Board of Pharmacy

INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Non-Resident Terminal Distributors

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

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

Applicability

This guide applies only to locations licensed as terminal distributor of dangerous drugs that meet the following definition of a "non-resident terminal distributor of dangerous drugs" in rule 4729:5-8-01 of the Ohio Administrative Code:

> *"Nonresident terminal distributor of dangerous drugs" or "nonresident terminal distributor" means any person located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio. A nonresident terminal distributor of dangerous drugs shall maintain a license in accordance with sections 4729.54 and 4729.55 of the Revised Code and shall comply with all requirements set forth in this chapter. A nonresident terminal distributor does not include a person shipping drugs into this state for destruction or disposal by an Ohio licensed reverse distributor.*

Nonresident terminal distributors include, but are not limited to, the following:

- Pharmacies dispensing drugs to patients residing in Ohio, including pharmacies servicing institutional facilities in this state;
- Prescriber clinics that meet the licensure requirements in ORC 4729.541 (for more information on these requirements visit: www.pharmacy.ohio.gov/prescriberTDDD); and
- Pharmacies conducting medication therapy management services in accordance with OAC 4729:5-12.
- Remote order entry & prescription order entry in accordance with the following rules:
    - 4729:5-9-02.14 - Remote medication order processing.
    - 4729:5-9-02.15 - Remote Order Entry - Technicians.
    - 4729:5-5-20 - Remote Outpatient Prescription Processing.
    - 4729:5-5-25 - Remote Prescription Entry - Technician.

REMINDER: This inspection guide **does not apply** to in-state terminal distributors of dangerous drugs, including those license types that have their own corresponding chapter of the Ohio Administrative Code:

- Outpatient Pharmacies – 4729:5-5
- Institutional Pharmacies and Facilities – 4729:5-9
- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Emergency Medical Services – 4729:5-14
- Animal Shelters – 4729:5-15
- Laboratories – 4729:5-16
- Office-Based Opioid Treatment Facilities – 4729:5-18
- Clinic and Prescriber Offices – 4729:5-19
- Veterinary Clinics – 4729:5-20
- Opioid Treatment Programs – 4729:5-21
- Non-limited Facilities – 4729:5-22
- Limited Facilities – 4729:5-23

Inspection Authority

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

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

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

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

Applicable Rules

The following provides a general list of rule chapters that apply to non-resident 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.
- 4729:5-3-15 – Use of hospital and other institution D.E.A. registrations.
- 4729:5-3-16 – Returned drugs.
- 4729:5-3-17 – Automated pharmacy systems.
- 4729:5-3-18 – Dangerous drug recall procedures.
- 4729:5-3-19 – Naloxone for emergency use and distribution via automated mechanisms.
- 4729:5-3-20 – Pharmacy pilot or research projects.
- 4729:5-3-21 – Point of dispensing locations during a public health emergency.
- 4729:5-3-22 - Continuous quality improvement programs in pharmacy services.
- 4729:5-3-24 - Dispensing dangerous drugs to an alternate location.

- **4729:5-4 – Disciplinary Actions**
  - 4729:5-4-01 - Disciplinary actions.

- **4729:5-8 – Nonresident Terminal Distributors of Dangerous Drugs**
  - 4729:5-8-01 - Definitions.
  - 4729:5-8-02 - Licensure.

- 4729:5-8-03 - Compliance.
- 4729:5-8-04 - Drugs compounded by a nonresident pharmacy.
- 4729:5-8-05 - Preparation, compounding, dispensing, and repackaging of radiopharmaceuticals by a nonresident pharmacy.

- **4729:5-12 – Medication Therapy Management**
  - 4729:5-8-01 - Definitions.
  - 4729:5-8-02 - Licensure.

- **Remote Order/ Remote Prescription Entry**
  - 4729:5-9-02.14 - Remote medication order processing.
  - 4729:5-9-02.15 - Remote Order Entry - Technicians.
  - 4729:5-5-20 - Remote Outpatient Prescription Processing.
  - 4729:5-5-25 - Remote Prescription Entry - Technician.

- **Non-Resident Pharmacies Servicing Ohio Institutional Facilities**
  - 4729:5-9-02 - Institutional pharmacies.
  - 4729:5-9-02.1 – Minimum standards for institutional pharmacies.
  - 4729:5-9-02.2 – Security, storage and control of dangerous drugs in an institutional facility.

