contingency drug supply?	The entity holding the terminal distributor of dangerous drugs license for an institutional facility's contingency stock shall determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included in the contingency drug supply.	OAC 4729:5-9-03.1

Does the facility have procedures for the inspection of contingency drug inventory to ensure proper utilization and replacement of the drug supply?	The entity holding the terminal distributor of dangerous drugs license for an institutional facility's contingency stock shall develop and implement procedures for the inspection of the contingency drug inventory to ensure proper utilization and replacement of the drug supply. Licensees should be able to demonstrate this by providing procedures and documentation on inspection of the contingency drug inventory.	OAC 4729:5-9-03.1

Security, Control, and Storage of Dangerous Drugs and Prescription Blanks – Institutional Facility

REMINDER: Per OAC 4729:5-9-03.2 (F), access to controlled substances shall be restricted to health care professionals authorized pursuant to the Revised Code to administer controlled substances as part of the professional's scope of practice.

Question	Guidance	Law/Rule
Are non-controlled dangerous drug emergency or contingency kits maintained by the facility properly secured?	Non-controlled dangerous drug emergency or contingency kits may be secured using a tamper-evident method. Drugs stored using a tamper-evident method shall be routinely inspected to detect unauthorized access in accordance with a policy developed by the facility. The policy shall be made readily retrievable. **REMINDER:** "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.	OAC 4729:5-9-03.2
Except for emergency or contingency kits, are all non-controlled dangerous drugs (see question above), including those dispensed by an institutional pharmacy to inpatients, shall be stored in a secure area to deter and detect unauthorized access?	Except for emergency or contingency kits, all non-controlled dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, shall be stored in a secure area to deter and detect unauthorized access. **IMPORTANT:** This provision does not apply to non-controlled dangerous drugs used as part of an emergency or contingency kit (see question above for those requirements).	OAC 4729:5-9-03.2
FOR CONTROLLED SUBSTANCES NOT STORED AS PART OF AN AUTOMATED DRUG STORAGE SYSTEM: Do controlled substances meet the security and storage requirements in accordance with the rule?	All controlled substance dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, maintained in areas outside of the institutional pharmacy that are not stored as part of an automated drug storage system, shall meet the following requirements: (1) The drugs shall be a securely locked in a substantially constructed cabinet or safe to deter and detect unauthorized access. (2) At every change of shift, a reconciliation shall be conducted by both the departing and incoming licensed health care professional	OAC 4729:5-9-03.2

	responsible for the security and control of the drugs in the area in which they are stored and shall include the following: (a) A physical count and reconciliation of the controlled substances and proof-of-use sheets or electronic records to ensure the accountability of all doses; (b) An inspection of the packaging to ensure its integrity; (c) The positive identification of the persons conducting the reconciliation; and (d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person's designee. (3) All controlled substances shall be packaged in tamper-evident containers, where unit-of-use packaging is not available. **NOTE:** A physical count and reconciliation is not required for emergency or contingency drug kits that are also secured using a tamper-evident method. **MEDICAL MARIJUANA STORAGE:** Medical marijuana obtained from the Ohio Medical Marijuana Control Program shall be secured as any other schedule II controlled substance. Medical marijuana must be stored in its original packaging, as required by OMMCP rules. The facility may opt to utilize a tamper-evident packaging (e.g., heat seal bag, tamper evident tape or label) in accordance with facility policy, but such a measure is not required.	
FOR CONTROLLED SUBSTANCES STORED AS PART OF AN AUTOMATED DRUG STORAGE SYSTEM: Do controlled substances meet the security and storage requirements in accordance with the rule?	All controlled substance dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, maintained in areas outside of the institutional pharmacy that are stored in an automated drug storage system shall meet the following requirements: (1) Access to all controlled substances stored in automated drug storage systems shall be limited to one drug and strength at a time.	OAC 4729:5-9-03.2

	(2) For automated drug storage systems that cannot limit access to one dose at a time, authorized personnel shall conduct a blind count each time a controlled substance is removed from the system. (3) The automated drug storage system shall be securely locked and substantially constructed to deter and detect unauthorized access. (4) The system shall document the positive identification of every person accessing the system and shall record the date and time of access. (5) At least annually, the responsible person shall cause a reconciliation of all controlled substances within an automated drug storage system to be conducted. The reconciliation shall include the following: (a) A physical count and reconciliation of the controlled substances to ensure the accountability of all doses; (b) An inspection of the packaging to ensure its integrity; (c) The positive identification of the persons conducting the reconciliation; and (d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person's designee. **NOTE:** "Blind count" means a physical inventory taken by a person authorized by the institutional facility's responsible person who performs a physical inventory without knowledge of or access to the quantities currently shown on electronic or other inventory systems.	
Are areas where dangerous drugs are stored dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?	All areas where dangerous drugs are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.	OAC 4729:5-9-03.2

Does the facility have a policy in place to prevent hypodermics from theft or acquisition by any unauthorized person?	In accordance with section 3719.172 of the Revised Code, an institutional facility shall develop and implement policies to prevent hypodermics from theft or acquisition by any unauthorized person.	OAC 4729:5-9-03.2
Does the facility have a policy governing the storage and access to uncompleted prescription blanks?	Uncompleted prescription blanks shall be secured when not in use and access shall be limited to personnel authorized in policy by the institutional facility.	OAC 4729:5-9-03.2

Automated Drug Storage Systems – Institutional Facility

"Automated drug storage system" means a mechanical system used for the secure storage of dangerous drugs used as floor stock or contingency drugs outside of an institutional pharmacy that collects, controls, and maintains transaction information and records.

Substantive Change: The rule on automated drug storage systems (OAC 4729:5-9-03.4) includes specific time-out requirements.

Question	Guidance	Law/Rule
Do automated drug storage systems utilized by the institutional facility comply with the electronic timeout requirements of the rule?	The computer program used to access all drugs within the automated drug storage system shall have an electronic timeout of sixty seconds of inactivity. **IMPORTANT:** This provision does not apply to automated drug storage systems used exclusively for administering anesthesia drugs that are under the immediate supervision of a licensed healthcare provider authorized to administer such drugs.	OAC 4729:5-9-03.4
Do automated drug storage systems utilized by the institutional facility exclusively for administering anesthesia drugs comply with the electronic timeout requirements of the rule?	For an automated drug storage system used exclusively for administering anesthesia drugs that is under the immediate supervision of a licensed healthcare provider authorized to administer such drugs, the computer program used to access all drugs within the automated drug storage system shall have an electronic timeout of no more than sixty minutes of inactivity, unless an alternative method to ensure the security of the drug stock is approved by the Board.	OAC 4729:5-9-03.4
Does the institutional facility have a policies and procedures for automated drug storage systems that comply with the requirements of the rule?	The institutional facility shall develop and implement policies and procedures for all automated drug storage systems that include the following: (1) Provide for a written or electronic record documenting access to the automated drug storage system. Such record shall include the names, titles, and positive identification of all personnel accessing medications, date and time of access, the name and quantity of drugs obtained, and the name of the patient. (2) Provide security controls to prevent diversion of the drugs.	OAC 4729:5-9-03.4

	(3) Develop policies and procedures to track access to emergency override access keys. (4) Provide procedures for the inspection of the systems to ensure proper utilization and replacement of the drug supply. (5) If override medications are utilized, the institutional facility shall develop and implement a policy that describes the types of medication overrides that will be reviewed for appropriateness and the frequency of the reviews. **NOTE:** All required policies and procedures shall be maintained in a readily retrievable manner.	

