Board of Pharmacy

INSPECTION GUIDE

Distributor of Dangerous Drugs

Updated 03/27/2024

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

Applicability

This guide applies only to locations licensed as drug distributors in accordance with section 4729.52 of the Revised Code, which includes the following license types:

- Wholesale distributors of dangerous drugs, including:
  - Brokers; and
  - Virtual wholesalers.
- Manufacturers of dangerous drugs.
- Outsourcing facilities.
- Third-party logistics providers.
- Repackagers of dangerous drugs.

Inspection Authority

Pursuant to section 3719.13 of the Revised Code and rule 4729:6-3-03 of the Administrative Code, a location licensed by the State Board of Pharmacy as a 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 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 licensed distributors of dangerous drugs:

- **4729:6-1 – Definitions**
- **4729:6-2 – Distributor of Dangerous Drugs**
- **4729:6-3 – General Wholesale Distributor Provisions**
  - 4729:6-3-01 | Disposal of controlled substances.
  - 4729:6-3-02 | Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.
  - 4729:6-3-03 | Inspections and corrective actions.
  - 4729:6-3-04 | Verification of licensure prior to sale or purchase.
  - 4729:6-3-05 | Suspicious Order Monitoring and Due Diligence.
  - 4729:6-3-06 | Controlled Substances Inventory Requirements.
  - 4729:6-3-07 | Sales of dangerous drugs on-line.
  - 4729:6-3-08 | Distributor of dangerous drugs samples and complimentary supplies.
- **4729:6-4 – Disciplinary Actions**
  - 4729:6-4-01 | Disciplinary actions.
- **4729:6-5 – Wholesale Distributors**
  - 4729:6-5-01 | Wholesale Distributors - General Operations.
  - 4729:6-5-02 | Wholesale distributors - recordkeeping.

- **4729:6-6 – Virtual Wholesalers**
    - 4729:6-6-01 | Virtual wholesalers - general operations.
- **4729:6-7 – Brokers**
    - 4729:6-7-01 | Brokers - general operations.
- **4729:6-8 – Manufacturer of Dangerous Drugs**
    - 4729:6-8-01 | Manufacturers - General Operations.
    - 4729:6-8-02 | Manufacturers - recordkeeping.
- **4729:6-9 – Repackagers of Dangerous Drugs**
    - 4729:6-9-01 | Repackagers - General Operations.
    - 4729:6-9-02 | Repackagers - recordkeeping.
- **4729:6-10 – Outsourcing Facilities**
    - 4729:6-10-01 | Outsourcing Facilities - General Operations.
    - 4729:6-10-02 | Outsourcing facilities - recordkeeping.
- **4729:6-11 – Third-Party Logistics Providers**
    - 4729:6-11-01 | Third-Party Logistics Providers - General Operations.
    - 4729:6-11-02 | Third-party logistics providers - recordkeeping.

Positive Identification Guidance

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

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

(2) A magnetic card reader;

(3) A bar code reader;

(4) A biometric method;

(5) A proximity badge reader;

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

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

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

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

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

Required Notifications or Document Submissions

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

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

Notification/Submission Requirement	How to Submit
Change in Business Description *OAC 4729:6-2-05* Any change in the ownership, business or trade name, category, or address of a 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 4729:6-2-06* A distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the Board of Pharmacy. The notice shall be submitted, in a manner determined by the Board, **at least thirty days in advance** of the proposed date of discontinuing business, unless waived by the Board's Executive Director or the Director's Designee due to extraordinary circumstances beyond the licensee's control.	Requires submission of a **Written Notice of Discontinuing Business Form**
Change of Responsible Person *OAC 4729:6-2-01* A location licensed as a distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified **within ten days** of the effective date of the appointment of the new responsible person.	Requires submission of a **Change of Responsible Person Form**
Notification of Off-Site Records Storage *OAC 4729:6-5-02* *OAC 4729:6-6-02* *OAC 4729:6-7-01*	Requires submission of a **Notification to Store Records Off Site Form**

OAC 4729:6-8-02 *OAC 4729:6-9-02* *OAC 4729:6-10-02* *OAC 4729:6-11-02* A distributor of dangerous drugs **located in this state** intending to maintain records at a location other than the location licensed by the State Board of Pharmacy shall notify the Board.	
Theft or Significant Loss of Dangerous Drugs and Drug Documents *OAC 4729:6-3-02* Licensees are required to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents.	To report theft or significant loss please use Board **portal**.
Drug Distributor Security Notification *OAC 4729:6-5-01* *OAC 4729:6-8-01* *OAC 4729:6-9-01* *OAC 4729:6-10-01* *OAC 4729:6-11-01* In-state distributors of dangerous drugs must notify the Board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs. This form may be submitted during the construction process but must be submitted **within 30 days** of the completion of any new facilities, work, or storage areas for dangerous drugs. **NOTE:** This requirement **does not apply** to Virtual Wholesalers and Brokers.	Requires submission of a **Drug Distributor Security Notification Requirement Form**.

Important Terms

- **"Access to drug stock"** includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, information technology, or other staff that may need limited supervised access to areas where dangerous drugs or Drug Enforcement Administration controlled substance order forms are stored.

- **"Broker"** means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs in or into Ohio who does not take physical possession of the dangerous drugs. A broker shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

- **"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; or

  (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; or

  (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.

- **"Manufacturer of dangerous drugs"** or "manufacturer" means a person, other than a pharmacist or prescriber, that meets the following criteria:

  (1) Meets the definition of a manufacturer pursuant in section 21 U.S. Code Section 360 eee (11/27/2013); and

  (2) Manufactures dangerous drugs and who is engaged in the sale or distribution of dangerous drugs in or into Ohio.

- **"Outsourcing facility"** means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States Food and Drug Administration.

- **"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.

- **"Repackager of dangerous drugs"** or "repackager" means a person that meets the following:

  (1) Repacks and relabels dangerous drugs for sale or distribution; and

  (2) Is required to register with the United States Food and Drug Administration to engage in the repackaging or relabeling of dangerous drugs.

- **"Terminal distributor of dangerous drugs"** or "terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.

- **"Third-party logistics provider"** means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

- **"Virtual wholesaler"** or "virtual wholesaler distributor" means any person engaged in wholesale distribution of dangerous drugs in or into Ohio who has title but does not take physical possession of the dangerous drugs. A virtual wholesale distributor shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a virtual wholesale distributor classification.

