INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Outpatient Pharmacy

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 "outpatient pharmacy" in rule 4729:5-5-01 of the Ohio Administrative Code:

> *"Outpatient pharmacy" means any pharmacy, including a clinic pharmacy, where drugs are dispensed for outpatient use. It does not include institutional pharmacies or institutional facilities, as defined in agency 4729 of the Administrative Code, where drugs are dispensed for use by inpatients.*

REMINDER: This inspection guide **does not apply** to institutional pharmacies, institutional facilities, 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
- 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 outpatient pharmacies 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).**

- **4729:5-5 – Outpatient Pharmacies**
  - 4729:5-5-01 - Definitions - outpatient pharmacies.
  - 4729:5-5-02 - Minimum standards for an outpatient pharmacy.
  - 4729:5-5-03 - Filing and storage of prescriptions.
  - 4729:5-5-04 - Record keeping.
  - 4729:5-5-05 - Prescription format requirements.
  - 4729:5-5-06 - Labeling of drugs dispensed on prescription.
  - 4729:5-5-07 - Patient profiles.
  - 4729:5-5-08 - Prospective drug utilization review.
  - 4729:5-5-09 - Patient counseling.
  - 4729:5-5-10 - Manner of processing a prescription.
  - 4729:5-5-11 - Prescription copy.
  - 4729:5-5-12 - Partial dispensing of schedule II controlled substances.
  - 4729:5-5-13 - Serial numbering of prescriptions.
  - 4729:5-5-14 - Prescription pick-up station.
  - 4729:5-5-15 - Manner of issuance of a prescription.
  - 4729:5-5-16 - Pharmacist modifications to a prescription.
  - 4729:5-5-17 - Drugs repackaged or relabeled by a pharmacy.
  - 4729:5-5-18 - Dispensing customized patient medication packages by an outpatient pharmacy.
  - 4729:5-5-19 - Central fill pharmacies.
  - 4729:5-5-20 - Remote Outpatient Prescription Processing.

- 4729:5-5-22 - Return to stock in an outpatient pharmacy.
- 4729:5-5-23 - Security, control and storage of dangerous drugs in an outpatient pharmacy.
- 4729:5-5-24 - Drug inventory records and other record keeping provisions.
- 4729:5-5-25 - Remote Prescription Entry - Technician.

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

(9) 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 *OAC 4729:5-5-24* An outpatient 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	Requires submission of an **Pharmacy Request to Store Records Off-Site Form**.

secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.	
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 *OAC 4729:5-5-23* An outpatient 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. **REMINDER: This is a current requirement per OAC 4729-9-11 (A)(2)(a).**	Requires submission of a **Pharmacy Security Request Form**.

Important Terms

- **"Central fill pharmacy"** means a 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.

- **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.

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

- **"Outpatient"** means any person who receives drugs for use outside of an institutional facility.

- **"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.

- **"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 a 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.

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Outpatient 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 Outpatient Pharmacy Requirements**
(REMINDER: New Outpatient Pharmacy Rules Effective 12/1/2020)

Licensing, Responsible Person & DEA Registration

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 pharmacy 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 that apply for a Category II license as a terminal distributor of dangerous drugs.	21 CFR 1301.11

Minimum Standards

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 of the following resources: ▪ The board's website (www.pharmacy.ohio.gov); ▪ Ohio Laws and Rules website (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 4729:5-5-02
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 4729:5-5-02
Are the pharmacy's hours publicly posted?	Notice to the public of operating hours of the pharmacy department must be posted.	OAC 4729:5-5-02
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). ***Substantive Change: New rule applies to all pharmacy staff regardless of whether the pharmacy staff is interfacing with the public.**	OAC 4729:5-5-02 OAC 4729:3-3-03 OAC 4729:3-3-04 OAC 4729:3-3-01

Does the pharmacy have prescription containers that comply with the Poison Prevention Packaging Act of 1970?	The stock of prescription containers shall include such containers as are necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Packaging Act (PPPA) of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products. **NOTE:** The PPPA requires a number of household substances, including prescription drugs, to be packaged in child-resistant packaging. The packaging required by the PPPA must be designed or constructed to be significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly. For prescription drugs, the purchaser may request a pharmacist to package a prescription in a regular package, or the physician, dentist, or other person who writes the prescription may specify in the prescription that the drug can be dispensed in regular packaging. Special packaging is not required for drugs dispensed within a hospital setting for inpatient administration. For more information on the PPPA, visit: https://www.cpsc.gov/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act	OAC 4729:5-5-02
Does the pharmacy use packaging that complies with compendial standards or standards as recommended by the manufacturer or distributor for non-compendial drug products?	The stock of prescription containers shall include such containers as are necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Packaging Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products. USP 659 contains the compendial standards for drug packaging. According to the chapter, packaging materials must not interact physically or chemically with a packaged article in a manner that causes its safety, identity, strength, quality, or purity to fail to conform to established requirements. If the pharmacy is using non-traditional packaging for the storage of drugs, the licensee must confirm that the packaging systems meet the applicable requirements specified in Containers—Glass ⟨660⟩, Plastic Packaging	OAC 4729:5-5-02

	Systems and Their Materials of Construction ⟨661⟩, Auxiliary Packaging Components ⟨670⟩.	
Are the library and equipment housed in a suitable, well-lit, and well-ventilated room or department and maintained in a clean, sanitary and orderly condition?	The library and equipment shall be housed in a suitable, well-lit, and well-ventilated room or department and maintained in a clean, sanitary and orderly condition.	OAC 4729:5-5-02
Are areas where drugs and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?	All areas where drugs and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition.	OAC 4729:5-5-02
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Storage areas must 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 4729:5-5-02
Are hypodermics stored in the pharmacy kept out of public view?	No manufacturer or distributor of, or dealer in, hypodermics or medication packaged in hypodermics, or their authorized agents or employees, and no terminal distributor of dangerous drugs, shall display any hypodermic for sale. No person authorized to possess a hypodermic shall negligently fail to take reasonable precautions to prevent any hypodermic in the person's possession from theft or acquisition by any unauthorized person.	ORC 3719.172

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.	

Filing and Storage of Prescriptions

Question	Guidance	Law/Rule
Are outpatient prescriptions filed in three separate files?	Outpatient prescriptions must be filed in the following manner: ▪ Prescriptions for schedule II controlled substances shall be maintained in a separate prescription file for schedule II prescriptions. ▪ Prescriptions for schedule III, IV, and V controlled substances shall be maintained in a separate prescription file for schedule III, IV, and V prescriptions. ▪ Prescriptions for non-controlled substances shall be maintained in a separate prescription file for non-controlled prescriptions. **NOTE:** Prescriptions containing multiple drug orders shall be filed in the most restrictive file.	OAC 4729:5-5-03
Is the pharmacy maintaining non-controlled hard copy prescriptions electronically (i.e. scanned images)?	If yes, the pharmacy must comply with the following: (1) All hard copy prescriptions for non-controlled dangerous drugs may be electronically filed and then destroyed **after 180 days** from the date of creation or receipt. (2) Disposal of the hard copy shall use a secure method of destruction to ensure privacy and confidentiality of the contents. (3) All hard copy prescriptions electronically filed must 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 prescription 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. **NOTE:** There is no standard method of notation required but it should be marked clearly so as to prevent duplication.	OAC 4729:5-5-03

	(4) The electronic form shows the exact and legible image of the original hard copy prescription. **IMPORTANT:** Controlled substance hard copy prescriptions may be scanned and stored electronically as outlined above. However, the pharmacy **is not** permitted to destroy any original hard copy-controlled substance prescriptions. ***Substantive Change: New rule allows for disposal of hard copy non-controlled prescription after 180 days if digitized in accordance with the standards set forth in the rule.**	
Are electronically transmitted prescriptions maintained in accordance with Ohio rules?	All electronically transmitted prescriptions, including faxed prescriptions received in an electronic format, shall be electronically stored. **NOTE:** Printing and filing hardcopy prescriptions is permissible for record keeping purposes but the pharmacy must also maintain these prescriptions electronically in the manner and format originally received.	OAC 4729:5-5-03
Are all prescription records maintained for a period of three years?	All prescription records stored in accordance with this rule shall be uniformly maintained for a period of three years.	OAC 4729:5-5-03

Positive Identification

Question	Guidance	Law/Rule
Does the record keeping system capture the positive identification of the individual entering prescription information?	All pharmacy record keeping systems must capture the positive identification of the person entering prescription information into the system. ***Substantive Change: Effective 6/30/2022, all pharmacy record keeping systems must capture the positive identification of prescription information entered into the pharmacy's record keeping system. This requires positive identification of pharmacists, interns and technicians that are entering prescription information into a pharmacy's record keeping system. [OAC 4729:5-5-04 (A)(1)]**	OAC 4729:5-5-04
Does the record keeping system capture the positive identification of the pharmacist conducting the prospective drug utilization review?	All pharmacy record keeping systems must capture the positive identification of the pharmacist conducting the prospective 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 4729:5-5-04
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 prescription, the pharmacist must record the date of such dispensing and the pharmacist's positive identification. ▪ When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.	OAC 4729:5-5-04 OAC 4729:5-5-10
Does the record keeping system capture the positive identification of	All pharmacy record keeping systems must capture the positive identification of the individual (pharmacist, pharmacy intern, or	OAC 4729:5-5-04

the individual transcribing an order received by telephone, facsimile, or recording device?	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.	
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. This applies to any modifications made to prescriptions by pharmacists in accordance with OAC 4729:5-5-16.	OAC 4729:5-5-04
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) Prescription 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 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.	OAC 4729:5-5-04

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 information in the printout 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; and (4) The system maintaining the printout contains daily back-up functionality to protect against record loss.	OAC 4729:5-5-04
Does the pharmacy use a tamper evident log book to capture positive identification?	**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 log book must comply with the following: Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book the following data for each prescription dispensed: (1) Date of dispensing; (2) Prescription number; (3) Patient name; (4) Name, strength and quantity of drug dispensed; (5) Identification of the pharmacist and pharmacy personnel responsible for any activity requiring positive identification; (6) Identification of controlled substances.	OAC 4729:5-5-04

	Each individual responsible for any activity requiring positive identification shall review this information at the end of each day, or at the end of the individual's shift, and must either: (1) Manually sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown; or (2) Manually initial each entry of the log book to indicate that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown. The log book must be readily retrievable and maintained at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.	