Temperature Monitoring – Institutional Facility

Substantive Change: New rule includes minimum requirements for temperature monitoring and temperature excursions.

Question	Guidance	Law/Rule
Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?	The facility must maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained: (1) Temperature logs with, at a minimum, daily observations; or (2) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion. Records of temperature control monitoring for refrigerators and freezers used for the storage of drugs must include any of the following: (1) For temperature logs, either: (a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or (b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded. (2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion. **REMINDER:** Temperature records must be maintained for a period of three years.	OAC 4729:5-9-03.2
Does the facility have a policy to respond to any out-of-range individual temperature readings or	The facility must develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.	OAC 4729:5-9-03.2

excursions to ensure the integrity of stored drugs?	The policy must be made available for review upon inspection and should describe, at a minimum, all the following: ▪ The actions to be taken in the event of temperature excursions outside the labelled storage conditions. ▪ The process for appropriately investigating, documenting, and assessing temperature excursions outside the labelled storage conditions to ensure the integrity of the drug stock (for example, stability data or technical justification).	
Are refrigerators and/or freezers used for the storage of drugs free of food or beverage products?	The facility is required to develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs. The policy must be made available for review upon inspection and all refrigerators and freezers used for drug storage will be examined to ensure compliance. **NOTE:** Facilities may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures.	OAC 4729:5-9-03.2

Drug Administration and General Record Keeping – Institutional Facility

Question	Guidance	Law/Rule
Does the institutional facility maintain the required drug administration records?	An institutional facility shall maintain a record of all dangerous drugs administered to patients that includes all the following information: (1) Name of the patient; (2) Name, strength, dosage form, route of administration, and quantity of the dangerous drugs administered; (3) Date and time the dangerous drugs were administered; (4) The positive identification of the person removing the dangerous drug for patient administration; and (5) Positive identification of the personnel administering the drug.	OAC 4729:5-9-03.3
If applicable, does the institutional facility document the positive identification of the person removing controlled substances from secure location for patient administration?	If removed from a secured location, the positive identification of the person removing the controlled substance for patient administration shall be documented.	OAC 4729:5-9-03.3
Does the facility document orders for drug administration for drugs administered by healthcare providers who are not prescribers?	Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of dangerous drugs shall be documented using positive identification. All orders for drugs for inpatients shall include the following: (1) Name of patient; (2) Name, strength, and dosage form of drug;	OAC 4729:5-9-03.3

	(3) Directions for use, including route of administration; (4) Date prescribed; and (5) The ordering prescriber's positive identification.	
Does the facility comply with the record keeping requirements for drugs that are personally furnished from the facility?	Records of dangerous drugs personally furnished at an institutional facility shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drug is personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.	OAC 4729:5-9-03.3
Does facility comply with the record keeping requirements for non-patient specific drugs received by the facility?	Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.	OAC 4729:5-9-03.3
Does the facility's record keeping system contain security features to prevent unauthorized access to the records?	All institutional pharmacy records required in accordance with this chapter shall be maintained under appropriate supervision and control to restrict unauthorized access. This access may include a username and password, security question, pin, fingerprint, etc.	OAC 4729:5-9-03.3
Does the facility maintain records on-site and in a readily retrievable manner?	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 4729:5-9-03.3
If maintaining records off-site, has the licensee submitted proper notification to the Board?	A terminal distributor intending to maintain records at a location other than the location licensed by the State Board of Pharmacy must notify the Board (see page 10 of this guide). **NOTE:** Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.	OAC 4729:5-9-03.3

Does the licensee maintain records electronically in compliance with rule 4729:5-9-03.3 of the Ohio Administrative Code?	All records maintained by the institutional facility may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following: (1) Complies with the requirements of this rule; (2) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user; (3) Contains security features, such as unique user names and passwords, to prevent unauthorized access; and (4) Contains daily back-up functionality to protect against record loss.	
Are protocols being used to administer dangerous drugs?	Protocols may only be used as follows: (1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks; (2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases; (3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns;	OAC 4729:5-3-12

	(4) The administration of erythromycin for prevention of ophthalmia neonatorum; and (5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729 of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention. If yes, Board staff will review protocols to ensure they meet the allowed uses and comply with the following: (1) Includes a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification; and date of signature. (2) Are maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.	
Are pre-printed orders used for the administration of dangerous drugs?	A "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. If yes, Board staff will confirm the following: (1) A prescriber completes an assessment and make an initial diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. (2) The order contains the following information: the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as calculations and patient physiologic data; signature of the prescriber or some other form of positive identification of the prescriber; and date of signature.	OAC 4729:5-3-12

Drug Purchases and Online Sales – Institutional Facility

Question	Guidance	Law/Rule
Does the licensee maintain complete and accurate records of drugs purchased?	Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. Records must be maintained for a period of three years.	OAC 4729:5-9-03.3
Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?	Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale (including samples), the terminal distributor shall query the board's online roster (elicense.ohio.gov) to confirm any of the following: (1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code (i.e. wholesaler, manufacturer, repackager, outsourcing facility or 3PL); or (2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code (i.e. pharmacies or other terminal distributors). If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.	OAC 4729:5-3-04
Does the licensee sell or offer to sell dangerous drugs on its website?	If yes, Board staff will confirm that the licensee is using a pharmacy or service that maintains accreditation as a Verified Internet Pharmacy Practice Site (VIPPS) from the National Association of Boards of Pharmacy. A list of VIPPS-Accredited sites can be accessed here: https://nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/	OAC 4729:5-3-08

	NOTE: This requirement does not apply to a licensee using online services to distribute naloxone pursuant to a physician protocol.	