- 4729:5-9-02.3 - Record keeping at an institutional pharmacy.
- 4729:5-9-02.4 - Dispensing of controlled substances by an institutional pharmacy.
- 4729:5-9-02.5 - Patient profiles.
- 4729:5-9-02.6 - Pharmacist drug utilization review.
- 4729:5-9-02.7 - Medication orders for inpatients and outpatient prescriptions.
- 4729:5-9-02.8 - Labeling of prescriptions for patients.
- 4729:5-9-02.9 - Licensure of outpatient institutional pharmacies.
- 4729:5-9-02.10 - Temporary absence of a pharmacist in an institutional pharmacy.
- 4729:5-9-02.11 - Dispensing customized patient medication packages by an institutional pharmacy.
- 4729:5-9-02.12 - Drugs repackaged or relabeled by an institutional pharmacy.
- 4729:5-9-02.13 - Institutional central fill pharmacies.
- 4729:5-9-02.14 - Remote medication order processing.
- 4729:5-9-02.15 - Remote order entry - technicians.
- 4729:5-9-03 - Institutional facilities.
- 4729:5-9-03.1 - Contingency drugs in an institutional facility and emergency access to an institutional pharmacy.
- 4729:5-9-03.2 - Security, storage and control of dangerous drugs in an institutional facility.

- 4729:5-9-03.3 - Record keeping in an institutional facility.
- 4729:5-9-03.4 - Automated drug storage systems in an institutional facility.
- 4729:5-9-03.5 - Hospital self-service employee prescription kiosks.
- 4729:5-9-03.6 - Point of care locations in an institutional facility.

Guidance Regarding Conflicts with Home State or Federal Law

Ohio's non-resident terminal distributor rule (OAC 4729:5-8-03) requires compliance with specific provisions of the Ohio Administrative Code [see paragraph (F) of the rule]. Additionally, the rule also requires compliance with all the statutory requirements of the state of Ohio set forth in Chapters 4729., 3719., 3715., and 2925. of the Revised Code for all drugs sold, dispensed, or personally furnished into this state.

Please be advised that both provisions include an opt-out clause **ONLY** if:

> *The non-resident terminal distributor can demonstrate that such compliance would cause the non-resident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements.*

Any conflicts with Ohio's requirements that would cause a licensee to violate its home state laws, should be properly documented in the event of a Board inspection or investigation. For specific questions regarding conflicting laws and rules, contact the Board's Compliance and Enforcement Department by visiting: https://www.pharmacy.ohio.gov/contact.aspx

Drug Database Reporting Requirements

Rule 4729:5-8-03 requires all non-resident terminal distributors to report to Ohio's prescription drug monitoring program, the Ohio Automated Rx Reporting System (OARRS). The following drugs that are dispensed or personally furnished to patients in Ohio must be reported to the system:

- Schedule II – V Controlled Substances
- Gabapentin
- Naltrexone (only formulations for the treatment of alcohol dependence or the prevention of relapse to opioid dependence, as indicated on the product labeling).

Dispensations must be reported no later than 24 hours after dispensing, although they may be submitted more frequently.

For more information on this process, visit the OARRS documents page and scroll down to the "Pharmacies & Prescribers" section.

The OARRS reporting rules can be found here: http://codes.ohio.gov/oac/4729:8

Health Insurance Portability and Accountability Act (HIPAA)

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

What is HIPAA?

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

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

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

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

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

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

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

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, **within thirty days of discontinuation of business** as a terminal distributor of dangerous drugs.	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. **For Non-Resident Nuclear Pharmacies:** A pharmacy licensed as a non-resident pharmacy that is engaged in the preparation and	Requires submission of a **Change of Responsible Person Request in eLicense Ohio.**