Dispensing Records and Patient Profiles

Question	Guidance	Law/Rule
Does the pharmacy maintain dispensing records containing the required information?	Dispensing records must include the all the following: (1) The original prescription number. (2) Date of issuance of the original prescription order by the prescriber. (3) Full name of the patient for whom the drug is intended; 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. (4) Residential address, including the physical street address and telephone number of the patient or owner. (5) Full name and address of the prescriber, including the physical address of the prescriber's practice location. (6) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription. (7) Directions for use. (8) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed. (9) The strength, dosage form, and quantity of the drug or device dispensed. (10) The prescriber's federal drug enforcement administration number, if applicable. (11) The total number of refills authorized by the prescriber. (12) The date of dispensing.	OAC 4729:5-5-04

	(13) The refill history of the prescription, including all of the following: (a) The prescription number; (b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed; (c) The date(s) of dispensing; and (d) The quantity dispensed. ***Substantive Change: New rule sets uniform requirements for animal prescription records (see #3 above).**	
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 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 4729:5-5-04
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; 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. (2) Residential address, including the physical street address and telephone number of the patient or owner. (3) Patient's date of birth. [**NOTE:** For animal prescriptions, use the best estimate for the patient's date of birth, as provided by the animal's owner.] (4) Patient's gender.	OAC 4729:5-5-07

	(5) 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; (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. (6) The pharmacist's comments relevant to the 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 prescription number. (2) Date of issuance of the original prescription by the prescriber. (3) Full name and address of the prescriber, including the physical address of the prescriber's practice location. (4) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription. (5) Directions for use. (6) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed. (7) The strength, dosage form, and quantity of the drug or device dispensed. (8) The prescriber's federal drug enforcement administration registration number, if applicable.	

	(9) The total number of refills authorized by the prescriber. (10) The date of dispensing. (11) The refill history of the prescription, including all the following: (a) The prescription number; (b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed; (c) The date(s) of dispensing; and (d) The quantity dispensed. **NOTE:** An "Insurance Patient Profile" or other similar documentation that does not contain all the required information does not meet the requirements of the rule.	
If using a computerized record keeping system, is the system used by the pharmacy able to capture records edited by authorized personnel and maintain an audit trail?	All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail.	OAC 4729:5-5-04
If using a computerized record keeping system, does the pharmacy have an auxiliary procedure for documenting refills in the event of an outage?	In the event that a pharmacy utilizes a computerized record keeping system that experiences an outage, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is recorded and retained.	OAC 4729:5-5-04
Does the pharmacy maintain prescription information entered into a computerized record keeping system for	Prescriptions entered into a computer system that are not dispensed must meet all of the following requirements: (1) The complete prescription information must be entered in the computer system.	OAC 4729:5-5-04

prescriptions that were not dispensed?	(2) The information must appear in the patient's profile. (3) There is positive identification of the person who is responsible for entering the prescription information into the system and the pharmacist responsible for verifying the prescription information. **NOTE:** The requirement above (#3) does not go into effect for non-pharmacist personnel until 12/01/2021. (4) The prescription must be assigned a prescription number. (5) The original prescription is filed according to rule 4729:5-5-03 of the Administrative Code.	

Serial Numbering of Prescriptions

Question	Guidance	Law/Rule
Are outpatient prescriptions serially numbered when entered into a computer system or when dispensed under a manual system?	All outpatient prescriptions must be serially numbered when entered into a computer system or when dispensed under a manual system. (1) The serial number must appear on the original prescription or be assigned to the prescription within an electronic record keeping system. (2) There must be a complete accounting of all numbers used in the serial numbering system. (3) All prescriptions that cannot be refilled, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon an authorization for additional dispensing by a prescriber or prescriber's agent.	OAC 4729:5-5-13

General Record Keeping Requirements

Question	Guidance	Law/Rule
Does the pharmacy's record keeping system contain security features to prevent unauthorized access to the records?	Required records must be maintained under appropriate supervision and control to restrict unauthorized access, including security features to prevent unauthorized access to computerized records. This access may include a user name and password, security question, pin, fingerprint, etc.	OAC 4729:5-5-24
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 4729:5-5-24
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 4729:5-5-24 ORC 3719.07
Does the pharmacy maintain required records outside of the confines of the pharmacy in accordance with Ohio rules?	**NOTE:** This applies to pharmacies maintaining records on-site but outside of the actual pharmacy. If yes, does the method for storing records comply with the following: (1) The designated area shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. NOTE: 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. (2) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.	OAC 4729:5-5-23

	The security approval request form can be accessed here: www.pharmacy.ohio.gov/security.	
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 outpatient 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. The security approval request form can be accessed here: www.pharmacy.ohio.gov/offsite.	OAC 4729:5-5-24

Drug Purchases and Online Sales

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 4729:5-5-24
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.	

Security, Control, and Storage of Dangerous Drugs

Question	Guidance	Law/Rule
Is a pharmacist providing supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs in the pharmacy?	A pharmacist shall provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs. 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 leave the pharmacy (but must stay on-site) to assist customers, use the bathroom, and eat meals.	OAC 4729:5-5-23
Is the pharmacy separated from the merchandising or public areas?	The pharmacy shall be separated from the merchandising or public areas. Pharmacies must have a clear delineation (counter, half wall, etc.) between the area used for the practice of pharmacy and merchandising and public areas.	OAC 4729:5-5-23
Is a pharmacist ensuring all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacists on duty or secured in a designated area?	If the pharmacy is located within a store or business, the pharmacists on duty shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacists on duty or secured in a designated area.	OAC 4729:5-5-23
Are there any unauthorized persons present in the pharmacy?	No person, other than a licensed pharmacist, may enter the pharmacy unless the person is on business directly concerning the operation (pharmacy intern, technicians, and support personnel), maintenance, or repair of the pharmacy and a pharmacist employed by the pharmacy is physically present at the same time.	OAC 4729:5-5-23

Are all schedule II controlled substances stored in a securely locked, substantially constructed cabinet or safe?	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. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs. ***Substantive Change: This is a policy change from the current requirements. Due to COVID-19, the Board has decided to delay the implementation of this requirement until 3/31/2021.** **Effective 3/31/2021, 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.**	OAC 4729:5-5-23
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
Can the pharmacy be secured by a physical barrier or alarm system?	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	OAC 4729:5-5-23

	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.	
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 or other methods of gaining access to the pharmacy. All keys to the pharmacy that are not in the possession of a licensed pharmacist that are maintained on-site 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.	OAC 4729:5-5-23
Are items, products, records, or equipment that must be accessible to non-pharmacists stored in the pharmacy?	No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the pharmacy.	OAC 4729:5-5-23
Does the pharmacy have a secure area only accessible by pharmacists for customers to deposit new or refill prescription orders when the pharmacy is closed?	If yes, new or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.	OAC 4729:5-5-23

Does the pharmacy maintain dangerous drugs or hypodermics outside of the confines of the pharmacy?	This applies to pharmacies maintaining dangerous drugs and hypodermics outside of the actual pharmacy (storage room, consult room, etc.). If yes, does the method for storing dangerous drugs comply with the following: (1) The designated area shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. **NOTE:** 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. The security approval request form can be accessed here: www.pharmacy.ohio.gov/security. (2) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area. (3) No controlled substances may be stored in the designated area. **NOTE:** This may apply to stock rooms or other areas outside the physical confines of the pharmacy. The designated area must be secured by a physical barrier with suitable locks and items that must be accessible to others (i.e. non-pharmacists) are not present in the secured area. Board staff will confirm that non-pharmacy personnel do not have access to the designated area (i.e. retail staff/managers) and that controlled substances are not present in the designated area.	OAC 4729:5-5-23
Does the pharmacy provide services by means of a secured drive-through facility?	A drive-through facility used by a pharmacy must be constructed and maintained in a manner, and with materials, that secures the premises of the pharmacy from unauthorized access.	OAC 4729:5-5-23

Temperature Monitoring

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 4729:5-5-23 OAC 4729:5-5-24
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 4729:5-5-23

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. **NOTE:** Facilities may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures.	OAC 4729:5-5-23

Theft or Significant Loss of Drugs and Drug Documents

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

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

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. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable.	OAC 4729:5-3-01
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:** While this provision will not generally apply to outpatient pharmacies, 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 4729:5-5-24
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 4729:5-5-24

Drug Collection Receptacles

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 pharmacy 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.	21 CFR 1317.40 [as required by OAC 4729:10-1-02 (A)]
Is the collection receptacle located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter)?	At a registered location, be located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter).	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. (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).	21 CFR 1317.40 [as required by OAC 4729:10-1-02 (A)] OAC 4729:10-1-02

	(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. **NOTE:** Much like access to the pharmacy, only pharmacists may have access to the areas where sealed inner liners are stored. Other individuals may have access to sealed inner liners only under the supervision of a pharmacist.	21 CFR 1317.05 [as required by OAC 4729:10-1-02 (A)]

Drug Samples

Question	Guidance	Rule/Law
Does the pharmacy have sample drugs as part its inventory?	Except for charitable pharmacies, an outpatient 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

