



# Board of Pharmacy

## INSPECTION GUIDE

**Terminal Distributor of Dangerous Drugs**

**Non-Resident Terminal Distributors**

**Updated 2/1/2022**

***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](http://www.pharmacy.ohio.gov/prescriberTDDD))
- 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
- [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](mailto: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.](#)
- **4729:5-4 – 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.](#)
  - [4729:5-9-02.3 - 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.](#)

## **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:

<b>Notification/Submission Requirement</b>	<b>How to Submit</b>
<p><b><u>Change in Business Description</u></b> OAC <a href="#">4729:5-2-03</a></p> <p>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 <b>within thirty days</b> of any change in the ownership, business or trade name, category, or address.</p>	<p>A change of business description must be completed online using Ohio's <a href="#">eLicense</a> system.</p> <p>Instructions on submitting this information can be accessed <a href="#">here</a>.</p>
<p><b><u>Discontinuation of Business</u></b> OAC <a href="#">4729:5-2-04</a></p> <p>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, <b>at least thirty days in advance</b> 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.</p>	<p>Requires submission of a <a href="#">Written Notice of Discontinuing Business Form</a>.</p>
<p><b><u>Change of Responsible Person</u></b> OAC <a href="#">4729:5-2-01</a></p> <p>A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.</p> <p>When there is a change of responsible person, the Board must be notified <b>within ten days</b> of the effective date of the appointment of the new responsible person.</p> <p><b>For Non-Resident Nuclear Pharmacies:</b> A pharmacy licensed as a non-resident pharmacy that is engaged in the preparation and distribution of radiopharmaceuticals shall have an Ohio licensed pharmacist as the responsible person on its license.</p>	<p>Requires submission of a <a href="#">Change of Responsible Person Form</a>.</p>

<p><b>NOTE:</b> 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: <a href="http://www.pharmacy.ohio.gov/NRPnuclear">www.pharmacy.ohio.gov/NRPnuclear</a>.</p> <p><b>For Non-Resident Compounding Pharmacies:</b> 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.</p> <p><b>NOTE:</b> 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: <a href="http://www.pharmacy.ohio.gov/NRPcompound">www.pharmacy.ohio.gov/NRPcompound</a>.</p>	
<p><b><u>Theft or Significant Loss of Dangerous Drugs and Drug Documents</u></b> OAC <a href="#">4729:5-3-02</a></p> <p>Licensees are required to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents. See <a href="#">page 16</a> of this document for more information.</p>	<p>For more information on this requirement, the Board developed this <a href="#">guidance</a> document.</p>
<p><b><u>Request to Ship Controlled Substances</u></b> OAC <a href="#">4729:5-8-03</a></p> <p>Unless approved by the Board's Executive Director, a non-resident terminal distributor of dangerous drugs <b>that is not a pharmacy</b> shall not be permitted to sell or personally furnish controlled substances to patients residing in this state.</p> <p><b>IMPORTANT REMINDER:</b></p> <p>Ohio law (ORC <a href="#">4729.291</a>) places the following limitations on personally furnishing controlled substance medications:</p> <ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ A prescriber may not, in any thirty-day period, personally furnish to all patients, taken as a whole, controlled substances</li> </ul>	<p>Requires submission of a <a href="#">Non-Resident Controlled Substance Sales Request Form</a>.</p>

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](http://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
<b>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?</b>	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 <a href="#">4729:5-2-03</a>
<b>Does the responsible person match what is indicated in eLicense?</b>	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: <a href="https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx">https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx</a> .	OAC <a href="#">4729:5-2-01</a> OAC <a href="#">4729:5-8-02</a>
<b>Does the pharmacy have a valid registration issued by the Drug Enforcement Administration?</b>	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.	<a href="#">21 CFR 1301.11</a>



	<b>NOTE:</b> 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).	
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**Record Keeping, Occasional Wholesale Sales & Drug Transfers**

<b>Question</b>	<b>Guidance</b>	<b>Law/Rule</b>
<p><b>Does the licensee maintain the required records for drugs dispensed or personally furnished into Ohio?</b></p>	<p>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:</p> <p>(1) Name, strength, dosage form, the serial number of the prescription, and quantity of the dangerous drug dispensed or personally furnished;</p> <p>(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</p> <p>(3) Residential address, including the physical street address and, if provided, the telephone number of the patient or owner.</p>	<p>OAC <a href="#">4729:5-8-03</a></p>
<p><b>Does the pharmacy maintain the required records for the sale or transfer of dangerous drugs sold or transferred into this state?</b></p>	<p>Maintain the following records of transfer or sale conducted in accordance with rule <a href="#">4729:5-3-09</a> 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.</p> <p><b>NOTE:</b> This is applicable to the occasional wholesale sale or transfer of non-patient specific drugs into Ohio.</p>	<p>OAC <a href="#">4729:5-8-03</a></p>
<p><b>Are all required records maintained for a period of three years in a readily retrievable manner?</b></p>	<p>All required records and documents shall be maintained for a period of three years in a readily retrievable manner.</p>	<p>OAC <a href="#">4729:5-8-03</a></p>

<b>For Pharmacies ONLY: Does the licensee exceed the threshold set for occasional wholesale sales?</b>	<p>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.</p> <p><b>NOTE:</b> If the nonresident terminal distributor exceeds this limit, they are required to obtain licensure as a wholesale distributor of dangerous drugs.</p>	OAC <a href="#">4729:5-8-03</a>
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## **Labeling**