Theft or Significant Loss of Drugs and Drug Documents – Institutional Facility

Question	Guidance	Law/Rule
Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?	A licensee is required to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or significant loss to the Board using the online portal within thirty days following the discovery of such theft or significant loss. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02
Has the licensee experienced any theft or loss of uncompleted prescription blank(s), written prescription order(s) not yet dispensed, or D.E.A. controlled substance order forms in the past twenty-four months?	A licensee is required to report, immediately upon discovery, to the Board any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or loss to the Board using the online portal within thirty days following the discovery of such theft or loss. **NOTE:** Unlike dangerous drugs, drug documents do not have a significant loss threshold. Therefore, all losses (in addition to thefts) must be reported to the Board. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02

Controlled Substance Inventory – Institutional Facility

Question	Guidance	Law/Rule
Does the licensee conduct an annual inventory of controlled substances?	All Category III licensees must complete an annual inventory **even if drugs are not on-site** (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory. Each inventory must contain a complete and accurate record of all controlled substances on hand the date the inventory is conducted. The inventory must have the names of the controlled substances, each finished form, the number of units, and/or the number of commercial containers of each finished form. If listed in Schedules I or II, make an exact count or measure of the contents. If listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case the licensee must make an exact count of the contents. **NOTE:** The annual inventory may be taken on any date which is within thirteen months of the previous inventory date. Board staff will review records to determine compliance.	OAC 4729:5-3-07
How does the licensee monitor its inventory of controlled substances?	Board staff will review and document how the licensee monitors its inventory of controlled substances (e.g. daily count, perpetual inventory, etc.).	

Drug Disposal – Institutional Facility

This section does not apply to pharmacies operating drug take back programs. See "Drug Collection Receptacles" section.

Question	Guidance	Rule/Law
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 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. **REMINDER:** The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method by any person legally authorized under Chapters 3719. and 4729. of the Revised Code and this division of the Administrative Code to possess controlled substance dangerous drugs. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable. A record of such destruction shall be	OAC 4729:5-3-01

	made in accordance with 21 C.F.R. 1304 and shall be maintained for a minimum of three years from the date of destruction and made readily retrievable to the Board of Pharmacy upon request. 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. If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee. 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 4729:5-9-03.3
Does the licensee maintain complete and accurate records of the disposal of an unused portion of a controlled substance resulting from administration to a patient?	If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal. **NOTE:** The 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.	OAC 4729:5-9-03.3
Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs?	Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, the positive identification of the licensed health care professional that performed the disposal.	OAC 4729:5-9-03.3

	NOTE: This does not apply to non-controlled wastage from administration or drug compounding. For non-controlled drugs, such documentation is not required. All records must be maintained for a period of three years.	

Drug Collection Receptacles – Institutional Facility

REMINDER: *A pharmacy the offers to collect non-controlled substances only must still comply with the federal requirements [See OAC 4729:10-1-02(B)].*

Question	Guidance	Rule/Law
Does the facility operate a drug take back program (i.e. collection receptacle)?	If yes, Board staff will review documentation to confirm the licensee has modified its Drug Enforcement Administration registration to become an "authorized collector." Modification to a DEA registration may also be confirmed online: www.pharmacy.ohio.gov/collectors. 21 CFR 1317.40 requires a pharmacy that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with 21 CFR 1301.51. **NOTE:** Authorized hospitals/clinics with an on-site pharmacy and retail pharmacies may maintain collection receptacles at long-term care facilities. Clinics that have a dispensing room that is not operated by a pharmacist are not considered entities with an on-site pharmacy.	21 CFR 1317.40 [as required by OAC 4729:10-1-02 (A)]
Is the receptacle located in compliance with DEA regulations?	**For Hospitals ONLY:** A collection receptacle must be located in an area regularly monitored by employees and shall not be located in the proximity of any area where emergency or urgent care is provided. **For Long-Term Care Facilities ONLY:** A collection receptacle must be located in a secured area regularly monitored by long-term care facility employees.	21 CFR 1317.75 [as required by OAC 4729:10-1-02 (A)] 21 CFR 1317.80 [as required by OAC 4729:10-1-02 (A)]
Does the collection receptacle meet the required design specifications?	A controlled substance collection receptacle shall meet the following design specifications: (1) Be securely fastened to a permanent structure so that it cannot be removed. (2) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner.	21 CFR 1317.40 [as required by OAC 4729:10-1-02 (A)] OAC 4729:10-1-02

	(3) The outer container shall include a small opening that allows contents to be added to the inner liner but does not allow removal of the inner liner's contents. The small opening in the outer container of the collection receptacle must be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed). (4) The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances. The signage must also indicate that the following are not acceptable: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). (5) The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.	
Are sealed inner liners containing drugs collected by a pharmacy stored in a manner consistent with the security requirements for Schedule II controlled substances?	21 CFR 1317.05 requires all inner liners and contents to be securely stored at the collector's registered location in a manner consistent with rules for Schedule II controlled substances until prompt destruction can occur. 21 CFR 1301.75 states that sealed inner liners shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access. **IMPORTANT:** Sealed inner liners may only be stored at the long-term care facility for *up to three business days* in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer.	21 CFR 1317.05 [as required by OAC 4729:10-1-02 (A)]

Return to Stock – Institutional Facility

IMPORTANT: *Drugs dispensed for patients, which have not been dispensed or personally furnished directly to the ultimate user, that require further manipulation prior to administration may be re-dispensed by a pharmacy [OAC 4729:5-3-16 (A)(4)].*

Question	Guidance	Rule/Law
Does the institutional pharmacy return dispensed drugs to stock shelves?	No drug that has been dispensed pursuant to a prescription or personally furnished by a prescriber and has left the physical premises of the terminal distributor of dangerous drugs shall be returned to the terminal distributor or dispensed or personally furnished again, except as follows: (1) Drugs dispensed for inpatients or personally furnished to inpatients provided that: (a) The drugs are packaged in unopened, single-dose or tamper-evident containers; and (b) The drugs have not been in the possession of the ultimate user. (2) Drugs dispensed for inpatients in accordance with rule 4729:5-9-02.11 of the Administrative Code (see Customized Patient Medication Packaging section).	OAC 4729:5-3-16

Drug Compounding – Institutional Facility

Question	Guidance	Rule/Law
Is the licensee engaged in either sterile or non-sterile drug compounding on site?	If engaged in drug compounding, the licensee may be subject to an additional inspection by a Board Specialist (i.e., pharmacist). For more information on pharmacy compounding, visit: www.pharmacy.ohio.gov/compounding For more information about prescriber compounding, visit: www.pharmacy.ohio.gov/prescribercompound	OAC 4729:7

Expired/Adulterated Drugs – Institutional Facility

Question	Guidance	Rule/Law
Are multi-dose vials properly labeled?	Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.	OAC 4729:5-9-03.2
Are there expired/adulterated drugs present in the licensee's active drug stock?	Board staff will conduct a check for expired drugs/adulterated drugs, including, but not limited to, the following: ▪ Expired drugs in common stock areas. ▪ Multidose vials that have been opened/punctured and exceed twenty-eight days from the date of puncture, unless otherwise specified by the manufacturer. ▪ Adulterated drugs in common stock areas (partial vials of single-dose injectable drugs). If the vial says single use and it is not stored in an ISO 5 space, and it has been punctured/used, it must be discarded and may not be used again.	OAC 4729:5-3-06
Are expired/adulterated drugs appropriately segregated and secured from the licensee's active drug stock?	Expired/adulterated drugs must be stored separately from active drug stock in a manner that prohibits access by unauthorized persons. Expired/adulterated drugs must be segregated from the active drug stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored in common stock areas but segregated in a manner that is clear to all who see it that the drugs may not be used. All expired/adulterated drugs must be stored within the pharmacy or a secured area at the licensed location.	OAC 4729:5-3-06
Are expired/adulterated drugs stored no longer than one year from the	Expired/adulterated drugs shall be stored no longer than one year from the date of expiration/adulteration by those holding a terminal distributor of dangerous drugs license.	OAC 4729:5-3-06

date of expiration/adulteration?	Board staff will review expired/adulterated drugs to confirm.	