Prescription Formatting and Manner of Issuance

Question	Guidance	Rule/Law
Do outpatient prescriptions comply with the manner of issuance rule (OAC 4729:5-5-15)?	All outpatient prescriptions issued by a prescriber shall: (1) Be dated as of and on the day when issued. (2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber. The prescriber's address shall include the physical address of the prescriber's practice location. (3) Indicate a telephone number where the prescriber can be contacted during normal business hours. (4) Indicate the full name and residential address of the patient; 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. The patient or owner's residential address shall include a physical street address. (5) Indicate the drug name and strength. (6) Indicate the quantity to dispense. (7) Indicate the appropriate and explicit directions for use. (8) Specify the number of times or the period of time for which the prescription may be refilled. **NOTE:** Prescriptions for non-controlled substance dangerous drugs bearing "PRN," "Ad lib," or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and, in no instance, shall such prescription be refilled beyond one year from the date of issue. The prescription shall not be refilled out of context with the dosage schedule indicated in the directions for use unless specifically authorized by the prescriber. This **is not permitted** for controlled substance prescriptions.	OAC 4729:5-5-15 21 CFR 1306.05

	(9) Not authorize any refills for schedule II controlled substances. (10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code. *ORC 3719.05 states: Prescriptions for schedule III and IV controlled substances may be refilled not more than five times in a six-month period from the date the prescription is given by a prescriber.* (11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances. (12) Identify the trade name or generic name of the drug(s) in a compounded prescription. (13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice. (14) For a controlled substance: Indicate the Drug Enforcement Administration registration number of the prescriber pursuant to 21 CFR 1306.05. Board staff will review a sample of prescriptions to determine compliance. ***Substantive Change: New rule permits PRN refills for non-controlled prescriptions (see #8 above).**	
Are all prescriptions issued on paper properly signed?	All prescriptions issued on paper to a patient by a prescriber shall be manually signed, *using a wet-ink signature*, on the day issued by the prescriber in the same manner as the prescriber would sign a check or legal document. Board staff will review a sample of prescriptions to determine compliance.	OAC 4729:5-5-15
Do outpatient prescriptions for controlled substance	*For Non-Hospice Prescriptions*	OAC 4729:5-5-05

drugs comply with the applicable prescription formatting requirements?	Outpatient prescriptions for controlled substances must comply with the following: (1) The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, computer-generated hard copy, or preprinted. (2) The quantity has been written both numerically and alphabetically. **NOTE:** For electronic prescriptions, the quantity is not required to be written alphabetically per the following Board resolution: *All electronic prescription transmission systems that meet the requirements of Chapter 4729:5-5 of the Administrative Code shall not be subject to the alphabetical spelling requirements for drug quantity as listed in paragraph (B)(3) of rule 4729:5-5-05. (Adopted 7/12/21)* (3) If preprinted, there is only one drug and strength combination printed on the form. *For Hospice Prescriptions* (1) Preprinted prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to the form. (2) Preprinted forms shall not contain prescription orders for schedule II controlled substances. Schedule II controlled substances may be manually added to the preprinted forms and signed by the prescriber. (3) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either: (a) Manually indicating the total drug orders authorized on the form; or (b) Manually initialing each drug order.	21 C.F.R. 1306.11

	(4) All written drug orders must be signed by the prescriber. (5) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy. (6) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II controlled substances. (7) All schedule II controlled substance prescriptions shall comply with 21 C.F.R. 1306.11 (3/31/2010). Board staff will review a sample of prescriptions to determine compliance.	
Do outpatient prescriptions for non-controlled substance drugs comply with the applicable prescription formatting requirements?	*For Non-Hospice Prescriptions* Outpatient prescriptions for non-controlled substances must comply with the following: (1) If handwritten, typewritten, or computer-generated hard copy, there are no more than three non-controlled substance prescription orders per prescription form. (2) If preprinted with multiple drug names or strength combinations: (a) There are no controlled substances among the choices; (b) There is only one prescription order selected per form. *For Hospice Prescriptions* (1) Preprinted prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to the form. (2) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either:	OAC 4729:5-5-05

	(a) Manually indicating the total drug orders authorized on the form; or (b) Manually initialing each drug order. (3) All written drug orders must be signed by the prescriber. (4) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy. (5) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II controlled substances. Board staff will review a sample of prescriptions to determine compliance.	
Are hardcopy prescription facsimiles transmitted with all of the required information?	In addition to the requirements of prescription, a facsimile of a prescription must include the identification number of the facsimile machine, which is used to transmit the prescription, the full name of the prescriber and, if applicable, the full name of the prescriber's agent transmitting the prescription to the pharmacy. ***Substantive Change: New rule no longer requires a faxed prescription to include header information.**	OAC 4729:5-3-11

Labeling

Question	Guidance	Rule/Law
Are outpatient prescriptions properly labeled?	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; (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.	OAC 4729:5-5-06 21 CFR 1306.05

	***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).**	

Patient Counseling

Question	Guidance	Rule/Law
Is counseling being offered for every outpatient prescription dispensed?	A pharmacist or the pharmacist's designee shall verbally offer to provide the service of counseling to a patient or caregiver whenever any prescription, new or refill, is dispensed. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the dispensed drug or incorporated as part of documentation, in a conspicuous manner, that is included with the dispensed drug. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population. **NOTE:** It is the expectation that every patient/caregiver who picks up a prescription in-person be asked if they have any questions for the pharmacist regarding the prescription. Board staff may observe and document the offering patient counseling to determine compliance.	OAC 4729:5-5-09

Prescription Processing

Pharmacists who are presented with a prescription from a prescriber experiencing a "change of status" must comply with the requirements of paragraph (J) of OAC 4729:5-5-10.

Per rule, a "change of status" includes, but is not limited to, the following: death, incapacity, suspension, surrender or revocation of the prescriber's license or registration, or permanent relocation. For more information, click here.

Question	Guidance	Rule/Law
Are hard copy prescriptions for controlled substances clearly notated to indicate receipt by the pharmacy?	The front of hard copy prescriptions for controlled substance dangerous drugs shall be clearly notated to indicate receipt 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. **NOTE:** There is no specific notation required. However, any notation should make it clear that the prescription was received by the pharmacy.	OAC 4729:5-5-10
Are oral prescriptions properly received by the pharmacy?	In addition to the required components of a prescription, a pharmacist, pharmacy intern, or certified pharmacy technician must make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. This includes prescriptions received from a recording device or voice mail service. **NOTE:** Pharmacy interns and certified technicians are authorized to receive oral prescriptions if all the following apply: (1) The pharmacist on duty who is personally supervising the activity of the intern or certified technician determines that the intern or technician is competent to perform this function. (2) The pharmacist on duty is responsible for the accuracy of the prescription. (3) The pharmacist on duty must be immediately available to answer questions or discuss the prescription with the prescriber or the prescriber's agent. (4) The pharmacy intern or certified pharmacy technician shall immediately transcribe the prescription, document the full name of	OAC 4729:5-5-10 OAC 4729:3-3-04

	the prescriber and, if transmitted by the prescriber's agent, the full name of the agent and shall review the prescription with the pharmacist on duty. (5) Prior to dispensing, positive identification of the intern or certified technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the oral order. **IMPORTANT: A certified pharmacy technician is permitted to receive oral prescriptions for non-controlled drugs only.**	
Does the pharmacy have a system to document the receipt of oral prescriptions using positive identification?	All pharmacy record keeping systems must capture the positive identification of the individual transcribing an order received by telephone, facsimile, or recording device. For certified technicians and pharmacy interns: Prior to dispensing, positive identification of the receiving certified pharmacy technician/pharmacy intern and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the prescription. **IMPORTANT: A certified pharmacy technician is permitted to receive oral prescriptions for non-controlled drugs only.**	OAC 4729:5-5-04 OAC 4729:5-5-10
Is the pharmacy conducting the initial dispensing of drugs within the required timeframe?	For non-opioid analgesics: A pharmacist shall not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription. For opioid analgesics: Except as provided below, a pharmacist shall not dispense the opioid analgesic if more than fourteen days have elapsed since the prescription was issued. A pharmacist may dispense the opioid analgesic after more than fourteen days have elapsed since the prescription was issued if, on the date the prescription was issued, the prescriber issued only one prescription for the drug to the patient and both of the following apply: (1) The prescriber provided written instructions on the prescription specifying the earliest date on which the prescription may be filled	OAC 4729:5-5-10 ORC 4729.46

	and not more than fourteen days have elapsed since the "DO NOT FILL UNTIL" date on the prescription. NOTE: This applies to single prescriptions and multiple concurrent prescriptions. (2) If the prescription for the opioid analgesic was partially filled within the applicable fourteen-day period, a pharmacist may dispense the remaining amount of the opioid analgesic after more than fourteen days have elapsed since the prescription was issued. **IMPORANT:** The fourteen-day limitation does not apply to an opioid analgesic used as part of an individual's treatment for opioid dependence or addiction.	
Is the pharmacy dispensing opioid analgesics that exceed a ninety-day supply?	A pharmacist shall not dispense the opioid analgesic in an amount that exceeds a ninety-day supply, as determined according to the prescription's directions for use of the drug, regardless of whether the prescription was issued for a greater amount. This section does not apply in any of the following circumstances: (1) When an opioid analgesic is to be delivered outside this state by mail, parcel post, or common carrier to a patient who resides outside this state; (2) When an opioid analgesic is to be used as part of an individual's treatment for opioid dependence or addiction; or (3) An opioid analgesic is dispensed for use in an implantable drug delivery system.* *Added via Board resolution issued on December 11, 2019.	ORC 4729.46