distribution of radiopharmaceuticals shall have an Ohio licensed pharmacist as the responsible person on its license. **NOTE:** If a non-resident pharmacy engages in the preparation of radiopharmaceuticals but does not ship radiopharmaceuticals into Ohio, they are not required to have a responsible person who is an Ohio-licensed pharmacist. For more information visit: **www.pharmacy.ohio.gov/NRPnuclear**. **For Non-Resident Compounding Pharmacies:** A pharmacy licensed as a non-resident pharmacy that is engaged in drug compounding shall have an Ohio licensed pharmacist as the responsible person on its license. **NOTE:** If a non-resident pharmacy engages in drug compounding but does not ship compounded drugs into Ohio, they are not required to have a responsible person who is an Ohio-licensed pharmacist. For more information visit: **www.pharmacy.ohio.gov/NRPcompound**.	
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. See page 16 of this document for more information.	For more information on this requirement, the Board developed this guidance document.
Request to Ship Controlled Substances *OAC 4729:5-8-03* Unless approved by the Board's Executive Director, a non-resident terminal distributor of dangerous drugs **that is not a pharmacy** shall not be permitted to sell or personally furnish controlled substances to patients residing in this state. **IMPORTANT REMINDER:**	Requires submission of a **Non-Resident Controlled Substance Sales Request Form**.

Ohio law (ORC 4729.291) places the following limitations on personally furnishing controlled substance medications: ▪ A prescriber may not personally furnish to a patient an amount of a controlled substance that exceeds the amount necessary for the patient's use in a seventy-two-hour period. ▪ A prescriber may not, in any thirty-day period, personally furnish to all patients, taken as a whole, controlled substances in an amount that exceeds a total of two thousand five hundred dosage units. ▪ "Dosage unit" means any of the following: (1) A single pill, capsule, ampule, tablet; (2) In the case of a liquid solution, one (1) milliliter; (3) In the case of a cream, lotion, or gel, one (1) gram; or (4) Any other form of administration available as a single unit. This provision does not apply to controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.	

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.

- **“Institutional facility”** for definition please see institutional pharmacy/facility inspection guide: www.pharmacy.ohio.gov/IPFinspect.

- **“Intracompany transfer”** means 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.

- **"Occasional wholesale sale"** means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs or any entity or person exempted from licensure as a terminal distributor of dangerous drugs by either:

  (1) A pharmacy licensed as a terminal distributor of dangerous drugs; or

  (2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section 4729.51 of the Revised Code.

- **"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.

- **"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.

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Non-Resident Terminal Distributor - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code

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

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 new responsible person must be designated using eLicense. For detailed instructions, use this link: **Change of Responsible Person Request in eLicense Ohio**.	OAC 4729:5-2-01 OAC 4729:5-8-02
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.	21 CFR 1301.11

	The certificate of registration must be maintained at the registered location and kept available for official inspection. **NOTE:** Does not apply to nonresident terminal distributors of dangerous drugs that apply for a Category II license (i.e., those that only distribute non-controlled medications).	

Record Keeping, Occasional Wholesale Sales & Drug Transfers

Question	Guidance	Law/Rule
Does the licensee maintain the required records for drugs dispensed or personally furnished into Ohio?	A non-resident terminal distributor of dangerous drugs shall maintain the following records of all dangerous drugs dispensed or personally furnished to persons in this state: (1) Name, strength, dosage form, the serial number of the prescription, and quantity of the dangerous drug dispensed or personally furnished; (2) Full name and date of birth 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; and (3) Residential address, including the physical street address and, if provided, the telephone number of the patient or owner.	OAC 4729:5-8-03
Does the pharmacy maintain the required records for the sale or transfer of dangerous drugs sold or transferred into this state?	Maintain the following records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code for drugs sold or transferred into this state: name, strength, dosage form, national drug code, 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. **NOTE:** This is applicable to the occasional wholesale sale or transfer of non-patient specific drugs into Ohio.	OAC 4729:5-8-03

Are all required records maintained for a period of three years in a readily retrievable manner?	All required records and documents shall be maintained for a period of three years in a readily retrievable manner.	OAC 4729:5-8-03
For Pharmacies ONLY: Does the licensee exceed the threshold set for occasional wholesale sales?	The dosage units of all dangerous drugs distributed by the pharmacy pursuant to this rule shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year. **NOTE:** If the nonresident terminal distributor exceeds this limit, they are required to obtain licensure as a wholesale distributor of dangerous drugs.	OAC 4729:5-8-03

Labeling

See Central Fill section of this guide for more information on labeling requirements for non-resident central fill pharmacies.