- **"Wholesale distributor of dangerous drugs"** or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale or the reverse distribution of dangerous drugs and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

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OAC = Ohio Administrative Code / ORC = Ohio Revised Code

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

Licensing and Responsible Person

Question	Description / Guidance	Law / Rule
Does the responsible person match what is indicated in eLicense?	A location licensed as a 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: www.pharmacy.ohio.gov/RPchange	OAC 4729:6-2-01
Does the responsible person meet the requirements to be the responsible person on the license?	Responsible person requirements for licensure are available at www.pharmacy.ohio.gov/rp.	OAC 4729:6-2-01
Is the responsible person providing adequate on-site supervision at the licensed site?	The responsible person must be physically present a sufficient amount of time to provide supervision and control of dangerous drugs on site. The responsible person is responsible for compliance with all applicable state and federal laws, regulations, and rules	OAC 4729:6-2-01

	governing the manufacture, sale, and distribution of dangerous drugs.	
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 4729:6-2-05
Does the facility 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 21 C.F.R. 1301.22 through 1301.26. The certificate of registration must be maintained at the registered location and kept available for official inspection. **NOTE:** Does not apply to a drug distributor that applies for a Category 2 license as a terminal distributor of dangerous drugs.	21 CFR 1301.11

Drug Disposal

Question	Description / Guidance	Law / Rule
Does the licensee dispose of controlled substances on-site using a method that renders the drug non-retrievable?	Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the Board of Pharmacy upon request. "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.	OAC 4729:6-3-01

	NOTE: Per the Drug Enforcement Administration, flushing (i.e. drain or toilet) does not meet the definition of non-retrievable. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable.	
Does the licensee use a reverse distributor for the disposal of controlled substances?	If yes, Board staff will document the name of the reverse distributor.	
Does the licensee maintain complete and accurate records of the disposal of controlled substances?	A licensee must use a DEA Form 41 to document the disposal of controlled substances. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	OAC 4729:6-3-01
Are non-controlled dangerous drugs destroyed utilizing proper methods of disposal?	Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons. **NOTE:** This question does not apply to brokers and virtual wholesalers.	OAC 4729:6-5-01 OAC 4729:6-8-01 OAC 4729:6-9-01 OAC 4729:6-10-01 OAC 4729:6-11-01

Do records of disposal of non-controlled dangerous drugs contain all required information?	Records must contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person who performed the destruction, and the positive identification of the person who witnessed the destruction. **NOTE:** This question does not apply to brokers and virtual wholesalers.	OAC 4729:6-5-01 OAC 4729:6-8-01 OAC 4729:6-9-01 OAC 4729:6-10-01 OAC 4729:6-11-01
Are non-controlled dangerous drugs donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code?	Dangerous drugs, other than controlled substances, may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. **NOTE:** This question does not apply to brokers and virtual wholesalers.	OAC 4729:6-5-01 OAC 4729:6-8-01 OAC 4729:6-9-01 OAC 4729:6-10-01 OAC 4729:6-11-01

Theft or Significant Loss of Drugs and Drugs Documents

Question	Description / Guidance	Law / Rule
Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?	A licensee is required to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or significant loss to the Board using the online portal within thirty days following the discovery of such theft or significant loss. **REMINDER:** For more information on reporting theft or loss, visit: http://www.pharmacy.ohio.gov/theft	OAC 4729:6-3-02
Has the licensee experienced any theft or loss of uncompleted prescription blanks(s), written prescription order(s) not yet dispensed, or D.E.A. controlled substance order forms in the past twenty-four months?	A licensee is required to report, immediately upon discovery, to the Board and law enforcement authorities, any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or loss to the Board using the online portal within thirty days following the discovery of such theft or loss.	OAC 4729:6-3-02

	NOTE: Unlike dangerous drugs, drug documents do not have a significant loss threshold. Therefore, all losses (in addition to thefts) must be reported to the Board. **REMINDER:** For more information on reporting theft or loss, visit: http://www.pharmacy.ohio.gov/theft	

Verification of Licensure Prior to Sale or Purchase

For additional guidance on verification requirements, visit: www.pharmacy.ohio.gov/Verify

Question	Description / Guidance	Law / Rule
Has the licensee performed and documented an annual query of eLicense prior to selling or distributing dangerous drugs?	Before a distributor of dangerous drugs may sell or distribute dangerous drugs, the drug distributor shall query the Board's roster by any of the following means: (1) The online roster maintained as part of the Board's eLicensing system (available on the Board's website: www.pharmacy.ohio.gov); (2) An electronic list of licensees and registrants if maintained by the Board; and (3) Any other format capable of meeting the requirements of ORC 4729.60 and this rule that has been approved by the Board. This does not apply to the following: ▪ 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 ▪ Any of the exempted persons listed in ORC 4729.541. **NOTE:** A third-party logistics provider is exempt from this requirement if the licensee has access to documentation indicating the entity responsible for directing the sale or	OAC 4729:6-3-04

	disposition of the drugs has complied with the requirements of this rule.	
Does the licensee sell dangerous drugs to any of the exempted persons listed in ORC 4729.541?	Please see ORC 4729.541 for a full list of exemptions. Exemptions are also covered in the following Board of Pharmacy guidance documents: ▪ www.pharmacy.ohio.gov/prescriberTDDD ▪ www.pharmacy.ohio.gov/npTDDD	OAC 4729:6-3-04
Does the drug distributor provide the exempted person with the requirements of when a TDDD license is required?	A drug distributor must provide the exempted person the requirements in Ohio law of when a person is required to hold a license as a terminal distributor of dangerous drugs.	OAC 4729:6-3-04
Does the drug distributor verify the exempted prescriber is appropriately licensed in Ohio to prescribe drugs or devices in their professional practice?	A drug distributor must verify the prescriber is appropriately licensed in this state to prescribe dangerous drugs or drug therapy related devices in the course of the individual's professional practice.	OAC 4729:6-3-04
Does the drug distributor require the exempted person to annually attest in writing that the prescriber meets the licensing exemptions in ORC 4729.541?	A drug distributor must verify the person who claims an exemption to the terminal distributor of dangerous drugs licensing requirement to attest in writing that the prescriber meets the licensing exemptions in section 4729.541 of the Revised Code on an annual basis. **NOTE**: Written attestation may include an electronic signature.	OAC 4729:6-3-04

Does the drug distributor maintain all attestations for three years after the sale or distribution of the dangerous drug?	A drug distributor must maintain all attestations for three years after the sale or distribution of the dangerous drug.	OAC 4729:6-3-04
Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?	This applies to drug distributors located in Ohio. If the drug distributor conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, then the distributor shall be deemed not to have violated this rule.	OAC 4729:6-3-04

Suspicious Order Monitoring

For more information on reporting suspicious orders, visit: http://www.pharmacy.ohio.gov/suspicious

IMPORTANT: This section only applies to the following drug distributors:

- Wholesale distributor of dangerous drugs
- Virtual wholesalers
- Manufacturers of dangerous drugs
- Outsourcing facilities

Question	Description / Guidance	Law / Rule
Does the drug distributor operate a system to identify and report suspicious orders by customers for drugs required to be reported to OARRS?	Suspicious orders include, but are not limited to, the following: (1) Orders of unusual size; (2) Orders deviating substantially from a normal pattern; and (3) Orders of unusual frequency.	OAC 4729:6-3-05
Are orders identified as suspicious independently analyzed prior to shipment?	Two people designated by the responsible person must determine the order is not likely to be diverted from legitimate channels to be able to proceed with the shipment and complete the sale.	OAC 4729:6-3-05
Are all suspicious orders submitted to the Board within five days of identification?	Suspicious orders must be reported electronically regardless of actual sale. **REMINDER:** For more information on reporting suspicious orders, visit: http://www.pharmacy.ohio.gov/suspicious	OAC 4729:6-3-05