Prescription Transfers

NOTE: *Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a licensed central fill pharmacy shall not be considered a prescription copy and is not subject to this section of the inspection guide. [OAC 4729:5-5-11 (F)]*

REMINDER: *Unless otherwise prohibited by law, no pharmacy shall refuse to transfer information about a prescription to another pharmacy when requested by the patient or patient's caregiver. Prescription information shall be transferred in accordance with this rule as soon as possible to ensure that the patient's drug therapy is not interrupted [OAC 4729:5-5-11 (D)(2)].*

Question	Guidance	Rule/Law
Do prescription transfers contain all of the required information?	The copy transferred shall be an exact duplicate of the original prescription, except that it shall also include the following: (1) Serial prescription number assigned to the prescription; (2) Name, address and, if a controlled substance prescription, the Drug Enforcement Administration (D.E.A.) registration number of the pharmacy transferring the copy; (3) Date of issuance of the prescription; (4) Date of last refill; (5) Number of valid refills or quantity remaining; and (6) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician. **IMPORTANT:** A pharmacy intern or certified pharmacy technician is not permitted to transfer a controlled substance.	OAC 4729:5-5-11
Are transferred prescriptions for controlled substances notated appropriately?	A pharmacist transferring a copy of a controlled substance prescription shall, either:	OAC 4729:5-5-11

	(1) For hard copy prescriptions: Write the word "VOID" on the face of the invalidated prescription in a manner that does not destroy any of the original information contained on the prescription. (2) For electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.	
Are transferred prescriptions for controlled substances properly recorded?	A pharmacist transferring a copy of a controlled substance prescription shall: (1) Record on the reverse of the invalidated prescription the name, address, and the D.E.A. registration number of the pharmacy to which it was transferred and the first and last name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record. (2) Record the date of the transfer and the name of the pharmacist transferring the information.	OAC 4729:5-5-11
Are prescriptions for controlled substances transferred by pharmacists?	Copies of prescriptions for controlled substances may only be communicated directly between two pharmacists and shall be transferred only one time. **NOTE:** The one-time limit does not apply to pharmacies electronically sharing a real time, online database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization. **IMPORTANT:** An unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances. **See Drug Enforcement Administration guidance**.	OAC 4729:5-5-11
Are prescriptions for controlled substances transferred invalidated within the pharmacy's record keeping system?	A pharmacist transferring a copy of a controlled substance prescription shall ensure copies of controlled substance prescriptions may only be transferred if the prescription record in the system is invalidated to prevent further dispensing at the original pharmacy.	OAC 4729:5-5-11

Are transferred prescriptions for non-controlled prescriptions properly recorded?	A pharmacist, pharmacy intern, or certified pharmacy technician transferring a copy of a non-controlled substance prescription shall: (1) Utilize a manual or electronic method for invalidating the prescription to prevent further dispensing at the original pharmacy. (2) Record the name and address of the pharmacy to which it was transferred. (3) If transferred orally, the first and last name of the pharmacist or authorized pharmacy personnel receiving the prescription information. ***[Substantive Change: NO LONGER APPLIES TO FAXED TRANSFERS]*** (4) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician transferring the information.	OAC 4729:5-5-11
Is the receipt of prescription transfers being properly recorded?	A pharmacist, pharmacy intern, or certified pharmacy technician receiving a copy of a prescription must comply with the following: (1) Exercise reasonable diligence to determine the validity of the copy. (2) Transcribe an oral prescription by recording all the information transferred. The oral prescription shall include all required information and the pharmacist, pharmacy intern, or certified pharmacy technician shall write the word "transfer" on the face of the prescription or indicate the prescription was transferred within a computerized record keeping system. (3) Record date of transfer on the face of the prescription or within a computerized record keeping system.	OAC 4729:5-5-11
Is the positive identification of the pharmacy personnel receiving prescription transfers being documented?	Pharmacist requirements: Prior to dispensing, positive identification of the receiving pharmacist shall be recorded to identify who is responsible for the receipt of the copy. Pharmacy intern requirements: Prior to dispensing, positive identification of the intern and the supervising	OAC 4729:5-5-11 OAC 4729:3-3-04

	pharmacist on duty shall be recorded to identify who is responsible for the receipt of the copy. Certified technician requirements: 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.	
Does the pharmacy transfer prescriptions using a facsimile machine?	A prescription copy may be transferred using a facsimile machine. A facsimile shall be considered a copy of the prescription if it contains all the required information, including invalidation of the original prescription. Facsimile copies must be recorded in writing pursuant or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction. **REMINDER:** Prescriptions transferred via facsimile machine must comply with the requirements of paragraph (A) of OAC 4729:5-5-11.	OAC 4729:5-5-11
Does the pharmacy ensure that prescription transfers may only occur at the request or consent of the patient or patient's caregiver?	A prescription may only be transferred upon the request or consent of the patient or patient's caregiver.	OAC 4729:5-5-11
Are prescriptions entered into a computer system but not dispensed transferred in compliance with Ohio rules?	Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy, at the request of the patient or patient's caregiver, if all of the following conditions are met: (1) The complete prescription information has been entered into the computer system. (2) The information is displayed on the patient's profile. (3) There is positive identification of the individual responsible for entering the prescription information into the system and the pharmacist responsible for verification of the information entered into the system.	OAC 4729:5-5-11

	(4) The original prescription is filed in accordance with rule 4729:5-5-03 of the Administrative Code. (5) The prescription is assigned a prescription number. (6) All requirements of OAC 4729:5-5-11 are met for the transfer of the prescription. (7) The transfer is conducted in accordance with all state and federal laws, rules and regulations. (8) A pharmacist may transfer an unfilled electronic prescription for a controlled substance to another pharmacist in accordance regulations or policies adopted by the United States Drug Enforcement Administration. **Guidance from DEA**: *Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA's policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.*	

Return to Stock

IMPORTANT: *The contents of a prescription vial or container cannot be returned to the manufacturer's stock bottle.*

Question	Guidance	Rule/Law
Is the pharmacy placing the expiration date on the prescription label?	The expiration date on the label shall not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, 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 one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging.	OAC 4729:5-5-22
Are the dangerous drugs returned to stock shelves maintained in the container in which they were filled?	The dangerous drug products returned to stock shelves shall be maintained in the container in which they were filled and shall maintain their original prescription label containing the original expiration date assigned. The label on the container shall not be removed, altered, or replaced with another label or have any other label added, except as follows: (1) Adding to or modifying the existing label, if the drug name, dose, and original expiration date are maintained. (2) Adding a new label over the existing label on the container. In this instance, the drug shall be verified by a pharmacist or an electronic verification system following the application of the new label. The new label shall include the expiration date assigned on the original label. **NOTE:** Rather than creating a new record, verification by the pharmacist can also be demonstrated by the pharmacist's initials on the new label.	OAC 4729:5-5-22

	(3) A prescription label may be removed if the prescription container is the manufacturer's original sealed packaging and the removal of the label does not remove or otherwise cause to make unreadable the expiration date and lot number on the manufacturer's packaging.	
Does the pharmacy use delivery agents?	"Pharmacy delivery agent" means an employee of the pharmacy, United States postal service, or common or contract carrier who delivers dangerous drugs that have been dispensed. If yes and the pharmacy engages in return to stock, the pharmacy must comply with all the following: (1) Develop and implement a policy to ensure that drugs are maintained by pharmacy delivery agents within temperatures as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling; **-AND-** (2) Either of the following: (a) Each dangerous drug prescription is dispensed in a tamper evident container or package prior to leaving the pharmacy; or (b) The dangerous drug prescription is dispensed in the manufacturer's original tamper evident packaging.	OAC 4729:5-5-22
Do drugs returned to stock shelves show any signs of tampering, adulteration, or exceeding the assigned expiration dates?	A dangerous drug that is dispensed and shows any signs of tampering or adulteration shall not be returned to stock shelves. A dangerous drug that exceeds its assigned expiration date shall be removed from the area for the storage of drugs used for dispensing and administration in accordance with rule 4729:5-3-06 of the Administrative Code.	OAC 4729:5-5-22
Is the pharmacy a government entity that delivers dangerous drugs to psychiatric outpatient facilities or to any service	"Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.	OAC 4729:5-5-22

provider licensed as a terminal distributor of dangerous drugs?	If yes and the pharmacy returns drugs to stock shelves, the pharmacy must ensure the returned drugs comply with the following: (1) The drugs are packaged in unopened, single-dose or tamper-evident containers; and (2) The drugs have not been in the possession of the ultimate user.	
Does the pharmacy transfer dangerous drugs returned to stock shelves?	A pharmacy may conduct transfer dangerous drugs that are returned to stock shelves that meet the requirements of this rule to another pharmacy if the transfer is conducted in accordance with paragraph (E) of rule 4729:5-3-09 of the Administrative Code, which states the following: *(E) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either 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.* ***Substantive Change: New rule allows intracompany transfers of medications returned to stock.**	OAC 4729:5-5-22 OAC 4729:5-3-09

Repackaging of Drugs

Substantive Change: New rule requires adherence to FDA repackaging standards (notably, the requirements for assigning an appropriate beyond-use date).