Question	Guidance	Rule/Law
Are prescriptions properly labeled?	A non-resident terminal distributor shall label all drugs dispensed or personally furnished into this state with the following minimum information: (1) The name or "doing business as" (DBA) name, or other legal or contractually affiliated name and address of the terminal distributor. (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.	OAC 4729:5-8-03 21 CFR 1306.05

	(9) The quantity of drug dispensed.	

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 forty-five (45) days following the discovery of such theft or significant loss. For nonresident terminal distributors of dangerous drugs, only drugs shipped to Ohio that are stolen or lost in transit must be reported. For drugs **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02

Verification of Licensure and Online Sales

For more information about Board of Pharmacy licensure exemptions for prescriber practices, visit: www.pharmacy.ohio.gov/prescriberTDDD

For more information on licensure verification requirements prior to sale, visit: www.pharmacy.ohio.gov/verify

***NOTE:** An occasional wholesale sale or drug transfer is the sale or transfer of non-patient specific drugs to an entity in the state. It does not include the dispensation or sale of patient-specific medication.*

Question	Guidance	Law/Rule
If performing an occasional wholesale sale or drug transfer in accordance with rule 4729:5-3-09, does the licensee comply with the licensure verification requirements prior to the sale or transfer?	Before a non-resident terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729:5-3-09 of the Administrative Code, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either: (1) A terminal distributor of dangerous drugs. For a limited terminal distributor of dangerous drugs license, a terminal distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drugs ordered. (2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code. **NOTE:** This verification requirement does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:	OAC 4729:5-3-04

	(1) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business; or (2) Any of the exempted persons described in section 4729.541 of the Revised Code.	
Does the licensee comply with the requirements for engaging in the occasional wholesale sale or transfer of dangerous drugs to persons exempted from Ohio licensure?	A non-resident terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section 4729.541 of the Revised Code in accordance with rule 4729:5-3-09 of the Administrative Code and shall ensure the purchaser meets the exemption criteria. To confirm a purchaser meets the exemption criteria, the terminal drug distributor shall comply with the all the following: (1) Provide the purchaser the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs (click here for requirements document); (2) If the purchaser is a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice; (3) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually	OAC 4729:5-3-04

	attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section 4729.541 of the Revised Code; and (4) Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.	
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 digital pharmacy from the National Association of Boards of Pharmacy. A list of digital pharmacy accreditations can be accessed here. **NOTE:** This requirement does not apply to a licensee using online services to distribute naloxone.	OAC 4729:5-3-08

Patient Counseling

Question	Guidance	Rule/Law
Is counseling being offered for every outpatient prescription dispensed?	If the non-resident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription dispensed. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. 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. The pharmacy shall have sufficient telephone service to provide access to incoming callers.	OAC 4729:5-8-03

Drug Compounding

For more information regarding non-resident pharmacy compounding requirements, visit:
www.pharmacy.ohio.gov/NRPcompound

Nuclear Pharmacies

For more information regarding non-resident nuclear pharmacy requirements, visit: www.pharmacy.ohio.gov/NRPnuclear

Central Fill Pharmacies

NOTE: *This section only applies to non-resident central fill pharmacies.*

Question	Guidance	Rule/Law
If not owned by the same owner as the originating pharmacy, does the central fill pharmacy have a written contract with the originating pharmacy?	If the central fill pharmacy does not have the same owner as the originating pharmacy, the central fill pharmacy shall 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, rules and regulations. For central fill pharmacies dispensing outpatient prescriptions, the contract shall also expressly state who is responsible for performing the patient counseling requirements (see Patient Counseling section).	OAC 4729:5-8-03
Does the central fill pharmacy maintain a record of all originating pharmacies?	The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and, if applicable, Drug Enforcement Administration registration number, for which it processes a request for the filling or refilling of a medication order or prescription received by the originating pharmacy.	OAC 4729:5-8-03
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 medication order or prescription.	OAC 4729:5-8-03

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 4729:5-8-03
For Institutional Central Fill Pharmacies ONLY: Do prescription labels contain the required information?	If the licensee is an institutional central fill pharmacy as defined in rule 4729:5-9-02.13 of the Administrative Code, the prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. If applicable, the date on which the medication order was dispensed shall be the date on which the central fill pharmacy filled the order. **NOTE:** Institutional central fill must fill or refill medication orders for an institutional pharmacy. An institutional pharmacy is a pharmacy that primarily provides inpatient pharmacy services to an institutional facility.	OAC 4729:5-8-03
For Outpatient Central Fill Pharmacies ONLY: Do prescription labels contain the required information?	If the licensee is a central fill pharmacy as defined in rule 4729:5-5-19 of the Administrative Code, 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 4729:5-8-03

	(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. 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.	