Does the drug distributor report any customer who may be engaging in possible drug diversion?	Any customer that may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels, including those to whom a drug distributor refuses to sell. This report must be made electronically within five days of refusal, cessation, or identification by the drug distributor. **REMINDER:** For more information on reporting customers, visit: http://www.pharmacy.ohio.gov/suspicious	OAC 4729:6-3-05
Does the drug distributor submit a zero report within fifteen days of the end of a calendar month if no suspicious orders were identified in the calendar month?	If no suspicious orders have been identified by the distributor in a calendar month, then the distributors must submit a zero report in a manner determined by the Board. The zero report shall be submitted within fifteen days of the end of the calendar month.	OAC 4729:6-3-05
Does the drug distributor exercise due diligence for current and prospective customers?	This is to identify and prevent the sale of reported drugs that are likely to be diverted from legitimate channels. Measures shall be conducted prior to an initial sale and on an annual basis and include, but are not limited to: ▪ Questionnaires and affirmative steps by the drug distributor to confirm the accuracy and validity of the information provided; ▪ For a customer who is a prescriber, confirmation of prescriber type (physician, dentist, veterinarian, etc.), specialty practice area (oncology, geriatrics, pain	OAC 4729:6-3-05

	management, etc.), and if the prescriber personally furnishes reported drugs and the quantity personally furnished; ▪ Review of drug utilization reports; and ▪ Obtaining and conducting a review of the following information: o The methods of payment accepted (cash, insurance, Medicaid, Medicare) and in what ratios; o The ratio of controlled vs. non-controlled drug orders and overall sales; o Orders for reported drugs from other drug distributors made available by the United States Drug Enforcement Administration's Automation of Reports and Consolidated Orders System; and o The proportion of out-of-state patients served compared to in-state patients. **REMINDER:** For more information on due diligence, visit: http://www.pharmacy.ohio.gov/suspicious	
Does the drug distributor conduct initial sales without completing due diligence?	Sales that meet the following criteria are exempted from a customer due diligence review prior to initial sale:	OAC 4729:6-3-05

	(1) The sale is to an institutional facility as defined in rule 4729:5-9-01 of the Administrative Code that is a new customer of the distributor; and (2) The drug distributor documents that the order is to meet an emergent need. **REMINDER:** The drug distributor is still required to complete a due diligence review no later than sixty days from the date of the initial sale.	
Does the drug distributor review and update the required suspicious order/customer due diligence policies and procedures on an annual basis?	All drug distributors shall maintain and implement policies and procedures that include all of the following: (1) The design and operation of a suspicious order monitoring and reporting system; (2) A system to collect the necessary information on customers; and (3) Mandatory training, to be conducted annually, for staff responsible for the processing of all orders for reported drugs that includes all the following: (a) The drug distributor's suspicious order monitoring system; (b) The process to collect all relevant information on customers;	OAC 4729:6-3-05

	(c) The process for submission of suspicious orders and customers who may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels to the Board; and (d) Information on submitting a confidential report of a suspicious order or customer engaging in possible activities that may cause reported drugs to be diverted from legitimate channels by using the Board's online electronic complaint form that can accessed by visiting: www.pharmacy.ohio.gov. The training shall remind all employees that complaints and all information submitted that identifies a complainant shall remain confidential pursuant to section 4729.23 of the Revised Code.	

Controlled Substance Inventory Requirements

Question	Description / Guidance	Law / Rule
Does the licensee conduct a biennial inventory of controlled substances?	Per DEA requirements, the drug distributor must take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. The drug distributor's responsible person shall be responsible for completing and maintaining this inventory record. All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable. Board staff will review records to determine compliance.	OAC 4729:6-3-06 21 CFR 1304.11
If there was a change of responsible person, was a complete inventory of controlled substances taken by the new responsible person?	A controlled substance inventory must be taken by the new responsible person no later than thirty days from the separation date of the previous responsible person. The new responsible person must be responsible for completing and maintaining this inventory record at the location licensed as a drug distributor. **NOTE:** This requirement is only for Category 3 licenses.	OAC 4729:6-2-01

Online Sales of Dangerous Drugs

Question	Description / Guidance	Law / Rule
Does the drug distributor sell or offer to sell dangerous drugs at retail or wholesale into, out of, or within Ohio?	If so, they must be properly licensed and make such sales only in compliance with all state and federal laws, rules and regulations governing the legal distribution of dangerous drugs.	OAC 4729:6-3-07
Does the drug distributor's website provide the required information to the public?	A website owned or maintained by a drug distributor must provide the following information to the public: (1) Name under which the dangerous drug distributor is licensed to do business as in Ohio; (2) Full address of licensed location; (3) Telephone number where the drug distributor may be contacted during regular business hours; (4) A list of the states in which the dangerous drug distributor may legally sell dangerous drugs; and (5) The name, address, and how the state licensing agency and the Drug Enforcement Administration may be contacted in each state in which the person is authorized to do business. This may include a link to the agency's and the DEA's website.	OAC 4729:6-3-07
Does the drug distributor request personal information from the	If so, the drug distributor must provide for security and confidentiality of the information. This portion of the website must also provide information regarding how the personal	OAC 4729:6-3-07

public via the internet (questionnaire forms or e-mail)?	information will be used, pursuant to all federal and state laws, rules, and regulations, and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.	

Distribution of Samples and Complimentary Supplies

Question	Description / Guidance	Law / Rule
Does the drug distributor or their representative (e.g., sales representatives) distribute drug samples or complimentary supplies?	A sample is a dangerous drug or pharmaceutical preparation which at one time had been placed in a container plainly marked as a sample by a manufacturer. Samples may only be provided to and furnished by a licensed prescriber as defined in OAC 4729:5-1-02 in accordance with OAC 4729:6-3-08 (B). A complimentary supply, also known as starter packs, initial dose packs, starter socks, replacement programs, or any other similar supply is a drug or pharmaceutical preparation that is distributed without charge to licensed TDDD pharmacies or to prescribers to assist patients in the initiation of drug therapy. Complimentary supplies shall not contain the markings or labeling of a sample drug.	OAC 4729:6-3-08
Does the drug distributor or their representative distribute samples to a licensed prescriber only upon the request of the prescriber?	A drug distributor or representative may not send unsolicited samples to a licensed prescriber. **NOTE**: Records of sample drug distribution must be maintained in the same manner as all other dangerous drug distribution.	OAC 4729:6-3-08

WHOLESALE DISTRIBUTORS

Facility Standards

Question	Description / Guidance	Law / Rule
Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?	All facilities must be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.	OAC 4729:6-5-01
Does the facility have areas designed to meet specified storage requirements?	All facilities must have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.	OAC 4729:6-5-01
Does the facility maintain a quarantine area for adulterated drugs?	All facilities must have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.	OAC 4729:6-5-01
Is the facility clean and orderly?	All facilities must be maintained in a clean and orderly condition.	OAC 4729:6-5-01
Is the facility free from infestation?	All facilities must be free from infestation by insects, rodents, birds, or vermin of any kind.	OAC 4729:6-5-01
Is the facility a registered business entity and operating in a commercial zone?	All facilities must be registered as a business entity with the appropriate state or local authority(s) and operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.	OAC 4729:6-5-01