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 4729:5-5-17
Are repackaged sterile drug products assigned	Beyond-use dates are specified in the FDA repackaging policy (https://www.fda.gov/media/90978/download) as follows:	OAC 4729:5-5-17 →

beyond-use dates in compliance with the requirements of the rule?	**For sterile drug products:** 1. **FDA-approved drug product with a specified in-use time:** If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling a time within which the opened product is to be used (an "in-use" time), the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter. *For example: If an approved drug product that includes a 3-day in-use time and an expiration date of January 15, 2017, on the label is repackaged on January 1, 2017, the applicable BUD for the repackaged drug product would be January 4, 2017, because the labeled in-use time of 3 days is shorter than the time until the labeled expiration date of the drug product (14 days). If the drug product is repackaged on January 14, 2017, the applicable BUD for the repackaged drug product would be January 15, 2017, because the time until the labeled expiration date of the approved drug product is 1 day, which is shorter than the labeled 3-day in-use time.* 2. **FDA-approved drug product without an in-use time or unapproved drug product:** If the drug product being repackaged is an FDA-approved drug product whose labeling does not specify an in-use time, or if it is an unapproved drug product on the FDA drug shortage list (which does not have an in-use time reviewed by FDA as part of the drug approval process), the repackaged drug product is assigned a BUD (1) that is established in accordance with the proposed revision to USP 797; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.	FDA Repackaging Policy
Are repackaged non-sterile drug products assigned beyond-use dates in compliance with the requirements of the rule?	**For non-sterile drug products:** 1. **FDA-approved drug product with a specified in-use time:** If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling an "in-	OAC 4729:5-5-17 → FDA Repackaging Policy

	use" time, the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter. 2. **FDA-approved drug product without an in-use time or unapproved drug product:** ▪ For nonaqueous formulations, the BUD does not exceed six months or the expiration date of the drug product being repackaged, whichever is shorter. ▪ For water-containing oral formulations, the BUD does not exceed 14 days or the expiration date of the drug product being repackaged, whichever is shorter. ▪ For water-containing topical/dermal and mucosal liquid and semisolid formulations, the BUD does not exceed 30 days or the expiration date of the drug product being repackaged, whichever is shorter.	
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 in accordance with the guidance listed in paragraph (C) of this rule. **REMINDER:** Repackaged medications dispensed for outpatient use must also comply with the labeling requirements of rule 4729:5-5-06 of the Administrative Code.	OAC 4729:5-5-17

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 or universal product code, 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; (5) Pharmacy control number; (6) Manufacturer's or distributor's expiration date; (7) The pharmacy's beyond-use date in accordance with the FDA repackaging policy; (8) The positive identification of the individual responsible for the repackaging of the drug; and (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.	OAC 4729:5-5-17
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 4729:5-5-17

Customized Patient Medication Packaging (Adherence Packaging)

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 outpatient 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 4729:5-5-18
Do the customized medication packages dispensed by the pharmacy comply with all applicable 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 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 this chapter of the Administrative Code, including the use of accessory labels. (5) 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: ▪ The drugs have not been in the possession of the ultimate user; and ▪ 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). (6) 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 4729:5-5-18

Do the customized medication packages have the correct expiration/beyond-use dates?	The package must include an 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.	OAC 4729:5-5-18
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: (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.	OAC 4729:5-5-18

Partial Dispensing of Schedule II Controlled Substances

Question	Guidance	Rule/Law
Are schedule II controlled substances partially dispensed for terminally ill patients or patients residing in a long-term care facility in accordance with applicable rules and regulations?	A prescription for a schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units in accordance with all the following: (1) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." (2) For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of the partial dispensing if different, and the manual initials or other form of positive identification of the dispensing pharmacist. (3) The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. (4) Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. **NOTE:** Per federal regulations, if there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the prescriber prior to partially filling the prescription.	OAC 4729:5-5-12 21 C.F.R. 1306.13
Are schedule II controlled substances partially dispensed for terminally ill patients or patients who DO NOT reside in a long-term care facility in accordance with applicable rules?	For a patient who is not terminally ill or residing in a long-term care facility, a pharmacist shall comply with the following: (1) The partial dispensing shall be requested by the patient or the prescriber that issued the prescription (or if the pharmacy is unable to supply the quantity in the prescription).	OAC 4729:5-5-12 21 USC 829 (f) 21 C.F.R. 1306.13

	(2) For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of the partial dispensing if different, and the manual initials or other form of positive identification of the dispensing pharmacist. (2) The total quantity dispensed in all partial dispensings shall not exceed the total quantity prescribed. (3) The remaining portions of a partially dispensed schedule II controlled substance prescription shall comply with either of the following: ▪ For prescriptions partially dispensed at the request of the patient or prescriber (21 USC 829 (f)): The remaining portion must be filled no later than thirty days after the date on which the prescription is written. **-OR-** ▪ For prescriptions partially dispensed as a result of the pharmacy unable to supply the full quantity (21 C.F.R. 1306.13): No further quantity may be supplied beyond 72 hours without a new prescription.	
Does the pharmacy maintain records documenting the partial dispensing of schedule II controlled substances?	At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription or within a computerized record keeping: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of the partial dispensing if different, and the manual initials or other form of positive identification of the dispensing pharmacist.	OAC 4729:5-5-12
For partial fills of schedule II controlled substances, does the pharmacy's computerized record keeping system comply	If a computerized record keeping system is being used and the system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.	OAC 4729:5-5-12

with the requirements of the rule?	(1) A notation must also be made in the record keeping system that identifies the new prescription number as a partial dispensing and provides the serial number of the original prescription. (2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription and all previous partial fills.	

Charitable Pharmacies

This section only applies to charitable pharmacies. Per Chapter 4729:5-7 of the Ohio Administrative Code, a charitable pharmacy means a pharmacy that meets all of the following requirements:

(1) Holds a terminal distributor of dangerous drug license issued under section 4729.54 of the Revised Code;

(2) Is exempt from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3) (5/28/2015); and

(3) Is not a hospital as defined in section 3727.01 of the Revised Code.

Question	Guidance	Rule/Law
Does the charitable pharmacy use support personnel to sort donations of non-controlled substance dangerous drugs?	A charitable pharmacy may designate employees and volunteers as support personnel, as defined in chapter 4729:3-1-01 of the Administrative Code, for the purposes of sorting donations of non-controlled substance dangerous drugs. (1) Drug sorting shall be conducted under the personal supervision of a licensed pharmacist. (2) Support personnel are not permitted to label, package, repackage or dispense dangerous drugs. (3) The charitable pharmacy shall have written policies and procedures for drug sorting by support personnel. Such policies and procedures shall require documentation of all activities related to drug sorting, including participation logs, support personal information (name, address, contact phone, etc.), and a daily activity log to be signed by the licensed pharmacist or pharmacists providing supervision. All documents and records must be readily retrievable and shall be maintained on-site for a period of three years.	OAC 4729:5-7-02
Does the charitable pharmacy receive sample drugs from eligible persons?	An eligible sample drug shall only be transferred directly to a charitable pharmacy by any of the following: (1) A manufacturer licensed in accordance with section 4729.52 of the Revised Code, including a representative of the manufacturer;	OAC 4729:5-7-03

	(2) A person (i.e. a drug distributor) licensed in accordance with section 4729.52 of the Revised Code acting on behalf of a manufacturer; or (3) A prescriber practicing at a location that is licensed as a terminal distributor of dangerous drugs, unless exempt from licensure pursuant to section 4729.541 of the Revised Code.	
Do the sample drugs received by the charitable pharmacy meet the eligibility requirements?	An eligible sample drug received by a charitable pharmacy shall meet all the following requirements: (1) The sample drug is in the original manufacturer's container and the container is clearly marked as a sample. (2) Prior to being transferred, the sample drug has been stored under the proper conditions to prevent deterioration or adulteration. (3) The sample drug is clearly marked with an expiration date and lot number. (4) The sample drug is not expired. (5) The sample drug is not a controlled substance.	OAC 4729:5-7-04
Do the drug samples dispensed by the charitable pharmacy meet the requirements in rule?	Drug samples shall comply with the same dispensing requirements of outpatient pharmacies. Additionally, the dispensing of samples shall comply with the following: (1) The sample drug shall be dispensed to the patient free of charge. (2) The sample drug may be dispensed: (a) In the manufacturer's original container where the container is clearly marked as a sample; or (b) By removing the sample drug from the original container only if the prescription label on the appropriate container, pursuant to all state and federal requirements, clearly states that the drug dispensed is a sample drug.	OAC 4729:5-7-05

OARRS & Prospective Drug Utilization Review

Rule 4729:5-5-08 of the Ohio Administrative Code requires a pharmacist to query request and review an OARRS report covering at least a one-year time period under circumstances. For more information on these requirements, a guidance document is available **here**.

REMINDER: Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Question	Guidance	Rule/Law
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 OAC 4729:5-5-08
Are pharmacists performing prospective drug utilization reviews prior to the dispensation of a prescription?	Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying the following: (1) Over-utilization or under-utilization; (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.	OAC 4729:5-5-08

Drug Compounding

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

Naloxone Dispensing

For more information on the naloxone dispensing, visit: www.pharmacy.ohio.gov/naloxone.