Recall Procedures

For more information on this rule, see our Recall Procedures for Terminal Distributors document: www.pharmacy.ohio.gov/recalls

Question	Description / Guidance	Law/Rule
Does the facility have a written procedure in place to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee?	A terminal distributor of dangerous drugs is required to develop and implement a written procedure to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee. Such procedures must be regularly updated as necessary and must be readily retrievable (e.g., produced within three business days) upon request.	OAC 4729:5-3-18
Do the facility's written recall procedures include all the requirements established in rule?	The written recall procedures must include all of the following: 1. The terminal distributor must, where appropriate, contact patients to whom the recalled drug products have been dispensed or personally furnished. 2. The terminal distributor must make a reasonable attempt to ensure that a recalled drug has been removed from inventory no later than the next business day after receipt of the recall notice by the terminal distributor's responsible person or the responsible person's designee, and quarantined until proper disposal, destruction, or return of the drug. **IMPORTANT:** If a	OAC 4729:5-3-18

	drug that is subject to a recall is maintained by the terminal distributor in a container without a lot number, the terminal distributor shall consider this drug included in the recall. 3. Maintaining all required documentation and records for activities taken by the terminal distributor in relation to a drug recall. **NOTE:** All records documenting recall activities shall be maintained for three years and shall be made readily retrievable.	
Does the facility maintain records documenting recall activities in a readily retrievable manner?	All records documenting recall activities shall be maintained for three years and shall be made readily retrievable (e.g., produced within three business days).	OAC 4729:5-3-18

Drug Repository Programs

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	ORC 3715.871

	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, 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 DRUGS DONATED THAT HAVE BEEN IN THE POSSESSION OF A LICENSED HEALTHCARE PROFESSIONAL OR TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS: Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**FOR DRUGS DONATED THAT HAVE BEEN IN THE POSSESSION OF A LICENSED HEALTHCARE PROFESSIONAL OR TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS:** ▪ The drugs are in their original sealed and tamper-evident unit dose packaging. ▪ The packaging shall 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.	OAC 4729:5-10-04

	▪ If the drugs were packaged by a pharmacy, the name of the pharmacy and any other pharmacy identifiers shall 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 have been stored according to federal and state requirements. ▪ The drugs shall include an expiration date on the label or packaging. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging. A repository program shall not dispense or personally furnish a donated drug that is beyond the expiration date. ▪ The drugs must not have any physical signs of tampering or adulteration. ▪ The drugs that are donated to a repository program shall not include the following:	

	○ Controlled substances, except for controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction. ○ Drug samples, unless the repository is operated by a charitable pharmacy. ○ Radiopharmaceuticals as defined in rule 4729:5-8-01 of the Administrative Code. ○ A drug for which the United States food and drug administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer. ○ Compounded drugs.	
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 have been stored according to federal and state requirements. ▪ The drugs shall include an expiration date on the label or packaging. If the prescription container is the manufacturer's	OAC 4729:5-10-04

	original sealed packaging, the expiration date is the expiration date listed on the packaging. A repository program shall not dispense or personally furnish a donated drug that is beyond the expiration date. ▪ The drugs do not require refrigeration, freezing, or storage at a special temperature. ▪ The drugs that are donated to a repository program shall not include the following: a. Controlled substances, except for controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction. b. Drug samples, unless the repository is operated by a charitable pharmacy. c. Radiopharmaceuticals as defined in rule 4729:5-8-01 of the Administrative Code. d. A drug for which the United States food and drug administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer.	