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

<b>Question</b>	<b>Guidance</b>	<b>Rule/Law</b>
<b>Are prescriptions properly labeled?</b>	<p>A non-resident terminal distributor shall label all drugs dispensed or personally furnished into this state with the following minimum information:</p> <ol style="list-style-type: none"><li>(1) The name or "doing business as" (DBA) name, or other legal or contractually affiliated name and address of the terminal distributor.</li><li>(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.</li><li>(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.</li><li>(4) Directions for use of the drug.</li><li>(5) The date of dispensing.</li><li>(6) Any cautions which may be required by federal or state law.</li><li>(7) The serial number of the prescription.</li><li>(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.</li><li>(9) The quantity of drug dispensed.</li></ol>	<p>OAC <a href="#">4729:5-8-03</a></p> <p><a href="#">21 CFR 1306.05</a></p>

## Theft or Significant Loss of Drugs and Drug Documents

Question	Guidance	Law/Rule
<b>Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?</b>	<p>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.</p> <p>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.</p> <p>For nonresident terminal distributors of dangerous drugs, only drugs shipped to Ohio that are stolen or lost in transit must be reported. For drugs</p> <p><b>REMINDER:</b> For more information on reporting theft or loss, visit: <a href="http://www.pharmacy.ohio.gov/theft">www.pharmacy.ohio.gov/theft</a></p>	OAC <a href="#">4729:5-3-02</a>

## **Verification of Licensure and Online Sales**

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

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

<b>Question</b>	<b>Guidance</b>	<b>Law/Rule</b>
<b>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?</b>	<p>Before a non-resident terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule <a href="#">4729:5-3-09</a> of the Administrative Code, the terminal distributor shall query the board's online roster (available on the board's website: <a href="http://www.pharmacy.ohio.gov">www.pharmacy.ohio.gov</a>) to determine if the purchaser is licensed as either:</p> <p>(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.</p> <p>(2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code.</p> <p><b>NOTE:</b> This verification requirement does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:</p> <p>(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</p>	OAC <a href="#">4729:5-3-04</a>

	<p>dangerous drugs by the state in which the distributor conducts business; or</p> <p>(2) Any of the exempted persons described in section <a href="#">4729.541</a> of the Revised Code.</p>	
<p><b>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?</b></p>	<p>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 <a href="#">4729.541</a> of the Revised Code in accordance with rule <a href="#">4729:5-3-09</a> 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:</p> <p>(1) Provide the purchaser the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs (<a href="#">click here for requirements document</a>);</p> <p>(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;</p> <p>(3) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section <a href="#">4729.541</a> of the Revised Code; and</p> <p>(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.</p>	<p>OAC <a href="#">4729:5-3-04</a></p>

<p><b>Does the licensee sell or offer to sell dangerous drugs on its website?</b></p>	<p>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.</p> <p>A list of VIPPS-Accredited sites can be accessed here:  <a href="https://nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/">https://nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/</a></p> <p><b>NOTE:</b> This requirement does not apply to a licensee using online services to distribute naloxone pursuant to a physician protocol.</p>	<p>OAC <a href="#">4729:5-3-08</a></p>
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## **Patient Counseling**

<b>Question</b>	<b>Guidance</b>	<b>Rule/Law</b>
<b>Is counseling being offered for every outpatient prescription dispensed?</b>	<p>If the non-resident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription dispensed.</p> <p>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.</p> <p>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.</p>	OAC <a href="#">4729:5-8-03</a>

### **Drug Compounding**

For more information regarding non-resident pharmacy compounding requirements, visit:

[www.pharmacy.ohio.gov/NRPcompound](http://www.pharmacy.ohio.gov/NRPcompound)

### **Nuclear Pharmacies**

For more information regarding non-resident nuclear pharmacy requirements, visit: [www.pharmacy.ohio.gov/NRPnuclear](http://www.pharmacy.ohio.gov/NRPnuclear)

## **Central Fill Pharmacies**

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

<b>Question</b>	<b>Guidance</b>	<b>Rule/Law</b>
<b>If not owned by the same owner as the originating pharmacy, does the central fill pharmacy have a written contract with the originating pharmacy?</b>	<p>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.</p> <p>For central fill pharmacies dispensing outpatient prescriptions, the contract shall also expressly state who is responsible for performing the patient counseling requirements (see <a href="#">Patient Counseling</a> section).</p>	OAC <a href="#">4729:5-8-03</a>
<b>Does the central fill pharmacy maintain a record of all originating pharmacies?</b>	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 <a href="#">4729:5-8-03</a>
<b>Does the central fill pharmacy have access to the required files to dispense or process medication orders/prescriptions?</b>	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 <a href="#">4729:5-8-03</a>
<b>Does the central fill pharmacy have a quality assurance program?</b>	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	OAC <a href="#">4729:5-8-03</a>

	<p>patient care, resolve identified problems, and ensure compliance with Ohio laws and rules. The quality assurance plan shall be reviewed and updated annually.</p>	
<p><b>For Institutional Central Fill Pharmacies ONLY: Do prescription labels contain the required information?</b></p>	<p>If the licensee is an institutional central fill pharmacy as defined in rule <a href="#">4729:5-9-02.13</a> 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.</p> <p><b>NOTE:</b> 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.</p>	<p>OAC <a href="#">4729:5-8-03</a></p>
<p><b>For Outpatient Central Fill Pharmacies ONLY: Do prescription labels contain the required information?</b></p>	<p>If the licensee is a central fill pharmacy as defined in rule <a href="#">4729:5-5-19</a> 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.</p> <p><b>NOTE:</b> If the originating pharmacy and the central fill pharmacy are not under common ownership, either of the following shall apply:</p> <p>(1) The name of the central fill pharmacy shall be included on the prescription label or an auxiliary label; or</p> <p>(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.</p>	<p>OAC <a href="#">4729:5-8-03</a></p>

	<p>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.</p>	
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