Drug Transfers or Occasional Wholesale Sales – Institutional Facility*

**This provision only applies to an institutional facility that has its own terminal distributor of dangerous drugs license. It does not apply to facilities that have a pharmacy supplied contingency stock license.*

REMINDERS:

- *Any drug transfers, including intracompany transfers, or occasional sales of controlled substances and gabapentin must be reported to OARRS as a wholesale transaction. Wholesale sales must be reported at least monthly. More information on reporting wholesale transactions can be accessed here: www.pharmacy.ohio.gov/wholesalereport*

- *A licensed terminal distributor of dangerous drugs that is **not a pharmacy** may ONLY make occasional sales of the following at wholesale:*

    1. *Naloxone;*

    2. *Dangerous drugs if the drugs being sold are in shortage, as defined in rules adopted under section 4729.26 of the Revised Code (see OAC 4729:5-3-09(G) for the definition of a shortage).*

Question	Guidance	Rule/Law
Does the licensee comply with the record keeping requirements for intracompany transfers or occasional wholesale sales?	If yes, records of transfers to other terminal distributors of dangerous drugs, including sales conducted in accordance with rule 4729:5-3-09 of the Administrative Code, shall contain the name, strength, dosage form, and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred and the date of transfer. Board staff will review a sample of records to determine compliance. **REMINDER:** • A licensee must verify appropriate Ohio licensure prior to engaging in a drug transfer or occasional wholesale per OAC 4729:5-3-04. • Licensure verification **DOES NOT** apply to sales or transfers to entities outside of the state. While Ohio does not have a prohibition on shipping drugs into another state, the licensee must comply with the requirements of the state where it is selling or transferring dangerous drugs.	OAC 4729:5-9-03.3 OAC 4729:5-3-09

Does the licensee exceed the annual limits on occasional wholesale sales?	For occasional sales, the dosage units of all dangerous drugs distributed by the pharmacy shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year. **NOTE:** There are no limits on intracompany transfers. An intracompany transfer includes any of the following: (1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control. (2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.	OAC 4729:5-3-09

Drug Repository Program – Institutional Facility

Section 3715.87 of the Revised Code permits a licensed terminal distributor of dangerous drugs (TDDD) to operate a drug repository program. A drug repository program is a program that receives eligible donated drugs to provide to patients who have no reasonable financial means to pay for the drug or who are patients of a nonprofit clinic. For additional information on drug repository programs, visit: www.pharmacy.ohio.gov/repository

Question	Guidance	Rule/Law
Does this facility operate a drug repository program?	If yes, Board staff should verify the licensee meets the eligibility requirements. **NOTE:** Only a pharmacy, hospital, or nonprofit clinic may elect to participate in a drug repository program. "Nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons as defined in section 2305.234 of the Revised Code. "Nonprofit clinic" does not include a hospital as defined in section 3727.01 of the Revised Code, a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit. "Hospital" means an institution classified as a hospital under section 3701.07 of the Revised Code in which are provided to inpatients diagnostic, medical, surgical, obstetrical, psychiatric, or rehabilitation care for a continuous period longer than twenty-four hours or a hospital operated by a health maintenance organization. "Hospital" does not include a facility licensed under Chapter 3721. of the Revised Code, a health care facility operated by the department of mental health and addiction services or the department of developmental disabilities, a health maintenance organization that does not operate a hospital, the office of any private licensed health care professional, whether organized for individual or group practice, or a clinic that provides ambulatory patient services and where patients are not regularly admitted as inpatients. "Hospital" also does not include an institution for the sick that is operated exclusively for patients who use spiritual means for healing and for whom the acceptance of medical care is inconsistent with their religious beliefs, accredited by a national accrediting organization,	ORC 3715.871

	exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986, 100 Stat. 2085, 26 U.S.C.A. 1, as amended, and providing twenty-four hour nursing care pursuant to the exemption in division (E) of section 4723.32 of the Revised Code from the licensing requirements of Chapter 4723. of the Revised Code.	
FOR NON-ORALLY ADMINISTERED CANCER DRUGS: Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**GENERAL REQUIREMENTS (DOES NOT APPLY TO ORALLY ADMINISTERED CANCER DRUGS):** ▪ The drugs are in their original sealed and tamper-evident unit dose packaging. ▪ The packaging must be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. ▪ If the drugs were packaged by a pharmacy, the name of the pharmacy and any other pharmacy identifiers must be removed from the packaging prior to dispensing or personally furnishing to a recipient patient. This may be accomplished by removing the drug from the pharmacy packaging or by removing the name from the outside packaging of a multiple dose, unit dose packaging system. ▪ The drugs have been in the possession of a licensed healthcare professional, terminal distributor of dangerous drugs, or drug distributor and not in the possession of the ultimate user. ▪ The drugs must have an expiration date of six months or greater. ▪ The packaging must list the expiration date of the drug. ▪ The drugs must not have any physical signs of tampering or adulteration.	OAC 4729:5-10-04

	▪ The drug packaging must not have any physical signs of tampering ▪ All confidential patient information must have been removed from the drug packaging. ▪ The drugs are not samples. ▪ The drugs are not controlled substances, except that controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction may be donated to a repository program.	
FOR ORALLY ADMINISTERED CANCER DRUGS: Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**REQUIREMENTS FOR ORALLY ADMINISTERED CANCER DRUGS:** ▪ The drugs do not have to be in an original sealed and tamper-evident unit dose packaging and may have been in possession of the ultimate user. ▪ The drugs must have an expiration date of six months or greater. ▪ The packaging must list the expiration date of the drug. ▪ The drugs must not have any physical signs of tampering or adulteration. **NOTE:** "Orally administered cancer drug" means either of the following: (1) An orally administered dangerous drug that is used to treat cancer or its side effects; or (2) An orally administered dangerous drug that is used to treat the side effects of a dangerous drug used to treat cancer.	OAC 4729:5-10-04
Does the repository program have standards and procedures to	The repository program shall develop and implement standards and procedures to determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing.	OAC 4729:5-10-04

determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing?	Board staff will review documentation containing standards and procedures. **NOTE:** This is a requirement for all drugs donated to the repository program.	
Are drugs donated by eligible persons?	The following may donate a dangerous drug, pursuant to the eligibility requirements of rule 4729:5-10-04 of the Administrative Code, to a pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program: (1) A licensed terminal distributor of dangerous drugs. (2) A licensed drug distributor. (3) A person who was legally dispensed or personally furnished a dangerous drug pursuant to a patient-specific drug order. Except for orally administered cancer drugs, a person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through a terminal distributor of dangerous drugs. **NOTE:** A person who resides in an institutional facility and was legally dispensed a dangerous drug pursuant to a patient-specific order may elect to sign and date a donor form prior to donating a drug, which shall state "from this day forward I wish to donate all my remaining unused drugs that are eligible, pursuant to rule 4729:5-10-04 of the Administrative Code, to a drug repository program." Board staff will review documentation to verify donated drugs are coming from eligible persons.	OAC 4729:5-10-03
Are donor forms and records maintained in accordance with applicable rules?	Each donor must sign a form stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The donor form must be completed prior to any donation and include at least the following:	OAC 4729:5-10-06