	e. Compounded drugs. **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.	
FOR ALL OTHER DRUGS DONATED BY A PATIENT OR CAREGIVER: Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**FOR ALL OTHER DRUGS DONATED BY A PATIENT OR CAREGIVER:** ▪ The drugs must be donated to a charitable pharmacy, hospital, or non-profit clinic. A for-profit pharmacy is not permitted to accept donations of drugs from an ultimate user (i.e., patient or caregiver). ▪ The drugs have been stored according to federal and state requirements. ▪ The drugs shall include an expiration date on the label or packaging. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging. A repository program shall not dispense or personally furnish a donated drug that is beyond the expiration date.	OAC 4729:5-10-04

	▪ The drugs shall not have any physical signs of tampering, misbranding, or adulteration. ▪ The drugs that are donated to a repository program shall not include the following: o Controlled substances, except for controlled substances in a long-acting or extended-release form used for the treatment of opioid dependence or addiction. o Drug samples, unless the repository is operated by a charitable pharmacy. o Radiopharmaceuticals as defined in rule 4729:5-8-01 of the Administrative Code. o A drug for which the United States food and drug administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer. o Compounded drugs.	
Does the repository program have standards and procedures to determine,	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

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 or facilitate the donation of a 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. Any pharmacy, drug manufacturer, or health care facility, or other person* or government entity may donate or give drugs to a drug repository program. 2. Any person or government entity may facilitate the donation or gift of drugs to the program. *Except for orally administered cancer drugs or drugs donated by patients (to a charitable pharmacy, hospital, or non-profit clinic), 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. **IMPORTANT REMINDERS:**	OAC 4729:5-10-03

	▪ 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.	
Are donor forms and records maintained in accordance with applicable rules?	Each donor must sign an electronic or physical 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: (1) The name of the person that was originally dispensed the drugs or the name of the entity that owns the drugs. (2) The full name, contact phone, and signature of the donor, which may include any of the following: ▪ The person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient; ▪ The executor, administrator, or trustee of the estate of a deceased patient;	OAC 4729:5-10-06

	▪ The responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor; ▪ The licensed prescriber or pharmacist responsible for the oversight of the entity donating the drug. (3) The address of the donor or the entity donating the drug. (4) 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 also be documented. This information may be documented on the original signed donor form or on an alternate record created by the repository program. 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 an electronic or physical 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 activities conducted under the drug repository program, all of the following apply: (1) A pharmacy, drug manufacturer, health care facility, or other person or government entity that donates or gives drugs to the program, and any person or government entity that facilitates the donation or gift, 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 distributes 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, dispenses, or personally furnishes drugs under the program on behalf of a pharmacy, hospital, or nonprofit clinic participating in the program, and the pharmacy,	OAC 4729:5-10-06

	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 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 constitutes willful and wanton misconduct. (5) In addition to the civil immunity granted under division (B)(1) of this section, a pharmacy, drug manufacturer, health care facility, or other person or government entity that donates or gives drugs to the program, and any person or government entity that facilitates the donation or gift, shall not be subject to criminal prosecution for matters related to activities that it conducts or another party conducts under the program, unless an action or omission of the party that donates, gives, or facilitates the donation or gift of the drugs does not comply with the provisions of this chapter or the rules adopted under it. (6) In the case of a drug manufacturer, the immunities from civil liability and criminal prosecution granted to another party under divisions (B)(1) and (5) of this section extend to the manufacturer when any drug it manufactures is the subject of an activity conducted under the program. This extension of immunities includes, but is not limited to, immunity from liability or prosecution for failure to	

	transfer or communicate product or consumer information or the expiration date of a drug that is donated or given.	
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 4729:5-10-06?	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. Recipient forms must be maintained for a minimum of three years in a readily retrievable manner by a pharmacy, hospital, or nonprofit clinic. A prescriber shall document the distribution of a personally furnished donated repository program drug to the prescriber's patient pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code and a pharmacy shall document the dispensing of a donated repository program drug pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code. Such records shall indicate that the drug distributed to a patient was from a repository program. If recipient forms are used with each	OAC 4729:5-10-06

	dispensing or personal furnishing, this information may be documented on the recipient form. Board staff will review records to verify compliance.	

Mobile Clinics and Medication Units

For more information on registering a mobile clinic or medication unit, visit: www.pharmacy.ohio.gov/mobile.