Question	Guidance	Rule/Law
Does the pharmacy dispense naloxone pursuant to a protocol?	Any pharmacy that dispenses naloxone pursuant to section 4729.44 of the Revised Code shall notify the board, in a manner determined by the Board, within thirty days of establishing a protocol. A pharmacy that no longer dispenses naloxone pursuant to section 4729.44 of the Revised Code shall notify the Board, in a manner determined by the board, within thirty days of discontinuation. A pharmacy must submit a naloxone notification form. To verify if your pharmacy has submitted a form, visit the Board's naloxone pharmacy page.	OAC 4729:1-3-04
Does the pharmacy have a supply of naloxone on-hand?	Except in the event of a drug shortage, a pharmacy submitting notification of naloxone dispensing shall ensure naloxone is made available.	OAC 4729:1-3-04
Does the pharmacy's dispensing protocol include the required information?	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. A physician-established protocol for the dispensing of naloxone by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following: (1) A description of the clinical pharmacology of naloxone. (2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol. (3) Precautions and contraindications concerning dispensing naloxone. (4) Naloxone products authorized to be dispensed, including all of the following information: (a) Name of product; (b) Dose;	OAC 4729:1-3-04

	(c) Route of administration and required delivery device; and (d) Directions for use. (5) Any patient instructions in addition to the required patient training. **NOTE:** A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs. Unlike most prescription medications, a pharmacy intern is permitted to dispense naloxone under the personal supervision of a pharmacist. Protocols must be renewed by a physician on a biennial basis. Board staff will review protocols to determine compliance.	
Does the pharmacy provide in-person training to individuals requesting naloxone that complies with the requirements of the rule?	A pharmacist or a pharmacist's designee that is appropriately trained shall provide in-person training, unless the in-person training requirement is waived by the board, and written educational materials to the individual to whom naloxone is dispensed that includes all the following: (1) Risk factors of opioid overdose; (2) Strategies to prevent opioid overdose; (3) Signs of opioid overdose; (4) Steps in responding to an overdose; (5) Information on the naloxone dispensed; (6) Procedures for administering the naloxone dispensed; (7) Proper storage and expiration of the naloxone dispensed; and (8) Information on where to obtain a referral for substance abuse treatment. Pharmacy staff may be asked to demonstrate the training provided. Providing the patient with a brochure without review of the materials contained in the brochure is not considered appropriate training. Training that incorporates written or audio/visual materials is acceptable. **REMINDER:** The training requirements do not apply if the patient has already received the training (i.e. has already been dispensed naloxone by the pharmacy) and all the following apply:	OAC 4729:1-3-04 OAC 4729:2-3-04

	(1) The patient is offered training and refuses; (2) The pharmacist or pharmacist designee has documentation confirming training pursuant to this rule has been provided within the previous twelve months; (3) A pharmacist who dispenses naloxone pursuant to this rule shall still instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone. **NOTE:** The rule allows for the Board to waive the in-person training requirements [OAC 4729:1-3-04 (D)]. To make a request, a licensee must submit a detailed request to: compliance@pharmacy.ohio.gov.	
Does the pharmacist or pharmacy intern instruct the individual to whom the naloxone is dispensed to summon emergency services?	A pharmacist or pharmacy intern who dispenses naloxone pursuant to this rule shall instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone. If provided verbally, Board staff will review training materials or documentation to ensure that this is part of the pharmacy's naloxone dispensing process.	OAC 4729:1-3-04 OAC 4729:2-3-04
Does the pharmacy provide annual training on the availability of naloxone pursuant to a protocol?	A pharmacy that has submitted notification of naloxone dispensing shall provide initial training to all new employees and annual training to existing employees on the availability of naloxone dispensing pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include: pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees, and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable. Board staff will review training documentation to determine compliance.	OAC 4729:1-3-04

	***Substantive Change: New rule requires employee training.**	

Expired/Adulterated Drugs

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 4729:5-5-23
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 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

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 transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code (i.e. intracompany transfer or occasional sale) must contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale. 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 4729:5-5-24 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.	OAC 4729:5-3-09

	(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.	

Prescription Pick-Up Stations

Question	Guidance	Rule/Law
Does the pharmacy accept prescriptions from pick-up stations or other intermediaries?	No pharmacist shall accept prescriptions obtained from a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled unless such place is a pharmacy as defined in section 4729.01 of the Revised Code and all of the following apply: (1) The site is licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code; (2) The receipt, storage, control, and distribution of prescriptions are in the full and actual charge of a pharmacist licensed pursuant to Chapter 4729. of the Revised Code; (3) A record keeping system is in place that will provide accountability for proper receipt, delivery, disposal and return of all prescriptions; (4) There is a documented method in place to ensure compliance with rule 4729:5-5-09 of the Administrative Code.	OAC 4729:5-5-14
Does the pharmacy dispense dangerous drugs to a facility that acts as a pick-up station?	In this scenario, a pick-up station is a facility that receives patient-specific prescriptions from the pharmacy and then distributes/administers the drugs to the patient. Document the types of prescriptions that are dispensed by the pharmacy. If yes, Board staff will confirm that the pharmacy only sends dispensed medications to any of the following: (1) A licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code; (2) An exempted entity pursuant to section 4729.541 of the Revised Code; or (3) A facility that is unlicensed and not exempt but that has been granted a waiver is granted by the Board.	OAC 4729:5-5-14

Is there clear and convincing evidence that the facility serving as a pick-up station in the interest of the patient or public health?	To serve as a pick-up station, there must be clear and convincing evidence that delivery of a prescription medication directly to the patient would result in: (a) Danger to public health or safety, or (b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy. A pick-up station is not for the convenience of the patient/prescriber or pharmacy. It is only valid for those situations where there is evidence it is in the best interest of the patient or the public to have the drug be provided by the prescriber. Examples include: -Injectable drugs the prescriber will administer on-site. -Distribution of specialty medications which require specialized storage or administration education, medications for patients in a mental health clinic, who should not (for safety reasons) have possession of large quantities of their medications without increased medical supervision. **NOTE:** Non-self-injectable cancer drugs are generally required by law (ORC 4729.43) to be sent from a pharmacy directly to a prescriber for administration.	OAC 4729:5-5-14
Is the receipt, storage, control and distribution of prescriptions or drugs in the full and actual charge of a licensed health care professional at the pick-up station location?	The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715. (Dental Practice Act), 4723. (Nurse Practice Act), 4729. (Pharmacy Practice Act), 4730. (Physician Assistant Practice Act), 4731. (Medical Practice Act), or 4741. (Veterinary Medical Practice Act) of the Revised Code.	OAC 4729:5-5-14
Is there a record keeping system in place to provide accountability for the proper receipt delivery and	Record keeping systems must include a record of patient specific prescriptions delivered to the facility acting as a pick-up station, a record of distribution or administration of the drugs to the individual patient, and a record of all medications returned to the pharmacy.	OAC 4729:5-5-14

return of all prescription medications?	Receipt of prescriptions should be an invoice such that each patient specific prescription is identifiable, including a date of delivery, and documentation of receipt. Board staff will review a sample of records to determine compliance.	

Immunization Administration - Ohio Requirements

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*

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. (2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for	ORC 4729.41 OAC 4729:1-3-02

	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: (1) Full name and address of the patient; (2) Patient's date of birth or age;	OAC 4729:5-5-04

	(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. **IMPORTANT:** On 1/11/2021, the Board issued the following resolution on the requirements for COVID-19 vaccine administration: *To ensure streamlined vaccine administration, the State of Ohio Board of Pharmacy temporarily authorizes records of COVID-19 vaccine administration by pharmacy personnel (pharmacists, interns, technicians) to comprise the following:* *Records of COVID-19 vaccine administration by pharmacy personnel shall contain the name, strength, dosage form, and quantity of the vaccine administered, the name and date of birth of the person to whom or for whose use the vaccine was administered, the date of administration, and the identification of the pharmacy personnel administering the drug. This resolution does not supersede any record keeping requirements from the Ohio Department of Health or any federal agency.*	
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:	ORC 4729.41 OAC 4729:1-3-02 OAC 4729:2-3-03

	(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.	
Do pharmacists or pharmacy interns administering immunizations maintain proof of successful completion of an immunization training course?	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. **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.	OAC 4729:1-3-02 OAC 4729:2-3-03
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.	OAC 4729:1-3-02 OAC 4729:2-3-03

Immunization Administration - Federal Requirements

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 (HHS). For more information visit: www.pharmacy.ohio.gov/COVIDvaccine and www.pharmacy.ohio.govCV2020*

Additionally, pharmacy technicians (registered and certified) are permitted to administer certain vaccines under the process established by the U.S. Department of Health and Human Services. For more information on visit: www.pharmacy.ohio.gov/TechVaccine

Question	Guidance	Rule/Law
Does the pharmacy offer immunizations?	The federal amendment permits administration of any of the following: ▪ Any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP-recommended vaccines). ▪ Any FDA-approved or FDA-licensed COVID-19 vaccines to persons ages 3 or older. Additional guidance can be accessed here: www.pharmacy.ohio.govCV2020 www.pharmacy.ohio.gov/COVIDvaccine www.pharmacy.ohio.gov/TechAdmin	HHS Process
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: (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;	HHS Process → OAC 4729:1-3-02

	(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. **IMPORTANT:** On 1/11/2021, the Board issued the following resolution on the requirements for COVID-19 vaccine administration: *To ensure streamlined vaccine administration, the State of Ohio Board of Pharmacy temporarily authorizes records of COVID-19 vaccine administration by pharmacy personnel (pharmacists, interns, technicians) to comprise the following:* *Records of COVID-19 vaccine administration by pharmacy personnel shall contain the name, strength, dosage form, and quantity of the vaccine administered, the name and date of birth of the person to whom or for whose use the vaccine was administered, the date of administration, and the identification of the pharmacy personnel administering the drug. This resolution does not supersede any record keeping requirements from the Ohio Department of Health or any federal agency.*	
Does a pharmacist document an order for immunization administration?	For the federal process only: Pharmacists must document the order for vaccine administration and those administered by a pharmacy intern they are supervising on a prescription form or other record, which may be assigned a number for record keeping purposes. Such records must be maintained for three years from the date of the order.	HHS Process
Do pharmacists or pharmacy interns administering immunizations maintain proof of successful completion of an immunization training course?	According to HHS, the licensed pharmacist or pharmacy intern must have completed the immunization training that the licensing state requires. Additional guidance can be accessed here: www.pharmacy.ohio.govCV2020 and www.pharmacy.ohio.gov/COVIDvaccine	HHS Process
Do pharmacy technicians administering immunizations maintain	The qualified pharmacy technician (i.e. registered or certified pharmacy technician) must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education	HHS Process

proof of successful completion of an immunization training course?	(ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.	
Do pharmacists, pharmacy interns, or technicians administering immunizations maintain certification to perform basic life-support procedures?	A pharmacist, intern, or technician immunizing under the federal requirements must have a current certificate in basic cardiopulmonary resuscitation. Unlike Ohio's requirements, the guidance from HHS does not specify an organization.	HHS Process
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 family physician or, if the individual has no family physician, 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.	HHS Process → ORC 4729.41 OAC 4729:1-3-02 OAC 4729:2-3-03
Does the pharmacy inform patients 18 years and younger of the importance of well-child visits?	Pharmacy staff (pharmacists, interns, or technicians) must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a	HHS Process

	well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate. The American Academy of Pediatrics offers information on well-child visits, including informational handouts: https://brightfutures.aap.org/Pages/default.aspx	