Do employees have appropriate training, experience, and/or education to assume responsibility for positions related to compliance with Ohio Administrative Code?	Personnel employed in the wholesale distribution of dangerous drugs must be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of OAC 4729:6.	OAC 4729:6-5-01

Security

Question	Description / Guidance	Law / Rule
Is the facility secure from unauthorized entry?	All facilities used for wholesale drug distribution must be secure from unauthorized entry and meet the following requirements: (1) Access from outside the premises shall be kept to a minimum and be well controlled; (2) The outside perimeter of the premises shall be well lit; (3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel; (4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours; and (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. **NOTE:** Drug distributors located **in Ohio** must notify the Board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs. Requires submission of a **Drug Distributor Security Notification Requirement Form**.	OAC 4729:6-5-01

Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?	A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.	OAC 4729:6-5-01
Does the licensee's public warehouse provide adequate security to guard against storage losses?	When storing drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses.	OAC 4729:6-5-01
Does the licensee's public warehouse store controlled substances in compliance with 21 CFR 1301.72?	The licensee must store controlled substances in a public warehouse which complies with the requirements set forth in 21 CFR 1301.72.	OAC 4729:6-5-01
Does the licensee employ precautions to guard against storage or in-transit losses?	Precautions may include ensuring shipping containers do not indicate that contents are controlled substances.	OAC 4729:6-5-01
Does the licensee have adequate security to guard against theft and diversion while dangerous drugs are being stored or handled by agent(s)?	When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.	OAC 4729:6-5-01

Temperature and Conditions

Question	Description / Guidance	Law / Rule
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Drugs must be stored in accordance with labeling requirements (if any) or with the requirements in the current edition of an official compendium. An example of an official compendium is the United States pharmacopoeia/national formulary (USP/NF). If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.	OAC 4729:6-5-01
Does the facility regularly document proper storage of dangerous drugs and maintain documentation for at least three years?	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs must be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation must be made readily retrievable and maintained for a period of not less than three years from the last documented temperature and humidity reading.	OAC 4729:6-5-01

Shipments of Dangerous Drugs

Question	Description / Guidance	Law / Rule
Are all outside shipping containers visually examined upon receipt?	Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	OAC 4729:6-5-01
Is each outgoing shipment carefully inspected?	Each outgoing shipment must be carefully inspected for the identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.	OAC 4729:6-5-01

Returned or Adulterated Drugs

Question	Description / Guidance	Law / Rule
Are expired/adulterated/damaged drugs appropriately segregated from the facility's active inventory?	Expired, damaged, deteriorated, misbranded, or adulterated drugs must be secured separately from active inventory in a manner that prohibits access by unauthorized persons. Any dangerous drugs where the immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and must be quarantined and physically separated from other dangerous drugs.	OAC 4729:6-5-01
Are expired/adulterated drugs stored no longer than two years from the date of expiration/adulteration?	Adulterated drugs must be stored no longer than two years from the date of adulteration or expiration.	OAC 4729:6-5-01
Are drugs destroyed or returned to the supplier if the conditions under which the dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity?	The drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping. Destruction or return of the doubtful dangerous drugs is not required if examination, testing, or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality, or purity.	OAC 4729:6-5-01

Written Policies and Procedures

Question	Description / Guidance	Law / Rule
Does the wholesale distributor have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?	Wholesale drug distributors must establish, maintain, and adhere to written policies and procedures which must be followed for the following: ▪ Receipt, security, storage, inventory, and distribution of dangerous drugs; ▪ Identifying, recording, and reporting losses or thefts; and ▪ Correcting all errors and inaccuracies in inventories.	OAC 4729:6-5-01
Does the facility have a written procedure for handling recalls and withdrawals of dangerous drugs?	Wholesale drug distributors must establish, maintain, and adhere to written policies and procedures which must be followed for handling recalls and withdrawals of dangerous drugs. Such procedure must be appropriate to deal with recalls and withdrawals due to: ▪ Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy. ▪ Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.	OAC 4729:6-5-01

	▪ Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.	
Does the facility have a written procedure in case of a natural disaster or emergency situation?	Wholesale drug distributors must establish, maintain, and adhere to written policies and procedures which must be followed to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.	OAC 4729:6-5-01
Does the facility have a procedure to ensure adulterated drugs are segregated prior to return or destruction?	This written procedure must provide for written documentation of the disposition of adulterated dangerous drugs and must be maintained for three years after disposition of the adulterated drugs.	OAC 4729:6-5-01

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-5-02
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale shall include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-5-02 OAC 4729:6-3-08

	(d) The name and principal address of the purchases or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution, as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-5-02
Does the facility maintain records at an off-site location?	A wholesale distributor located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-5-02
Does the facility maintain an executed agreement with the off-site storage location?	This agreement must authorize an agent of the Board access to records within three business days if records are maintained at a location other than the licensed location or via a computerized recordkeeping system.	OAC 4729:6-5-02
Does the wholesale distributor submit wholesale information to the drug database?	Wholesale information must be submitted in accordance with ORC 4729.78.	OAC 4729:6-5-02 ORC 4729.78

	The following must be submitted for all drug deliveries to prescribers or TDDDs: (1) Purchaser identification; (2) Identification of the drug sold; (3) Quantity of the drug sold; (4) Date of sale; and (5) The license number issued by the Board. For more information on reporting sales to the drug database, visit: www.pharmacy.ohio.gov/wholesalereport	

VIRTUAL WHOLESALERS

Security

Question	Description / Guidance	Law / Rule
Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?	A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.	OAC 4729:6-6-01
Does the licensee's public warehouse provide adequate security to guard against storage losses?	When storing drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses.	OAC 4729:6-6-01
Does the licensee's public warehouse store controlled substances in compliance with 21 CFR 1301.72?	The licensee must store controlled substances in a public warehouse which complies with the requirements set forth in 21 CFR 1301.72.	OAC 4729:6-6-01
Does the licensee employ precautions to guard against storage or in-transit losses?	Precautions may include assuring shipping containers do not indicate that contents are controlled substances.	OAC 4729:6-6-01
Does the licensee have adequate security to guard against theft and diversion while dangerous drugs are being stored or handled by agent(s)?	When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.	OAC 4729:6-6-01

Written Policies and Procedures & Employee Training

Question	Description / Guidance	Law / Rule
Does the virtual wholesaler have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?	Virtual wholesalers must establish, maintain, and adhere to written policies and procedures which must be followed for the following: ▪ Receipt, security, storage, inventory, and distribution of dangerous drugs; ▪ Identifying, recording, and reporting losses or thefts; and ▪ Correcting all errors and inaccuracies in inventories.	OAC 4729:6-6-01
Does the facility have a written procedure to follow for handling recalls and withdrawals of dangerous drugs?	Virtual wholesalers must establish, maintain, and adhere to written policies and procedures which must be followed for handling recalls and withdrawals of dangerous drugs. Such procedure must be appropriate to deal with recalls and withdrawals due to: ▪ Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy. ▪ Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.	OAC 4729:6-6-01