	(1) The name of the person that was originally dispensed the drugs or the name of the terminal distributor of dangerous drugs or drug distributor that owns the drugs. (2) The signature of the donor, which may include the person designated by durable power of attorney, a guardian, an individual responsible for the care and wellbeing of a patient, or the signature of the responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor. (3) The date the form was signed. **NOTE:** A licensee may opt to have a patient sign a donor form in advance of receiving treatment in the event the patient discontinues treatment. Additionally, the following donor information must be documented on the donor form or an alternate record. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph. (1) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#). (2) The strength of the drug donated. (3) The quantity of the drug donated. (4) The date the drug was donated.	
Do the recipient forms comply with the requirements of Ohio law?	Prior to receiving donated drugs from a drug repository program, each recipient must sign a form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code. ORC 3715.872 (B) states: For matters related to donating, giving, accepting, or dispensing drugs under the drug repository program, all of the following apply:	OAC 4729:5-10-06

	(1) Any person, including a pharmacy, drug manufacturer, or health care facility, or any government entity that donates or gives drugs to the drug repository program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property. (2) A pharmacy, hospital, or nonprofit clinic that accepts or dispenses drugs under the program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct. (3) A health care professional who accepts or dispenses drugs under the program on behalf of a pharmacy, hospital, or nonprofit clinic, and the pharmacy, hospital, or nonprofit clinic that employs or otherwise uses the services of the health care professional, shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the health care professional, pharmacy, hospital, or nonprofit clinic constitutes willful and wanton misconduct. (4) The state board of pharmacy and the director of health shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property, unless an action or omission of the board or director constitutes willful and wanton misconduct.	
Does the repository charge a handling fee that complies with the limit set forth in rule?	A pharmacy, hospital, or nonprofit clinic may charge the recipient of a donated drug a handling fee up to twenty dollars to cover restocking and dispensing costs. If a drug repository program chooses to charge a handling fee, then the fees collected in any given year shall not exceed the program's total restocking and dispensing costs for that given year.	OAC 4729:5-10-07
Are all applicable records maintained in accordance with rule 4729:5-10-07?	Donor forms must be maintained for a minimum of three years in a readily retrievable manner by a terminal distributor of dangerous drugs, a distributor of dangerous drugs, or an institutional facility.	OAC 4729:5-10-07

	Recipient forms must be maintained for a minimum of three years in a readily retrievable manner by a pharmacy, hospital, or nonprofit clinic. Except for a licensee that donates to its own repository program, copies of invoices from the donor location must be maintained for a minimum of three years in a readily retrievable manner. The invoice must contain the following information: (1) The name and address of the donor location. (2) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#). (3) The strength of the drug. (4) The quantity of the drug. (5) The date the drug was sent to the pharmacy, hospital, or nonprofit clinic. (6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic. Records of personally furnishing and administration are maintained in accordance with OAC 4729:5-11-04. Board staff will review records to verify compliance.	

Temporary Removal of Drugs – Institutional Facility

Question	Description / Guidance	Law/Rule
Does the licensee engage in the temporary off-site storage of dangerous drugs?	This may occur in the following three scenarios: (1) A licensed health professional authorized to prescribe drugs may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. **NOTE:** This would only apply to pharmacists who are practicing under a consult agreement. (2) A person authorized to personally furnish or dispense naloxone in accordance with a physician approved protocol The Board approved a resolution allowing indefinite off-site storage of naloxone at non-licensed locations. (3) A licensed health care professional (pharmacist or pharmacy intern), in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients.	OAC 4729:5-3-13
Are drugs removed from the terminal distributor returned within 24-hours?	The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the Board. The Board has approved the following extensions to this provision: (1) Naloxone to be personally furnished in accordance with a physician approved protocol. The Board approved a resolution allowing indefinite off-site storage of naloxone at non-licensed locations. (2) Dangerous drugs used by dental anesthesiologists. *All dangerous drugs temporarily removed from a licensed terminal distributor of dangerous drugs by a dental anesthesiologist to treat current or prospective patients shall*	OAC 4729:5-3-13

	be returned to the licensed terminal distributor of dangerous drugs no later than seventy-two hours. (R-2017-382)	
Does the person temporarily removing drugs from a licensed location maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the licensed location?	The person temporarily removing drugs from a licensed location shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. "Direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.	OAC 4729:5-3-13
If direct supervision is not provided, are the drugs that are temporarily removed securely stored at temperatures and conditions which will ensure the integrity of the drugs?	If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/ NF and/or the manufacturer's or distributor's labeling. Securely stored means that the drugs are secured in a manner that prevents unauthorized access. This may include the following: a locked drawer, filing cabinet, locked room, safe, lock box, or any other method that can be locked to prevent unauthorized access.	OAC 4729:5-3-13

Pharmacist Consult Agreements – Institutional Facility

Question	Guidance	Law/Rule
Does the consult agreement contain all the required information?	**NOTE:** "Practitioner" includes all of the following: (1) Physicians (MD/DO); (2) Physician assistants, if entering into a consult agreement is authorized by one or more supervising physicians; (3) Clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), or certified nurse practitioners (CNPs), if entering into a consult agreement is authorized by one or more collaborating physicians. **NOTE:** This does not include CRNAs. A consult agreement must contain all the following: (1) Identification of the Ohio-licensed practitioners(s) and pharmacist(s) authorized to enter into the agreement. This may include: (a) Individual names of practitioners and pharmacists; (b) Provider or pharmacist practice groups; or (c) Identification based on institutional credentialing or privileging. (2) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid. (3) A description of the drugs or drug categories managed as part of the agreement. (4) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement. (5) A description of the types of diagnostic tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate to	ORC 4729.39 OAC 4729:1-6-02

	the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement. (6) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification. (7) A description of how communication between a managing pharmacist and practitioner acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement. The agreement may include a requirement that a managing pharmacist send a consult report to each consulting practitioner. (8) A provision that allows a practitioner to override a decision made by the managing pharmacist when appropriate. (9) A quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement. (10) A description of a continuous quality improvement (CQI) program used to evaluate the effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement. (11) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria. (12) An effective date and expiration date. (13) The agreement shall be signed by the primary practitioners, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:	