Question	Description/Guidance	Law/Rule
Does the licensee meet the criteria to operate a mobile clinic or medication unit?	OAC 4729:5-3-23 authorizes the following terminal distributors of dangerous drugs to operate a mobile clinic or medication unit: 1. A nonprofit organization, corporation, or association as defined in the Ohio Revised Code; or 2. A for-profit entity for the purpose of providing services to an individual needing treatment for a substance use disorder, a mental health condition, and any related medical issue.	OAC 4729:5-3-23
Does the mobile clinic or medication unit have a satellite license affiliated with an existing terminal distributor of dangerous drugs?	Mobile clinics or medication units are required to be registered for a no-cost, satellite license affiliated with an existing terminal distributor of dangerous drugs. For more information, visit: www.pharmacy.ohio.gov/mobile.	OAC 4729:5-3-23
Are the drugs in the mobile clinic or satellite license in full charge of a licensed or registered health care professional, or else secured to provide unauthorized access?	If the mobile clinic is distributing dangerous drugs that have already been dispensed or personally furnished, the drugs must be in full and actual charge of a licensed or registered health care professional authorized under Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code.	OAC 4729:5-3-23

	If there is no health care professional present on the mobile unit, all dangerous drugs shall be secured using physical locks to prevent unauthorized access.	
Does the mobile unit maintain records for prescription medications in a readily retrievable manner?	Mobile units are required to implement a record keeping system that will provide accountability for proper receipt, delivery, disposal, and return of all prescription medications in accordance with applicable record keeping provisions in division 4729:5 of the Administrative Code.	OAC 4729:5-3-23
Are dangerous drugs removed from the mobile unit when the unit is not in operation?	Except for mobile units that are stored in a locked garage with access control, dangerous drugs shall not be left in the mobile unit during the hours that the mobile unit is not in operation. Without exception, a terminal distributor shall not maintain controlled substances in the mobile unit when the unit is not in use.	OAC 4729:5-3-23
Is the mobile unit dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?	All mobile units shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas for dangerous drugs shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.	OAC 4729:5-3-23
Is the mobile unit secured with a lock?	Mobile units are required to be secured with suitable locks capable of preventing unauthorized access.	OAC 4729:5-3-23

Outpatient Pharmacy Delivery Services

For the purposes of this section, "temperature sensitive drug" means any drug that is required to be stored at temperatures outside of controlled room temperature (59 degrees Fahrenheit to 86 degrees Fahrenheit).

Question	Guidance	Law/Rule
Does the outpatient pharmacy offer delivery services?		
Does the outpatient pharmacy have a process to obtain consent prior to delivery or does it have a policy to refund unneeded and unwarranted drugs?	The outpatient pharmacy must contact the patient or patient's caregiver for consent prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services. In lieu of contacting the patient or patient's caregiver to obtain consent, the pharmacy shall provide a refund if the patient or patient's caregiver notifies the pharmacy that a dispensed drug or device was unneeded or unwanted.	OAC 4729:5-8-03 OAC 4729:5-5-26
Does the outpatient pharmacy notify the patient of their delivery information?	In accordance with the patient's communication preferences, the outpatient pharmacy must notify the patient or patient's caregiver of the date shipped, method of delivery (e.g., mail, courier, etc.), and expected arrival. This information can be provided by electronic, telephonic, or any other manner that allows the patient to access this information.	OAC 4729:5-8-03 OAC 4729:5-5-26
Does the pharmacy ensure that temperature sensitive	The outpatient pharmacy must take all appropriate measures to ensure that temperature-sensitive drugs will be maintained within	OAC 4729:5-8-03