	▪ Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.	
Does the facility have a written procedure in case of natural disaster or emergency situation?	Virtual wholesalers must establish, maintain, and adhere to written policies and procedures which must be followed to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.	OAC 4729:6-6-01
Does the facility have a procedure to ensure adulterated drugs are segregated prior to return or destruction?	This written procedure shall provide for written documentation of the disposition of adulterated dangerous drugs and shall be maintained for three years after disposition of the adulterated drugs.	OAC 4729:6-6-01

Facility Operations and Employee Training

Question	Description / Guidance	Law / Rule
Do employees have appropriate training, experience, and/or education to assume responsibility for positions related to compliance with Ohio Administrative Code?	Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of OAC 4729:6.	OAC 4729:6-6-01
Does the virtual wholesaler engage in any other activity relating to the distribution of dangerous drugs?	Additional licensure is required for operations conducted pursuant to drug distribution rules.	OAC 4729:6-6-01

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-6-01
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale shall include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-6-01 OAC 4729:6-3-08

	(d) The name and principal address of the purchases or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution, as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-6-01
Does the facility maintain records at an off-site location?	A virtual wholesaler located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-6-01
Does the facility maintain an executed agreement with the off-site storage location?	This agreement must authorize an agent of the Board access to records within three business days if records are maintained at a location other than the licensed location or via a computerized recordkeeping system.	OAC 4729:6-6-01

Does the virtual distributor submit wholesale information to the drug database in accordance with ORC 4729.78?	Wholesale information must be submitted in accordance with ORC 4729.78. The following must be submitted for all drug deliveries to prescribers or TDDDs: (1) Purchaser identification; (2) Identification of the drug sold; (3) Quantity of the drug sold; (4) Date of sale; and (5) The license number issued by the Board. For more information on reporting sales to the drug database, visit: www.pharmacy.ohio.gov/wholesalereport	OAC 4729:6-6-01

BROKERS

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-7-01
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-7-01 OAC 4729:6-3-08

	(d) The name and principal address of the purchases or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-7-01
Does the facility maintain records at an off-site location?	A broker located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-7-01
Does the facility maintain an executed agreement with the off-site storage location?	This agreement must authorize an agent of the Board access to records within three business days if records are maintained at a location other than the licensed location or via a computerized recordkeeping system.	OAC 4729:6-7-01

Operations

Question	Description / Guidance	Law / Rule
Does the broker only engage in wholesale distribution and sale of unopened dangerous drugs packaged in the manufacturer's original container?	Brokers must only engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are unopened (i.e., no partial stock bottles) and packaged in the manufacturer's original container.	OAC 4729:6-7-01
Does the broker engage in wholesale distribution and sale of only non-controlled dangerous drugs?	Brokers must not engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are controlled substances.	OAC 4729:6-7-01
Does the broker engage in any other activity relating to the distribution of dangerous drugs?	Additional licensure is required for operations conducted pursuant to drug distribution rules.	OAC 4729:6-7-01

MANUFACTURERS

Facility Standards

Question	Description / Guidance	Law / Rule
Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?	All facilities must be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.	OAC 4729:6-8-01
Does the facility have areas designed to meet specified storage requirements?	All facilities must have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.	OAC 4729:6-8-01
Does the facility maintain a quarantine area for adulterated drugs?	All facilities must have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.	OAC 4729:6-8-01
Is the facility clean and orderly?	All facilities must be maintained in a clean and orderly condition.	OAC 4729:6-8-01
Is the facility free from infestation?	All facilities must be free from infestation by insects, rodents, birds, or vermin of any kind.	OAC 4729:6-8-01
Is the facility a registered business entity and operating in a commercial zone?	All facilities must be registered as a business entity with the appropriate state or local authority(s) and operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.	OAC 4729:6-8-01

Do employees have appropriate training, experience, and/or education to assume responsibility for positions related to compliance with Ohio Administrative Code?	Personnel employed in the wholesale distribution of dangerous drugs must be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of OAC 4729:6.	OAC 4729:6-8-01
Does the manufacturer comply with current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug, and Cosmetic Act?	A manufacturer shall comply with current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug, and Cosmetic Act (5/28/2015).	OAC 4729:6-8-01

Security

Question	Description / Guidance	Law / Rule
Is the facility secure from unauthorized entry?	All facilities used for manufacturers must be secure from unauthorized entry and meet the following requirements: (1) Access from outside the premises shall be kept to a minimum and be well controlled. (2) The outside perimeter of the premises shall be well lit. (3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel. (4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours. (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. **NOTE:** Drug distributors located in Ohio must notify the Board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs. Requires submission of a Drug Distributor Security Notification Requirement Form.	OAC 4729:6-8-01

Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?	A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.	OAC 4729:6-8-01
Does the licensee's public warehouse provide adequate security to guard against storage losses?	When storing drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses.	OAC 4729:6-8-01
Does the licensee store controlled substances in public warehouses in compliance with 21 CFR 1301.72?	The licensee must store controlled substances in a public warehouse which complies with the requirements set forth in 21 CFR 1301.72.	OAC 4729:6-8-01
Does the licensee employ precautions to guard against storage or in-transit losses?	Precautions may include ensuring shipping containers do not indicate that contents are controlled substances.	OAC 4729:6-8-01
Does the licensee have adequate security to guard against theft and diversion while dangerous drugs are being stored or handled by agent(s)?	When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.	OAC 4729:6-8-01

Temperature and Conditions

Question	Description / Guidance	Law / Rule
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Drugs must be stored in accordance with labeling requirements (if any) or with the requirements in the current edition of an official compendium. An example of an official compendium is the United States pharmacopoeia/national formulary (USP/NF). If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.	OAC 4729:6-8-01
Does the facility regularly document proper storage of dangerous drugs and maintain documentation for at least three years?	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than three years from the last documented temperature and humidity reading.	OAC 4729:6-8-01

Shipments of Dangerous Drugs

Question	Description / Guidance	Law / Rule
Are all outside shipping containers visually examined upon receipt?	Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	OAC 4729:6-8-01
Is each outgoing shipment carefully inspected?	Each outgoing shipment must be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.	OAC 4729:6-8-01

Returned or Adulterated Drugs

Question	Description / Guidance	Law / Rule
Are expired/adulterated/damaged drugs appropriately segregated from the facility's active inventory?	Expired, damaged, deteriorated, misbranded, or adulterated drugs must be secured separately from active inventory in a manner that prohibits access by unauthorized persons. Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and must be quarantined and physically separated from other dangerous drugs.	OAC 4729:6-8-01
Are expired/adulterated drugs stored no longer than two years from the date of expiration/adulteration?	Adulterated drugs must be stored no longer than two years from the date of adulteration or expiration.	OAC 4729:6-8-01
Are drugs destroyed or returned to the supplier if the conditions under which the dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity?	The drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping. Destruction or return of the doubtful dangerous drugs is not required if examination, testing, or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality, or purity.	OAC 4729:6-8-01