	(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs. Board staff will ask the licensee to review current agreements to determine compliance.	
Is a pharmacist able to manage controlled substances as part of a consult agreement?	If yes, a pharmacist shall be required to maintain a valid controlled substance prescriber registration issued by the State Board of Pharmacy by submitting an application and a valid consult agreement, in a manner determined by the board, authorizing the pharmacist to prescribe controlled substances. Additionally, a pharmacist managing controlled substances shall also obtain and maintain a valid registration with the U.S. Drug Enforcement Administration (D.E.A.). For more information on obtaining a controlled substance registration, visit: www.pharmacy.ohio.gov/consult **REMINDER:** Per federal law, a pharmacist may not prescribe controlled substances for the treatment of opioid use disorder.	OAC 4729:1-6-02

Hospital Self-Service Employee Prescription Kiosks – Institutional Facility

- *"Hospital" means a public hospital or hospital as defined in section 3701.01 or 5122.01 of the Revised Code.*
- *"Self-service employee prescription kiosk" or "kiosk" means a self-service kiosk for the pickup of new or refill prescriptions only for hospital employees and their family members.*

REMINDER: Prior to the operation of a kiosk, the board shall receive a request for approval from the responsible person on the terminal distributor of dangerous drugs license. Upon notification, the Board shall conduct an inspection of the area where the kiosk shall be located and review system specifications to determine if it meets the requirements of this rule. Requests must be sent in writing using the following form: Hospital Self-Service Employee Prescription Kiosk – Installation Request

NOTE: This requirement **does not** apply to kiosks that have previously been approved by the Board.

Question	Description / Guidance	Law/Rule
Does the hospital operate a self-service kiosk?	If yes, the licensee must comply with the requirements of this section.	OAC 4729:5-9-03.5
Does the kiosk meet the location requirements of the rule?	A self-service employee prescription kiosk shall meet all the security requirements of this rule and be located either: (1) On the campus of a hospital licensed as a terminal distributor of dangerous drugs and located in the immediate proximity of a pharmacy, unless otherwise approved by an agent of the board; or (2) At a location that is licensed as a terminal distributor of dangerous drugs that not located on the campus of a hospital but is owned by the hospital. A kiosk located not located on the campus of a hospital shall be placed in an area that is restricted to hospital employees and is secured by both a physical barrier with suitable locks and an electronic barrier to detect unauthorized entry.	OAC 4729:5-9-03.5
Do the kiosks meet the security requirements of the rule?	A self-service employee prescription kiosk shall meet all the following: (1) Is electronically protected against unauthorized access; (2) Be bolted to the floor or installed in a wall;	OAC 4729:5-9-03.5

	(3) Be constructed in such manner as to prevent tampering, break-in and theft of inventory; and (4) Is able to either: (a) Sound an alarm if a break-in is attempted; or (b) Transmit a notification to on-site security if a break-in is attempted.	
Do the drugs maintained in the kiosk comply with the requirements of the rule?	Only a dangerous drug prescription dispensed by a hospital-owned pharmacy may be provided to the patient or employee representative of the patient via a self-service kiosk. A kiosk shall not provide any of the following: (1) Any drug that must be refrigerated; or (2) Any hazardous drug, except for conventionally manufactured hazardous drugs that are tablets or capsules that do not require any further manipulation other than counting or repackaging. **NOTE:** As used in this rule, "hazardous drug" means any 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 as referenced in rule 4729:7-1-01 of the Administrative Code.	OAC 4729:5-9-03.5
Are kiosks maintained under continuous video monitoring?	All kiosks shall be continuously monitored by one or more video cameras that possess the capability of having its picture recorded. The video camera(s) shall provide one hundred percent video coverage of the kiosk. Camera recordings shall be maintained for at least ninety days and shall made available within three business days of a request by an agent of the state board of pharmacy. The kiosk location must have adequate lighting to produce clear digitally recorded and still picture production.	OAC 4729:5-9-03.5

Are kiosks stocked by authorized personnel?	A kiosk shall only be stocked by a hospital employed pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician or pharmacy technician trainee.	OAC 4729:5-9-03.5
Do the kiosks employ a method of two factor authentication to identify a patient or employee representative of the patient?	A kiosk shall employ a method of two-factor authentication to identify a patient or employee representative of the patient such that a finished prescription is delivered from a kiosk only to its intended recipient.	OAC 4729:5-9-03.5
Do the kiosks display the required patient counseling notification?	A kiosk must prominently display notification that patient counseling is available pursuant to rule 4729:5-5-09 of the Administrative Code. Counseling may be provided by a pharmacist reachable at a toll-free telephone number who has access to the patient profile. Instructions on how to contact a pharmacist via toll-free telephone must be displayed by the kiosk and must also be printed on the customer receipt or included with the patient instructions.	OAC 4729:5-9-03.5
Are all drugs and devices within the kiosks maintained in a clean and orderly condition and at the proper temperature?	All drugs and devices in a kiosk shall be maintained in a clean and orderly condition. Kiosks shall be maintained at temperatures which will ensure the integrity of the drugs as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.	OAC 4729:5-9-03.5

Point of Care Locations - Institutional Facility

- *"Point of care location" means a location within an institutional facility that stores dangerous drugs and all the following apply:*

  (1) The point of care location is licensed as a terminal distributor of dangerous drugs;

  (2) The dangerous drugs are not owned by the institutional facility where the point of care location is located;

  (3) The dangerous drugs stored are owned by another institutional facility licensed as a terminal distributor of dangerous drugs; and

  (4) The location may be used for the administration, personally furnishing, or dispensing of dangerous drugs, including controlled substances.