Drug Administration (Non-Immunization)

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

Dispensing Epinephrine Autoinjectors via Protocol

For additional information on Ohio's epinephrine dispensing laws, visit: www.pharmacy.ohio.gov/epilaws

Question	Guidance	Rule/Law
Does the pharmacy dispense epinephrine autoinjectors via protocol?	A pharmacist/pharmacy intern may dispense an epinephrine autoinjector without a prescription to either of the following in accordance with a physician-established protocol: (1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs; or (2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code. **NOTE:** Individual must be 18 years of age or older.	ORC 4729.47 OAC 4729:1-3-06 OAC 4729:2-3-06
Does the pharmacy's dispensing protocol include the required information?	A physician-established protocol for the dispensing of epinephrine autoinjectors by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following: (1) Indications for use of epinephrine autoinjectors, including criteria for identifying persons eligible to receive an autoinjector under the protocol. (2) Precautions and contraindications related to the dispensing of epinephrine autoinjectors. (3) Epinephrine autoinjectors authorized to be dispensed, including all the following information: (a) Name of product; (b) Dose; (c) Quantity to be dispensed; and (d) Directions for use. (4) Any patient instructions in addition to the required patient training. Board staff will review protocol to determine compliance.	OAC 4729:1-3-06

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. Board staff will review protocol to determine compliance.	OAC 4729:1-3-06
Does the pharmacy provide in-person training to individuals requesting epinephrine?	A pharmacist/pharmacy intern who dispenses an epinephrine autoinjector via protocol shall provide the following training to the individual to whom the epinephrine autoinjector is dispensed: (1) Instruction, either verbally or in writing, to summon emergency services as soon as practicable either before or after administering epinephrine. (2) Instruction on the proper method of administering epinephrine with the device.	OAC 4729:1-3-06 OAC 4729:2-3-06
Does the pharmacy notify an individual's primary care provider, if known, or the prescriber who issued the individual the initial prescription for an epinephrine autoinjector?	A pharmacist or pharmacy intern who dispenses epinephrine via protocol shall provide notice of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for epinephrine. 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; (7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.	OAC 4729:1-3-06 OAC 4729:2-3-06

Diagnostic Laboratory Testing

REMINDER: *Pharmacists are permitted to order and administer COVID-19 testing and pharmacy interns, certified pharmacy technicians, and registered pharmacy technicians are permitted to administer COVID-19 testing. For more information, visit: www.pharmacy.ohio.gov/COVIDtest*

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

Drug Repository Program

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

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

Question	Guidance	Law/Rule
Does the consult agreement contain all the required information?	**NOTE:** "Practitioner" include 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. 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	OAC 4729:1-6-02

Pseudoephedrine or Ephedrine Products

Question	Guidance	Law/Rule
Does the licensee maintain a log book of all purchases of pseudoephedrine or ephedrine products in compliance with Ohio law?	A retailer or terminal distributor of dangerous drugs that sells, offers to sell, holds for sale, delivers, or otherwise provides a pseudoephedrine product or ephedrine product to the public shall maintain a log book of all purchases of pseudoephedrine products or ephedrine products made without a valid prescription. The log book may be maintained in a tangible format, in an electronic format, or in both formats. As part of fulfilling this requirement, the retailer or terminal distributor of dangerous drugs shall do all of the following: (1) Require each individual who purchases a pseudoephedrine product or ephedrine product without a valid prescription to sign an entry in the log book; (2) Determine whether the name signed in the entry in the log book corresponds with the name on a government-issued identification card; and (3) Retain the log book in a tangible format, in an electronic format, or in both formats for a minimum of one year after the date of the last purchase recorded in the log book or as required by federal law.	ORC 3715.051
Does the licensee incorporate the required statement for selling pseudoephedrine or ephedrine products?	The following statement must be incorporated into the log book or posted in a conspicuous location: *"Ohio law prohibits the over-the-counter purchase of a consumer product containing a total amount of base pseudoephedrine or base ephedrine that exceeds either three and six tenths grams in a single day or nine grams within any period of thirty consecutive days. If, without a valid prescription, you purchase a consumer product containing pseudoephedrine or ephedrine, you are required to sign a log book that may be accessible to law enforcement officers and provide a government-issued identification card to verify your identity. Except in limited circumstances, the purchase of more than the permissible amount of a consumer product*	ORC 3715.051

	containing pseudoephedrine or ephedrine, and the purchase by any individual under eighteen years of age of a consumer product containing pseudoephedrine or ephedrine, are subject to criminal prosecution or delinquency proceedings in accordance with Ohio law. Also, the provision of false information concerning an individual's name, age, or other identification for the purpose of acquiring a consumer product containing pseudoephedrine or ephedrine is subject to criminal prosecution or delinquency proceedings in accordance with Ohio law." **NOTE:** If the statement is incorporated into the log book, it must comply with either of the following: (1) If the log book is maintained in an electronic format, the statement shall be set forth in such a manner that it is presented on the viewing screen to each purchaser who is signing an entry in the log book before the purchaser may sign the entry. (2) If the log book is maintained in a tangible format, the statement shall be set forth on the cover of the log book and on each page of the log book.	

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

Outpatient Central Fill Pharmacies – Originating Pharmacy

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

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

- *"Central fill pharmacy" means an outpatient 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.* ***IMPORTANT: Central fill pharmacies must comply with all applicable outpatient 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?	A central fill pharmacy shall either have the same owner as the originating pharmacy or have 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. Licensees must ensure that the central fill pharmacy is appropriately licensed as a terminal distributor of dangerous drugs. The contract shall expressly state who is responsible for performing the patient counseling requirements in accordance with rule 4729:5-5-09 of the Administrative Code.	OAC 4729:5-5-19
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 4729:5-5-19
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 4729:5-5-07 of the Administrative Code prior to sending a prescription to the central fill pharmacy. As a reminder, patient profiles consist of both a patient data record and a drug therapy record.	OAC 4729:5-5-19

	A patient data record shall contain all the following information: (1) Full name of the patient for whom the drug is intended; 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. (2) Residential address, including the physical street address and telephone number of the patient or owner. (3) Patient's date of birth. (4) Patient's gender. (5) 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; (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. (6) The pharmacist's comments relevant to the 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 prescription number. (2) Date of issuance of the original prescription by the prescriber. (3) Full name and address of the prescriber, including the physical address of the prescriber's practice location.	

	(4) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription. (5) Directions for use. (6) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed. (7) The strength, dosage form, and quantity of the drug or device dispensed. (8) The prescriber's federal drug enforcement administration registration number, if applicable. (9) The total number of refills authorized by the prescriber. (10) The date of dispensing. (11) The refill history of the prescription, including all the following: (a) The prescription number; (b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed; (c) The date(s) of dispensing; and (d) The quantity dispensed. **NOTE:** An "Insurance Patient Profile" or other similar documentation that does not contain all the required information does not meet the requirements of the rule.	
Do prescription labels contain the required information?	In addition to the labeling requirements established in rule 4729:5-5-06, the prescription label attached to the container shall contain the name and address of the originating pharmacy. The date on which the prescription was dispensed shall be the date on which the central fill pharmacy filled the prescription. **NOTE:** If the originating pharmacy and the central fill pharmacy are not under common ownership, either of the following shall apply:	OAC 4729:5-5-19

	1. The name of the central fill pharmacy shall be included on the prescription label or an auxiliary label; or 2. A statement is included on the prescription information accompanying the dangerous drug that indicates a central fill pharmacy was used to fill the prescription and includes the name of the central fill pharmacy.	
Is the originating pharmacy able to provide the name and address of the central fill pharmacy and a contact phone number where the patient or caregiver can receive further assistance regarding prescriptions filled by a central fill pharmacy?	The originating pharmacy shall provide, upon the request of a patient or caregiver, the name and address of the central fill pharmacy and a contact phone number where the patient or caregiver can receive further assistance regarding prescriptions filled by a central fill pharmacy.	OAC 4729:5-5-19
Does the originating pharmacy maintain all original prescription orders?	The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law, rules, and regulations.	OAC 4729:5-5-19
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 4729:5-5-19
	The central fill pharmacy and originating pharmacy shall each maintain records to capture the positive identification of the licensed or registered individuals responsible for performing respective activities in accordance with paragraph (A) of rule 4729:5-5-04 of the Administrative Code.	OAC 4729:5-5-19

Outpatient Central Fill Pharmacies – Central Fill Pharmacy

This section applies to in-state outpatient 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 outpatient pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill a prescription.*