Written Policies and Procedures

Question	Description / Guidance	Law / Rule
Does the manufacturer have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?	Manufacturers must establish, maintain, and adhere to written policies and procedures which must be followed for the following: ▪ Receipt, security, storage, inventory, and distribution of dangerous drugs; ▪ Identifying, recording, and reporting losses or thefts; and ▪ Correcting all errors and inaccuracies in inventories.	OAC 4729:6-8-01
Does the facility have a written procedure for handling recalls and withdrawals of dangerous drugs?	Manufacturers must establish, maintain, and adhere to written policies and procedures which must be followed for handling recalls and withdrawals of dangerous drugs. Such procedure must be appropriate to deal with recalls and withdrawals due to: ▪ Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy. ▪ Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.	OAC 4729:6-8-01

	▪ Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.	
Does the facility have a written procedure in case of a natural disaster or emergency situation?	Manufacturers must establish, maintain, and adhere to written policies and procedures which must be followed to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.	OAC 4729:6-8-01
Does the facility have a procedure to ensure adulterated drugs are segregated prior to return or destruction?	This written procedure must provide for written documentation of the disposition of adulterated dangerous drugs and must be maintained for three years after disposition of the adulterated drugs.	OAC 4729:6-8-01

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-8-02
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-8-02 OAC 4729:6-3-08

	(d) The name and principal address of the purchases or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution, as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-8-02
Does the facility maintain records at an off-site location?	A manufacturer located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-8-02
Does the facility maintain an executed agreement with the off-site storage location?	This agreement must authorize an agent of the Board access to records within three business days if records are maintained at a location other than the licensed location or via a computerized recordkeeping system.	OAC 4729:6-8-02

Does the manufacturer submit wholesale information to the drug database?	Wholesale information must be submitted in accordance with ORC 4729.78. The following must be submitted for all drug deliveries to prescribers or TDDDs: (1) Purchaser identification; (2) Identification of the drug sold; (3) Quantity of the drug sold; (4) Date of sale; and (5) The license number issued by the Board. For more information on reporting sales to the drug database, visit: www.pharmacy.ohio.gov/wholesalereport	OAC 4729:6-8-02

REPACKAGERS

Facility Standards

Question	Description / Guidance	Law / Rule
Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?	All facilities must be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.	OAC 4729:6-9-01
Does the facility have areas designed to meet specified storage requirements?	All facilities must have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.	OAC 4729:6-9-01
Does the facility maintain a quarantine area for adulterated drugs?	All facilities must have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.	OAC 4729:6-9-01
Is the facility clean and orderly?	All facilities must be maintained in a clean and orderly condition.	OAC 4729:6-9-01
Is the facility free from infestation?	All facilities must be free from infestation by insects, rodents, birds, or vermin of any kind.	OAC 4729:6-9-01
Is the facility a registered business entity and operating in a commercial zone?	All facilities must be registered as a business entity with the appropriate state or local authority(s) and operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.	OAC 4729:6-9-01

Do employees have appropriate training, experience, and/or education to assume responsibility for positions related to compliance with Ohio Administrative Code?	Personnel employed in the repackaging and distribution of dangerous drugs must be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements in OAC 4729:6.	OAC 4729:6-9-01

Security

Question	Description / Guidance	Law / Rule
Is the facility secure from unauthorized entry?	All facilities used for repackagers must be secure from unauthorized entry and meet the following requirements: (1) Access from outside the premises shall be kept to a minimum and be well controlled. (2) The outside perimeter of the premises shall be well lit. (3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel. (4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours. (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. **NOTE:** Drug distributors located in Ohio must notify the Board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs. Requires submission of a Drug Distributor Security Notification Requirement Form.	OAC 4729:6-9-01

Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?	A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.	OAC 4729:6-9-01
Does the licensee's public warehouse provide adequate security to guard against storage losses?	When storing drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses.	OAC 4729:6-9-01
Does the licensee's public warehouse store controlled substances in compliance with 21 CFR 1301.72?	The licensee must store controlled substances in a public warehouse which complies with the requirements set forth in 21 CFR 1301.72.	OAC 4729:6-9-01
Does the licensee employ precautions to guard against storage or in-transit losses?	Precautions may include assuring shipping containers do not indicate that contents are controlled substances.	OAC 4729:6-9-01
Does the licensee have adequate security to guard against theft and diversion while dangerous drugs are being stored or handled by agent(s)?	When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.	OAC 4729:6-9-01

Temperature and Conditions

Question	Description / Guidance	Law / Rule
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Drugs must be stored in accordance with labeling requirements (if any) or with the requirements in the current edition of an official compendium. An example of an official compendium is the United States pharmacopoeia/national formulary (USP/NF). If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.	OAC 4729:6-9-01
Does the facility regularly document proper storage of dangerous drugs?	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs must be utilized to regularly document proper storage of dangerous drugs.	OAC 4729:6-9-01

Shipments of Dangerous Drugs

Question	Description / Guidance	Law / Rule
Are all outside shipping containers visually examined upon receipt?	Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	OAC 4729:6-9-01
Is each outgoing shipment carefully inspected?	Each outgoing shipment must be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.	OAC 4729:6-9-01

Returned or Adulterated Drugs

Question	Description / Guidance	Law / Rule
Are expired/adulterated/damaged drugs appropriately segregated from the facility's active inventory?	Expired, damaged, deteriorated, misbranded, or adulterated drugs must be secured separately from active inventory in a manner that prohibits access by unauthorized persons. Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and must be quarantined and physically separated from other dangerous drugs.	OAC 4729:6-9-01
Are expired/adulterated drugs stored no longer than two years from the date of expiration/adulteration?	Adulterated drugs must be stored no longer than two years from the date of adulteration or expiration.	OAC 4729:6-9-01
Are drugs destroyed or returned to the supplier if the conditions under which the dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity?	The drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping. Destruction or return of the doubtful dangerous drugs is not required if examination, testing, or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality, or purity.	OAC 4729:6-9-01

Written Policies and Procedures

Question	Description / Guidance	Law / Rule
Does the wholesale distributor have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?	Repackagers must establish, maintain, and adhere to written policies and procedures which must be followed for the following: ▪ Receipt, security, storage, inventory, and distribution of dangerous drugs; ▪ Identifying, recording, and reporting losses or thefts; and ▪ Correcting all errors and inaccuracies in inventories.	OAC 4729:6-9-01
Does the facility have a written procedure for handling recalls and withdrawals of dangerous drugs?	Repackagers must establish, maintain, and adhere to written policies and procedures which must be followed for handling recalls and withdrawals of dangerous drugs. Such procedure must be appropriate to deal with recalls and withdrawals due to: ▪ Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy. ▪ Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.	OAC 4729:6-9-01