drugs are maintained within temperature ranges recommended by the manufacturer?	the temperature ranges recommended by the manufacturer until the delivery has been completed.	OAC 4729:5-5-26
Does the pharmacy provide the required patient notification for temperature sensitive drugs?	If the patient's prescription is a temperature sensitive drug, the outpatient pharmacy must provide notification to the patient of the timeliness in addressing proper storage of the medication.	OAC 4729:5-8-03 OAC 4729:5-5-26
Does the pharmacy require proof of delivery for controlled substance medications?	The outpatient pharmacy must arrange for any controlled substances to require proof of delivery, which may include the signature of the receiving party.	OAC 4729:5-8-03 OAC 4729:5-5-26
Does the pharmacy have a process to assist patients in obtaining medication from a local pharmacy if the pharmacy is unable to deliver within the expected timeframe?	The outpatient pharmacy must assist patients with arranging access to medication or device from a local pharmacy if unable to deliver within the expected timeframe.	OAC 4729:5-8-03 OAC 4729:5-5-26
Does the pharmacy have a method for a patient to notify the pharmacy of delivery irregularities or interruptions?	The patient or patient's caregiver must be able to notify the pharmacy of any irregularity in the delivery of the drug or service, which includes all of the following: (1) Timeliness of delivery. (2) Condition of the drug or device upon delivery.	OAC 4729:5-8-03 OAC 4729:5-5-26

	(3) Failure to receive the proper drug or device. Additionally, the pharmacy must have a process to notify affected patients if their scheduled delivery is going to be interrupted or late.	
Does the pharmacy have a process to inform patients of any delays in the scheduled delivery?	The outpatient pharmacy shall have a process to inform the patient or patient's caregiver within 2 business days of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.	OAC 4729:5-8-03 OAC 4729:5-5-26
Does the pharmacy have a process to replace any drug or device that has been compromised or lost in transit at no additional cost to the patient?	Upon notification of the dispensing pharmacy by the patient or patient's caregiver, any drug or device which is compromised or lost in transit shall be replaced at no additional cost to the patient.	OAC 4729:5-8-03 OAC 4729:5-5-26
Is the pharmacy maintaining records for the delivered drugs and devices?	The outpatient pharmacy shall maintain the following records for all drugs and devices that are being delivered: (1) Patient name; (2) Patient address; (3) Prescription number of drug or device being delivered; (4) Name (brand name or generic) and dosage of each drug or device being delivered; (5) Name and contact information of the pharmacy delivery agent who performed, or attempted to perform, the delivery as follows:	OAC 4729:5-8-03 OAC 4729:5-5-26

	a. For the United State Postal Service (USPS) or a common carrier, the record shall indicate either the USPS or the name of the common carrier (e.g., UPS, Fedex, etc.). b. For a contract carrier, the record shall indicate the name of the contract carrier and the individual conducting the delivery on behalf of the contract carrier. c. For an employee of the terminal distributor of dangerous drugs, the record shall include the full name of the employee All records maintained shall be readily retrievable and uniformly maintained for a period of three years.	
If the pharmacy utilizes delivery services from a third party, do they have a contract with the company on file?	An outpatient pharmacy that utilizes a third party to deliver drugs and devices must enter into a contract to ensure that required records are provided to the pharmacy and that the third party agrees to cooperate with all investigations regarding theft or loss of drugs and devices and will produce required records within three business days of the request of a Board of Pharmacy employee. **NOTE:** A contract is not required if the outpatient pharmacy is using the United States Postal Service or common carrier as their delivery service.	OAC 4729:5-8-03 OAC 4729:5-5-26

Non-Resident Terminal Distributor of Dangerous Drugs - Update History

Update Date	Section Update	Update
8/13/2024	Recall Procedures	Adds a recall procedure section of the guide to comply with the requirements of OAC 4729:5-3-18. For more information, see our Recall Procedures for Terminal Distributors document: www.pharmacy.ohio.gov/recalls
12/19/2024	Verification of Licensure and Online Sales	Updates the type of accreditation required for online sales of dangerous drugs.
12/19/2024	Drug Repository Program	Added drug repository program section to reflect current law.
12/19/2024	Mobile Clinics or Medication Units	Added section to inspect for compliance with OAC 4729:5-3-23.
3/24/2025	Required Notifications or Document Submissions	Updated Discontinuation of Business section to require businesses submit a notice to the Board within 30 days of discontinuation of business and removing the mention of a waiver for extraordinary circumstances.
4/18/2025	Outpatient Pharmacy Delivery Services	Added section to inspect for compliance with OAC 4729:5-5-26 as required by OAC 4729:5-8-03 (effective 6/30/2025).

7/14/2025	Required Notifications or Document Submissions	Updated link from Change of Responsible Person Form to the **Change of Responsible Person Request in eLicense Ohio**.