- *"Central fill pharmacy" means an outpatient 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.* ***IMPORTANT: Central fill pharmacies must comply with all applicable outpatient 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?	A central fill pharmacy shall either have the same owner as the originating pharmacy or have 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. Licensees must ensure that the originating pharmacy is appropriately licensed as a terminal distributor of dangerous drugs. The contract shall expressly state who is responsible for performing the patient counseling requirements in accordance with rule 4729:5-5-09 of the Administrative Code.	OAC 4729:5-5-19
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 of dangerous drugs license number, and, if applicable, drug enforcement administration registration number, for which it processes a request for the filling or refilling of a prescription received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.	OAC 4729:5-5-19
Does the central fill pharmacy have access to	The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or	OAC 4729:5-5-19

the required files to dispense or process medication orders/prescriptions?	have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.	
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 Ohio laws and rules. The quality assurance plan shall be reviewed and updated annually.	OAC 4729:5-5-19
Do prescription labels contain the required information?	In addition to the labeling requirements established in rule 4729:5-5-06, the prescription label attached to the container shall contain the name and address of the originating pharmacy. The date on which the prescription was dispensed shall be the date on which the central fill pharmacy filled the prescription. **NOTE:** If the originating pharmacy and the central fill pharmacy are not under common ownership, either of the following shall apply: 1. The name of the central fill pharmacy shall be included on the prescription label or an auxiliary label; or 2. A statement is included on the prescription information accompanying the dangerous drug that indicates a central fill pharmacy was used to fill the prescription and includes the name of the central fill pharmacy.	OAC 4729:5-5-19
Does the central fill facility capture the positive identification in accordance with rule 4729:5-5-04?	The central fill pharmacy and originating pharmacy shall each maintain records to capture the positive identification of the licensed or registered individuals responsible for performing respective activities in accordance with paragraph (A) of rule 4729:5-5-04 of the Administrative Code.	OAC 4729:5-5-19
Does the central fill pharmacy comply with the requirements to dispense directly to patients?	A central fill pharmacy may dispense a prescription directly to a patient pursuant to the following requirements:	OAC 4729:5-5-19

	1. A prospective drug utilization review is conducted pursuant to a written contract or agreement in accordance with rule 4729:5-5-08 of the Administrative Code; 2. Patient counseling is provided pursuant to a written contract or agreement in accordance with rule 4729:5-5-09 of the Administrative Code; and 3. The dispensing is conducted in accordance with all other applicable state and federal laws, regulations and rules, including those specified in Federal Register Citation 68 FR 37405 (7/24/2003).	

Dispensing Nicotine Replacement Therapy (NRT)

This section applies to dispensing of nicotine replacement therapy via a physician-approved protocol. For more information, the Board developed the following guidance document: www.pharmacy.ohio.gov/NRT.

REMINDER: *"Nicotine replacement therapy" is defined as a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation including for the cessation of alternative nicotine delivery systems, such as e-cigarettes.*

NRT does not include the dispensation of nicotine cessation medications such as varenicline tartrate (Chantix) and buproprion hydrochloride (Zyban). Those medications may only be dispensed in accordance with a valid prescription. It does include OTC nicotine formulations (patch, gum, lozenge) and prescription nicotine formulations (inhaler and nasal spray).

Question	Guidance	Law/Rule
Does the licensee dispense NRT pursuant to a physician-approved protocol?		OAC 4729:1-3-07
Does the physician-approved dispensing protocol meet the requirements of the rule?	Protocol must be established by an Ohio-licensed physician (MD/DO) and must be renewed by the physician on a biennial basis. Protocols for NRT may not be authorized by other prescribers (nurse practitioners, physician assistants, etc.). The protocol is required to include **ALL** the following: 1. A definitive set of treatment guidelines and the locations where a pharmacist may dispense nicotine replacement therapy. 2. The types of nicotine replacement therapy that may be dispensed. 3. The provisions of implementation, which **must** include: a. A screening procedure (recommended by the U.S. Centers for Disease Control and Prevention or another organization approved by the Board) to determine if	OAC 4729:1-3-07

	an individual is a good candidate to receive nicotine replacement therapy. **IMPORTANT:** If a patient is identified as a candidate, the pharmacist is required to provide notice to the patient's primary care provider no later than 72 hours after a screening. If the patient's primary care provider is unknown, the pharmacist shall provide the same information to the patient. The notice should include: the results of the screening, dispensing record, and follow-up care plan. The pharmacist should keep a copy of the notice for their records (record must be maintained for three years from date of creation). b. A requirement that the pharmacist refer high-risk individuals or individuals with contraindications to a primary care provider or to another type of provider (if appropriate). c. A requirement that the pharmacist must develop and implement a follow-up care plan, including a recommendation by the pharmacist that the individual seek additional assistance with behavior change, including assistance from the Ohio Tobacco Quit Line made available by the Ohio Department of Health. **NOTE:** The follow-up plan must include the following: 1. A recommendation that the patient notify their provider regarding their attempt to quit tobacco use. 2. A plan to deal with the psychological aspects of tobacco addiction, including information regarding how to seek services from the Ohio Tobacco Quit Line. 3. A plan for how to deal with potential side effects of the nicotine replacement medication.	

	4. Instructions for how, when, and how many times to refill the nicotine replacement therapy medication. 5. A timeline for when to follow-up with patient, which should occur within a clinically appropriate length of time after the initiation of the nicotine replacement therapy as deemed appropriate by the pharmacist. 6. How and when to stop using nicotine replacement therapy. 7. Instructions to seek assistance from the pharmacist or provider before continuing to use the medication if a relapse occurs and tobacco use is reinitiated. 8. If a patient returns to the pharmacy to report a relapse, the follow-up care plan should include efforts to identify smoking cues and triggers and consider an alternative coping strategy before a follow-up attempt to quit tobacco. 9. Instructions to seek assistance from a prescribing provider to add prescription-only smoking cessation medication to the pharmacist-initiated nicotine replacement therapy, if dual therapy is indicated for the patient. **IMPORTANT:** All physician-established protocols must be signed and dated by the physician **prior to implementation**. A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.	
Does the pharmacist performing NRT dispensing pursuant to a protocol have the requisite training?	A pharmacist must successfully complete a course on nicotine replacement therapy that is taught by a provider that is accredited by the Accreditation Council for Pharmacy Education, or another provider approved by the State Board of Pharmacy. [See FAQ #6 of this document for Board-approved providers.] Pharmacists must be able to provide documentation demonstrating compliance with this requirement.	OAC 4729:1-3-07

Outpatient Pharmacy - Update History

Update Date	Section Update	Update
12/21/2020	Important Terms (Pages 10-11)	Updated definition of "securely locked, substantially constructed cabinet or safe" to remove the specific requirement that the cabinet or safe must be constructed of metal. The definition now states the cabinet or safe must be "substantially constructed to generally resist entry by unauthorized persons."
12/28/2020	Return to Stock	Removed duplicate question.
1/11/2021	Filing and Storage of Prescriptions	Removed requirement to mark "copy" on prescriptions received electronically that are printed for record keeping purposes.
1/11/2021	Immunization Administration - Ohio Requirements	Added reference to Board resolution on record keeping requirements for COVID-19 vaccine administration.
1/11/2021	Immunization Administration - Ohio Requirements	Added reference to Board resolution on record keeping requirements for COVID-19 vaccine administration.
1/11/2021	Pharmacist Consult Agreements	Expands from physician to provider to account for changes to section section 4729.39 of the Ohio Revised Code (HB 203 – 133rd General Assembly) that expanded the type of providers with whom a pharmacist may enter into a consult agreement. For more information visit: www.pharmacy.ohio.gov/consult.
1/25/2021	Immunization Administration - Federal Requirements Immunization Administration - Ohio Requirements	Updated sections to reflect alternate record keeping resolution for COVID-19 vaccines.

3/30/2021	Naloxone for Emergency Use	Added new section to inspect for compliance with OAC 4729:5-3-19.
3/30/2021	Distribution of Naloxone Via Automated Mechanism	Added new section to inspect for compliance with OAC 4729:5-3-19.
6/7/2021	Applicable Rules	Added hyperlink to "Applicable Rules" section to include the following: ○ 4729:5-3-17 - Automated pharmacy systems. ○ 4729:5-3-19 - Naloxone for emergency use and distribution via automated mechanisms.
6/29/2021	Immunization Administration – Ohio Requirements	Updated questions to reflect changes made to Ohio law (ORC 4729.41) from HB 6 (134th General Assembly).
6/29/2021	Drug Compounding	Added reference to updated pharmacy compounding guidance: www.pharmacy.ohio.gov/compounding
7/28/2021	Prescription Formatting and Manner of Issuance	Clarified that for electronic prescriptions, the drug quantity is not required to be written alphabetically per the following Board resolution: *All electronic prescription transmission systems that meet the requirements of Chapter 4729:5-5 of the Administrative Code shall not be subject to the alphabetical spelling requirements for drug quantity as listed in paragraph (B)(3) of rule 4729:5-5-05. (Adopted 7/12/21)*
11/23/2021	Positive Identification	Per Board resolution, updated the effective date for capturing positive identification as follows:

		Effective 6/30/2022, all pharmacy record keeping systems must capture the positive identification of prescription information entered into the pharmacy's record keeping system. This requires positive identification of pharmacists, interns and technicians that are entering prescription information into a pharmacy's record keeping system. [OAC 4729:5-5-04 (A)(1)]
12/7/2021	Dispensing Records and Patient Profiles	Added the following guidance regarding date of birth for animal prescriptions: *(3) Patient's date of birth. [**NOTE:** For animal prescriptions, use the best estimate for the patient's date of birth, as provided by the animal's owner.]*
2/1/2022	Outpatient Central Fill Pharmacies – Originating Pharmacy	Added new section to inspect for compliance with OAC 4729:5-5-19.
2/1/2022	Outpatient Central Fill Pharmacies – Central Fill Pharmacy	Added new section to inspect for compliance with OAC 4729:5-5-19.
6/23/2022	Dispensing Nicotine Replacement Therapy (NRT)	Added new section to inspect for compliance with OAC 4729:1-3-07.
7/21/2022	Positive Identification	Updated to reflect new requirement that requires positive identification of ALL pharmacy personnel (pharmacists, interns, and technicians) that are entering prescription information into a pharmacy's record keeping system.
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.