	▪ Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.	
Does the facility have a written procedure in case of a natural disaster or emergency situation?	Repackagers must establish, maintain, and adhere to written policies and procedures which must be followed to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.	OAC 4729:6-9-01
Does the facility have a procedure to ensure adulterated drugs are segregated prior to return or destruction?	This written procedure must provide for written documentation of the disposition of adulterated dangerous drugs and must be maintained for three years after disposition of the adulterated drugs.	OAC 4729:6-9-01

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-9-02
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-9-02 OAC 4729:6-3-08

	(d) The name and principal address of the purchases or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution, as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-9-02
Does the facility maintain records at an off-site location?	Repackagers located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-9-02
Does the facility maintain an executed agreement with the off-site storage location?	This agreement must authorize an agent of the Board access to records within three business days if records are maintained at a location other than the licensed location or via a computerized recordkeeping system.	OAC 4729:6-9-02
Does the repackager submit wholesale information to the drug database?	Wholesale information must be submitted in accordance with ORC 4729.78.	OAC 4729:6-9-02 ORC 4729.78

	The following must be submitted for all drug deliveries to prescribers or TDDDs: (1) Purchaser identification; (2) Identification of the drug sold; (3) Quantity of the drug sold; (4) Date of sale; and (5) The license number issued by the Board. For more information on reporting sales to the drug database, visit: www.pharmacy.ohio.gov/wholesalereport	

OUTSOURCING FACILITIES

Facility Standards

Question	Description / Guidance	Law / Rule
Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?	All facilities must be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.	OAC 4729:6-10-01
Does the facility have areas designed to meet specified storage requirements?	All facilities must have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.	OAC 4729:6-10-01
Does the facility maintain a quarantine area for adulterated drugs?	All facilities must have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.	OAC 4729:6-10-01
Is the facility clean and orderly?	All facilities must be maintained in a clean and orderly condition.	OAC 4729:6-10-01
Is the facility free from infestation?	All facilities must be free from infestation by insects, rodents, birds, or vermin of any kind.	OAC 4729:6-10-01
Is the facility a registered business entity and operating in a commercial zone?	All facilities must be registered as a business entity with the appropriate state or local authority(s) and operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.	OAC 4729:6-10-01

Do employees have appropriate training, experience, and/or education to assume responsibility for positions related to compliance with Ohio Administrative Code?	Personnel employed in the wholesale distribution of dangerous drugs must be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of OAC 4729:6.	OAC 4729:6-10-01
Does the outsourcing facility comply with current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug, and Cosmetic Act?	An outsourcing facility shall comply with current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug, and Cosmetic Act (5/28/2015).	OAC 4729:6-10-01
Does the outsourcing facility sell or dispense patient-specific drugs?	If yes, then the entity must also maintain a TDDD license. All laws and rules applicable to licensure as a TDDD apply to the dispensing of patient-specific drugs.	OAC 4729:6-10-01

Security

Question	Description / Guidance	Law / Rule
Is the facility secure from unauthorized entry?	All facilities used for wholesale drug distribution must be secure from unauthorized entry and meet the following requirements: (1) Access from outside the premises shall be kept to a minimum and be well controlled. (2) The outside perimeter of the premises shall be well lit. (3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel. (4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours. (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. **NOTE:** Drug distributors located in Ohio must notify the Board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs. Requires submission of a Drug Distributor Security Notification Requirement Form.	OAC 4729:6-10-01

Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?	A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.	OAC 4729:6-10-01
Does the licensee's public warehouse provide adequate security to guard against storage losses?	When storing drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses.	OAC 4729:6-10-01
Does the licensee's public warehouse store controlled substances in compliance with 21 CFR 1301.72?	The licensee must store controlled substances in a public warehouse which complies with the requirements set forth in 21 CFR 1301.72.	OAC 4729:6-10-01
Does the licensee employ precautions to guard against storage or in-transit losses?	Precautions may include assuring shipping containers do not indicate that contents are controlled substances.	OAC 4729:6-10-01
Does the licensee have adequate security to guard against theft and diversion while dangerous drugs are being stored or handled by agent(s)?	When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.	OAC 4729:6-10-01

Temperature and Conditions

Question	Description / Guidance	Law / Rule
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Drugs must be stored in accordance with labeling requirements (if any) or with the requirements in the current edition of an official compendium. An example of an official compendium is the United States pharmacopoeia/national formulary (USP/NF). If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.	OAC 4729:6-10-01
Does the facility regularly document proper storage of dangerous drugs and maintain documentation for at least three years?	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than three years from the last documented temperature and humidity reading.	OAC 4729:6-10-01

Shipments of Dangerous Drugs

Question	Description / Guidance	Law / Rule
Are all outside shipping containers visually examined upon receipt?	Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	OAC 4729:6-10-01
Is each outgoing shipment carefully inspected?	Each outgoing shipment must be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.	OAC 4729:6-10-01

Returned or Adulterated Drugs

Question	Description / Guidance	Law / Rule
Are expired/adulterated/damaged drugs appropriately segregated from the facility's active inventory?	Expired, damaged, deteriorated, misbranded, or adulterated drugs must be secured separately from active inventory in a manner that prohibits access by unauthorized persons. Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and must be quarantined and physically separated from other dangerous drugs.	OAC 4729:6-10-01
Are expired/adulterated drugs stored no longer than two years from the date of expiration/adulteration?	Adulterated drugs must be stored no longer than two years from the date of adulteration or expiration.	OAC 4729:6-10-01
Are drugs destroyed or returned to the supplier if the conditions under which the dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity?	The drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping. Destruction or return of the doubtful dangerous drugs is not required if examination, testing, or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality, or purity.	OAC 4729:6-10-01

Written Policies and Procedures

Question	Description / Guidance	Law / Rule
Does the outsourcing facility have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?	Outsourcing facilities must establish, maintain, and adhere to written policies and procedures which must be followed for the following: ▪ Receipt, security, storage, inventory, and distribution of dangerous drugs; ▪ Identifying, recording, and reporting losses or thefts; and ▪ Correcting all errors and inaccuracies in inventories.	OAC 4729:6-10-01
Does the facility have written policies and procedures for correcting all errors and inaccuracies in inventories?	Outsourcing facilities must establish, maintain, and adhere to written policies and procedures which shall be followed for correcting all errors and inaccuracies with inventories.	OAC 4729:6-10-01
Does the facility have a written procedure for handling recalls and withdrawals of dangerous drugs?	Outsourcing facilities must establish, maintain, and adhere to written policies and procedures which must be followed for handling recalls and withdrawals of dangerous drugs. Such procedure must be appropriate to deal with recalls and withdrawals due to: ▪ Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy.	OAC 4729:6-10-01

	▪ Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market. ▪ Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.	
Does the facility have a written procedure in case of a natural disaster or emergency situation?	Outsourcing facilities must establish, maintain, and adhere to written policies and procedures which must be followed to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.	OAC 4729:6-10-01
Does the facility have a procedure to ensure adulterated drugs are segregated prior to return or destruction?	This written procedure must provide for written documentation of the disposition of adulterated dangerous drugs and must be maintained for three years after disposition of the adulterated drugs.	OAC 4729:6-10-01