REMINDER: *This rule does not apply to pharmacy-supplied contingency drugs in an institutional facility licensed as a terminal distributor of dangerous drugs.*

Question	Description / Guidance	Law/Rule
Does the hospital operate a point of care location?	If yes, the licensee must comply with the requirements of this section.	OAC 4729:5-9-03.6
Does the point of care location meet the security requirements of the rule?	Dangerous drugs maintained at a point of care location shall be in a securely locked, substantially constructed cabinet, including an automated drug storage system, or safe to deter and detect unauthorized access.	OAC 4729:5-9-03.6
Does the point of care location have a Responsible Person who is an employee of the institutional pharmacy that owns the drug stock?	The Responsible Person for the point of care location shall be an employee of the institutional pharmacy that owns the drug stock.	OAC 4729:5-9-03.6
If applicable, does the point of care location operate under a valid DEA registration?	If dangerous drugs that are controlled substances are stored at the point of care location, the owner of the drug stock shall either: (1) Obtain a drug enforcement administration (DEA) registration for the point of care location; or	OAC 4729:5-9-03.6

	(2) Utilize the DEA registration of the institutional facility where the point of care location is located. The institutional facility where the point of care location is located shall be responsible for compliance with all federal and state laws, rules, and regulations relating to the possession and use of controlled substances.	
Does the point of care location have appropriate record keeping procedures?	The Responsible Person for the point of care location shall be responsible for implementing record keeping procedures to account for drugs removed from the point of care location and for capturing the positive identification of the person who obtained the drugs from the point of care location.	OAC 4729:5-9-03.6
Does the Responsible Person comply with the access requirements for the point of care location?	The Responsible Person for the point of care location shall: (1) Designate those who may obtain access to the drug stock; (2) Determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included at the point of care location; and (3) Provide controls to prevent the diversion of the drug stock.	OAC 4729:5-9-03.6
Does the point of care location have procedures for the inspection and replacement of drug stock?	The Responsible Person for the point of care location shall provide procedures for the inspection of the point of care location to ensure proper utilization and replacement of the drug stock.	OAC 4729:5-9-03.6

Naloxone for Emergency Use

Naloxone for emergency use is the off-site storage of naloxone by a licensed terminal distributor of dangerous drugs for use in an emergency (i.e., responding to an overdose). This guidance does not apply to service entities that maintain naloxone for emergency use to respond to an overdose that occurs on the premise of the service entity. Rather, it is for naloxone that is maintained off-site for emergency purposes (similar to the use of automated external defibrillators).

***REMINDER:** The requirements of this section **DOES NOT** apply to a service entity that maintains naloxone for emergency administration by service entity personnel/volunteers in accordance section 4729.514 of the Revised Code.*

For more information about service entities, visit: www.pharmacy.ohio.gov/Service

For more information about naloxone for emergency use, visit: www.pharmacy.ohio.gov/naloxoneaccess

Question	Guidance	Law/Rule
Does the licensee provide naloxone for emergency use?		OAC 4729:5-3-19
Does the licensee provide written materials regarding the emergency administration of naloxone to any individual who accesses the naloxone?	A terminal distributor of dangerous drugs shall provide written materials regarding the emergency administration of naloxone to any individual who accesses the naloxone, to include: (1) Specific instruction to summon emergency services pursuant to division (D) (2) of section 4729.515 of the Revised Code. This section states the following: *An individual who administers naloxone as authorized by this section shall make a good faith effort to activate or have another individual activate an emergency medical services system as soon as possible, except that this requirement does not apply if the individual administering the naloxone is doing so as part of an emergency medical services system or at a hospital, as defined in section 3727.01 of the Revised Code.* (2) Procedures for administering naloxone contained within the kit, including the possible administration of multiple doses.	OAC 4729:5-3-19

	(3) Performing rescue breathing and the use of a face shield or other rescue breathing barrier device, which shall be provided with the naloxone. (4) Proper method for placing an individual into the recovery position.	
Does the licensee specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of it being accessed?	A licensee shall specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of its being accessed. This can include any of the following: (1) Documented checks of the emergency naloxone and its required components, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs. The terminal distributor shall include a telephone number where persons can report that the emergency naloxone has been used and needs replenishment. (2) An automated alert that notifies the terminal distributor when the emergency naloxone is accessed. (3) Any other method approved by the Board's Executive Director or the Director's designee. Licensee's requesting another notification process, should submit a detailed proposal to contact@pharmacy.ohio.gov.	OAC 4729:5-3-19
Is the naloxone replaced within 48-hours of notification the naloxone has been accessed?	Except in instances where naloxone is not commercially available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler, a terminal distributor of dangerous drugs must replace any naloxone and, if missing or used, any required components (instructions, rescue breathing barrier device, etc.) no later than forty-eight hours following notification (using one of the methods listed in the previous question) that naloxone has been accessed.	OAC 4729:5-3-19
Is naloxone maintained in accordance with the manufacturer's instructions?	A licensee shall maintain naloxone in accordance with the manufacturer's instructions. **NOTE:** The naloxone must be stored in accordance with the labeling on the package. For example, naloxone nasal spray must be stored	OAC 4729:5-3-19

	at controlled room temperature 59°F to 77°F (15°C to 25°C) and cannot be frozen.	
Is the naloxone sealed in a tamper-evident manner?	All naloxone maintained for emergency use in accordance with this paragraph shall be sealed in a tamper-evident manner to ensure the integrity of the drug. "Tamper-evident" means a package, storage container or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.	OAC 4729:5-3-19
Does the naloxone maintained for emergency use show any signs of tampering?	Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs and replaced within forty-eight hours of discovering the naloxone has been tampered with or is adulterated.	OAC 4729:5-3-19
Does the licensee have a policy to ensure any naloxone that exceeds its manufacturer's expiration date is removed and properly disposed?	A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed. The licensee's policy should be available for review by Board of Pharmacy staff.	OAC 4729:5-3-19
Does the licensee maintain a complete list of where naloxone for emergency use is maintained?	A terminal distributor shall maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains the naloxone for emergency use. **NOTE:** The list must be immediately available for inspection upon request of an employee of the Board.	OAC 4729:5-3-19
Does the licensee maintain records of the naloxone maintained for emergency use?	A terminal distributor shall keep a record of the naloxone maintained for emergency use that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years. **REMINDER:** The purpose of this provision is to be able to track what is maintained for emergency use in the event of a drug recall.	OAC 4729:5-3-19

Is the naloxone maintained in a container or device that is securely fastened to a permanent structure and is clearly marked to indicate naloxone is available for emergency use?	A terminal distributor shall ensure the naloxone is maintained in a container or device that is securely fastened to a permanent structure and is clearly marked to indicate naloxone is available for emergency use.	OAC 4729:5-3-19

Distribution of Naloxone Via Automated Mechanism

Automated mechanisms for naloxone distribution do not require a protocol or prescription to distribute naloxone. This guidance applies to all automated mechanisms used to distribute naloxone.