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-10-02
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale shall include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-10-02 OAC 4729:6-3-08

	(d) The name and principal address of the purchases or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution, as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-10-02
Does the facility maintain records at an off-site location?	An outsourcing facility located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-10-02
Does the facility maintain an executed agreement with the off-site storage location?	This agreement must authorize an agent of the Board access to records within three business days if records are maintained at a location other than the licensed location or via a computerized recordkeeping system.	OAC 4729:6-10-02
Does the outsourcing facility submit wholesale information to the drug database?	Wholesale information must be submitted in accordance with ORC 4729.78.	OAC 4729:6-10-02

	The following must be submitted for all drug deliveries to prescribers or TDDDs: (1) Purchaser identification; (2) Identification of the drug sold; (3) Quantity of the drug sold; (4) Date of sale; and (5) The license number issued by the Board. For more information on reporting sales to the drug database, visit: www.pharmacy.ohio.gov/wholesalereport	
Does the outsourcing facility comply with all recordkeeping requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act?	Outsourcing facilities shall comply with all recordkeeping requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015).	OAC 4729:6-10-02

THIRD-PARTY LOGISTICS PROVIDERS

Facility Standards

Question	Description / Guidance	Law / Rule
Is the facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?	All facilities must be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.	OAC 4729:6-11-01
Does the facility have areas designed to meet specified storage requirements?	All facilities must have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.	OAC 4729:6-11-01
Does the facility maintain a quarantine area for adulterated drugs?	All facilities must have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.	OAC 4729:6-11-01
Is the facility clean and orderly?	All facilities must be maintained in a clean and orderly condition.	OAC 4729:6-11-01
Is the facility free from infestation?	All facilities must be free from infestation by insects, rodents, birds, or vermin of any kind.	OAC 4729:6-11-01
Do employees have appropriate training, experience, and/or education to assume responsibility	Personnel employed in the wholesale distribution of dangerous drugs must be required to have appropriate education, experience, and training to assume responsibility	OAC 4729:6-11-01

for positions related to compliance with the Ohio Administrative Code?	for positions related to compliance with the requirements of OAC 4729:6.	

Security

Question	Description / Guidance	Law / Rule
Is the facility secure from unauthorized entry?	All facilities used for TPLs must be secure from unauthorized entry and meet the following requirements: (1) Access from outside the premises shall be kept to a minimum and be well controlled. (2) The outside perimeter of the premises shall be well lit. (3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel. (4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours. (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. **NOTE:** Drug distributors located in Ohio must notify the Board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs. Requires submission of a Drug Distributor Security Notification Requirement Form.	OAC 4729:6-11-01

Does the licensee's common or contract carriers have adequate security to guard against in-transit losses?	A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.	OAC 4729:6-11-01
Does the licensee employ precautions to guard against storage or in-transit losses?	Precautions may include assuring shipping containers do not indicate that contents are controlled substances.	OAC 4729:6-11-01

Temperature and Conditions

Question	Description / Guidance	Law / Rule
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Drugs must be stored in accordance with labeling requirements (if any) or with the requirements in the current edition of an official compendium. An example of an official compendium is the United States pharmacopoeia/national formulary (USP/NF). If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.	OAC 4729:6-11-01
Does the facility regularly document proper storage of dangerous drugs and maintain documentation for at least three years?	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs must be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation must be made readily retrievable and maintained for a period of not less than three years from the last documented temperature and humidity reading.	OAC 4729:6-11-01

Shipments of Dangerous Drugs

Question	Description / Guidance	Law / Rule
Are all outside shipping containers visually examined upon receipt?	Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	OAC 4729:6-11-01
Is each outgoing shipment carefully inspected?	Each outgoing shipment must be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.	OAC 4729:6-11-01

Returned or Adulterated Drugs

Question	Description / Guidance	Law / Rule
Are expired/adulterated/damaged drugs appropriately segregated from the facility's active inventory?	Expired, damaged, deteriorated, misbranded, or adulterated drugs must be secured separately from active inventory in a manner that prohibits access by unauthorized persons. Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and must be quarantined and physically separated from other dangerous drugs.	OAC 4729:6-11-01
Are expired/adulterated drugs stored no longer than two years from the date of expiration/adulteration?	Adulterated drugs must be stored no longer than two years from the date of adulteration or expiration.	OAC 4729:6-11-01
Are drugs destroyed or returned to the supplier if the conditions under which the dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity?	The drug distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping. Destruction or return of the doubtful dangerous drugs is not required if examination, testing, or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality, or purity.	OAC 4729:6-11-01

Written Policies and Procedures

Question	Description / Guidance	Law / Rule
Does the third-party logistics provider have written policies and procedures for the receipt, security, storage, inventory, and distribution of dangerous drugs?	Third-party logistics providers must establish, maintain, and adhere to written policies and procedures which must be followed for the following: ▪ Receipt, security, storage, inventory, and distribution of dangerous drugs; ▪ Identifying, recording, and reporting losses or thefts; and ▪ Correcting all errors and inaccuracies in inventories.	OAC 4729:6-11-01
Does the facility have a written procedure for handling recalls and withdrawals of dangerous drugs?	Third-party logistics providers must establish, maintain, and adhere to written policies and procedures which shall be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to: ▪ Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy. ▪ Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.	OAC 4729:6-11-01

	▪ Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.	
Does the facility have a written procedure in case of a natural disaster or emergency situation?	Third-party logistics providers must establish, maintain, and adhere to written policies and procedures which must be followed to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.	OAC 4729:6-11-01
Does the facility have a procedure to ensure adulterated drugs are segregated prior to return or destruction?	This written procedure must provide for written documentation of the disposition of adulterated dangerous drugs and must be maintained for three years after disposition of the adulterated drugs.	OAC 4729:6-11-01

Recordkeeping

Question	Description / Guidance	Law / Rule
Do records of receipt contain all required information?	Records of receipt must include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned; (c) The dates of receipt; and (d) The name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.	OAC 4729:6-11-02
Do records of sale, distribution, or other disposition of dangerous drugs contain all required information?	Records of sale shall include, but not be limited to: (a) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped; (b) The name, NDC, and quantity of drugs distributed or sold; (c) The date of sale or distribution; and	OAC 4729:6-11-02 OAC 4729:6-3-08

	(d) The name and principal address of the purchasers or receiver and the address of the location where the drugs were shipped. **NOTE:** Recordkeeping requirements apply to sample drug and complimentary supply distribution, as well as to damaged, deteriorated, misbranded, or adulterated drugs.	
Are records made readily retrievable?	Records must be made readily retrievable for inspection and copying by federal, state, and local law enforcement agencies for a period of five years following disposition of the drugs.	OAC 4729:6-11-02
Does the facility maintain records at an off-site location?	Third-party logistics providers located in this state intending to maintain records at a location other than the location licensed by the state Board of Pharmacy must send a notification in a manner determined by the Board. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the wholesale distributor. The off-site notification form can be accessed here.	OAC 4729:6-11-02