For more information about naloxone distribution via automated mechanism, visit: www.pharmacy.ohio.gov/naloxoneaccess

Question	Guidance	Law/Rule
Does the licensee distribute naloxone via automated mechanism?		OAC 4729:5-3-19
Does the automated mechanism meet the security requirements of the rule?	A terminal distributor shall ensure the mechanism is securely fastened to a permanent structure or is of an appropriate size and weight to reasonably prevent it from being removed from its intended location.	OAC 4729:5-3-19
Does the licensee have a process to monitor and replenish the inventory of naloxone maintained in the automated mechanism?	The process must include any of the following: (1) Documented checks of the mechanism, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs. (2) An electronic system to monitor the inventory of naloxone within the mechanism. (3) Any other method approved by the Board's Executive Director or the Director's designee. Licensee's requesting another method, should submit a detailed proposal to contact@pharmacy.ohio.gov.	OAC 4729:5-3-19
Does the licensee provide written educational materials to the person accessing the naloxone appropriate to the dosage form of naloxone distributed?	A terminal distributor shall provide written educational materials to the person accessing the naloxone appropriate to the dosage form of naloxone distributed, including, but not limited to, all of the following: (1) Risk factors of opioid overdose. (2) Strategies to prevent opioid overdose. (3) Signs of opioid overdose.	OAC 4729:5-3-19

	(4) Steps in responding to an overdose, including: (a) The proper method for placing an individual into the recovery position. (b) Specific instruction to summon emergency services. (5) Information on naloxone. (6) Procedures for administering naloxone. (7) Proper storage and expiration of naloxone product distributed. (8) Information on where to obtain a referral for substance abuse treatment. (9) Information on where individuals may call for additional questions regarding naloxone administration. The telephone number must include the hours where an appropriately trained representative is available to answer questions.	
Is the naloxone maintained in accordance with the manufacturer's instructions?	A licensee shall maintain naloxone in accordance with the manufacturer's instructions. **NOTE:** The naloxone must be stored in accordance with the labeling on the package. For example, naloxone nasal spray must be stored at controlled room temperature 59°F to 77°F (15°C to 25°C) and cannot be frozen.	OAC 4729:5-3-19
Does the naloxone maintained in the automated mechanism show any signs of tampering?	Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs.	OAC 4729:5-3-19
Does the licensee have a policy to ensure any naloxone that exceeds its manufacturer's expiration date is removed and properly disposed?	A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed. The licensee's policy should be available for review by Board of Pharmacy staff.	OAC 4729:5-3-19

Does the licensee maintain a complete list of where the naloxone is maintained?	A terminal distributor shall maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains an automated mechanism. **NOTE:** The list must be immediately available for inspection upon request of an employee of the Board.	OAC 4729:5-3-19
Does the licensee maintain records of the naloxone stored within the automated mechanism?	A terminal distributor shall maintain a record of the naloxone stored within the automated mechanism that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years.	OAC 4729:5-3-19

Institutional Pharmacy and Facility - Update History

Update Date	Section Update	Update
11/22/2021	Applicability	Added the following to the definition of institutional facility: *(8) A residential care facility licensed under Chapter 3721. of the Revised Code that provides skilled nursing care to its residents, including medication administration as authorized in Chapter 3701-16 of the Administrative Code, provided the facility meets the following requirements:* *(a) The administration of medication shall be in compliance with this Chapter and Chapter 3701-16 of the Administrative Code, including the requirement to maintain individual medication records and documentation of medication orders; and* *(b) The residential care facility maintains an executed contract or agreement with an institutional pharmacy for the provision of institutional pharmacy services. The executed contract or agreement shall be maintained in a readily retrievable manner.*
11/22/2021	Temperature Monitoring – Institutional Pharmacy	Updated to allow for policy to permit foods and beverages used for medication administration or med pass.
11/22/2021	Important Terms	Updated definition to include the following examples for controlled substances that are temperature controlled: ▪ A refrigerator or freezer secured with a lock; or ▪ A lockbox that is securely fastened to the refrigerator or freezer.

11/22/2021	Medication Orders & Outpatient Prescriptions	Added the following clarification: Drugs dispensed on an inpatient basis that are provided upon discharge are not required to be reported to OARRS. New prescriptions dispensed for the purposes of discharge (i.e., outpatient prescriptions) are still required to be reported to OARRS.
11/22/2021	Medication Orders & Outpatient Prescriptions	The following stop order policies were incorporated into the inspection guide as examples: ▪ Routine monitoring of patient's drug therapy by a pharmacist; ▪ Routine monitoring of the patient's drug therapy by the patient's physician/prescriber in accordance with facility policies and procedures; ▪ A facility-approved, drug class-specific, automatic stop order policy covering those drug orders not specifying a number of doses or duration of therapy.
11/22/2021	Medication Orders & Outpatient Prescriptions	Added the following reminder: *Electronic prescriptions transmitted by facsimile may be stored electronically if the system maintains the original prescription for three years.*
11/22/2021	Contingency Drugs – Institutional Facility	Added the following reminder: *Access to controlled substances shall be restricted to health care professionals authorized pursuant to the Revised Code to administer controlled substances as part of the professional's scope of practice.*
11/22/2021	Labeling – Institutional Pharmacy	Added the following clarification:

		For medications dispensed in blister cards, the label may be applied to the blister card directly.
11/22/2021	Repackaging of Drugs – Institutional Pharmacy	Updated beyond-use dating requirement for repackaged drugs to the following: *Unless otherwise specified in the individual monograph or in the absence of stability data to the contrary, the beyond-use date shall be not later than the expiration date on the manufacturer's container or one-year from the date the drug is repackaged, whichever is earlier.* *Sterile compounded drug preparations shall comply with United States pharmacopeia chapter as referenced in rule 4729:7-1-01 of the Administrative Code.*
11/22/2021	Security, Control, and Storage of Dangerous Drugs and Prescription Blanks – Institutional Facility	Added the following clarification regarding medical marijuana: *Medical marijuana obtained from the Ohio Medical Marijuana Control Program shall be secured as any other schedule II controlled substance. Medical marijuana must be stored in its original packaging, as required by OMMCP rules. The facility may opt to utilize a tamper-evident packaging (e.g., heat seal bag, tamper evident tape or label) in accordance with facility policy, but such a measure is not required.*
12/7/2021	Applicability	Added the following to the definition of institutional facility: ▪ *A facility providing services under contract with the department of developmental disabilities under section 5123.18 of the Revised Code.*

		▪ *A facility providing **inpatient hospice care** operated by a hospice care program licensed under section 3712.04 of the Revised Code.* ▪ *A facility operated by a pediatric respite care program licensed under section 3712.041 of the Revised Code.*
1/11/2022	Pharmacist Drug Utilization Review & OARRS – Institutional Pharmacy	The requirement to conduct a retrospective review has been temporarily suspended by the following Board resolution: *To address workforce shortages and to provide additional guidance to institutional pharmacies, the State of Ohio Board of Pharmacy hereby suspends the enforcement of retrospective drug utilization review requirements in paragraph 4729:5-9-02.6 (F) until further notice. This resolution does not exempt an institutional pharmacy from complying with the remaining provisions of rule 4729:5-9-02.6 of the Ohio Administrative Code. (Adopted 1/10/22)*
2/1/2022	Institutional Central Fill Pharmacies – Originating Pharmacy	Added new section to inspect for compliance with OAC 4729:5-9-02.13.
2/1/2022	Institutional Central Fill Pharmacies – Central Fill Pharmacy	Added new section to inspect for compliance with OAC 4729:5-9-02.13.
8/17/2023	Drug Administration (Non-Immunization)	Updated to reflect the Board's updated enforcement guidance that now permits the administration of controlled substances used to treat addiction in a long-acting or extended-release form.