INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Laboratory

Updated 3/10/2022

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

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

Applicability

This guide applies only to locations licensed as terminal distributor of dangerous drugs that meet the following definition of a "laboratory" in rule 4729:5-16-01 of the Ohio Administrative Code:

> *"Laboratory" means any facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where dangerous drugs and controlled substances are possessed for scientific, clinical or instructional purposes. A laboratory does not include any of the following:*
>
> > *(1) A laboratory licensed under Chapter 3796. of the Revised Code (Medical Marijuana Control Program); or*
> >
> > *(2) Any other person or facility licensed as a terminal distributor of dangerous drugs that is specifically defined and required to comply with another chapter of this division (EMS organization, veterinary clinic, pain management clinic, animal shelter, etc.).*

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

- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Animal Shelters – 4729:5-15
- Office-Based Opioid Treatment Facilities – 4729:5-18
- Clinic and Prescriber Offices – 4729:5-19
- Veterinary Clinics – 4729:5-20
- Opioid Treatment Programs – 4729:5-21
- Non-limited Facilities – 4729:5-22
- Limited Facilities – 4729:5-23

Inspection Authority

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

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

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

After the completion of the inspection, the authorized Board agent will provide an inspection report for review and any corrective actions required. If the inspection report requires a written response, responses must be 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 clinics and prescriber offices licensed as terminal distributors of dangerous drugs:

- **4729:5-1 – Definitions**
- **4729:5-2 – Licensing**
- **4729:5-3 – General Terminal Distributor Provisions**
- **4729:5-4 – Disciplinary Actions**
- **4729:5-16 – Laboratories**
    - 4729:5-16-01 – Laboratories – definitions.*
    - 4729:5-16-02 – Security, control and storage of dangerous drugs.*
    - 4729:5-16-03 – Record Keeping.
    - 4729:5-19-02 (required by 4729:5-16-01) – Personally furnishing dangerous drugs.

The rule is currently pending but will be effective by March 1, 2020.

Clarification on Exempt Chemical Preparations

Controlled substances do not include exempt chemical preparations approved by the United States Drug Enforcement Administration pursuant to 21 CFR 1308.23. The most recent list of exempt chemical preparations is available here: https://www.deadiversion.usdoj.gov/schedules/

Health Insurance Portability and Accountability Act (HIPAA)

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

What is HIPAA?

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

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

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

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

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

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

Positive Identification Guidance

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

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

(2) A magnetic card reader;

(3) A bar code reader;

(4) A biometric method;

(5) A proximity badge reader;

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

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

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

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

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

Required Notifications or Document Submissions

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

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

Notification/Submission Requirement	How to Submit
Change in Business Description *OAC 4729:5-2-03* Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted **within thirty days** of any change in the ownership, business or trade name, category, or address.	A change of business description must be completed online using Ohio's eLicense system. Instructions on submitting this information can be accessed **here**.
Discontinuation of Business *OAC 4729:5-2-04* A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the Board of Pharmacy. The notice shall be submitted, in a manner determined by the Board, **at least thirty days in advance** of the proposed date of discontinuing business, unless waived by the Board's Executive Director or the Director's Designee due to extraordinary circumstances beyond the licensee's control.	Requires submission of a **Written Notice of Discontinuing Business Form**.
Change of Responsible Person *OAC 4729:5-2-01* A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified **within ten days** of the effective date of the appointment of the new responsible person.	Requires submission of a **Change of Responsible Person Form**.
Notification of Off-Site Records Storage *OAC 4729:5-16-03* A terminal distributor intending to maintain records at a location other than the location licensed by the State Board of Pharmacy must notify the Board.	Requires submission of an **Off-Site Records Notification Form**.
Theft or Significant Loss of Dangerous Drugs and Drug Documents *OAC 4729:5-3-02* Licensees are required to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents.	For more information on this requirement, the Board developed this guidance document.

Important Terms

- **"Dangerous drug"** means any of the following:

  (1) Any drug to which either of the following applies:

  (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

  (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

  (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

  (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

  (4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

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

  (1) Wholesale distributors of dangerous drugs, including:

  (a) Brokers; and

  (b) Virtual wholesalers.

  (2) Manufacturers of dangerous drugs.

  (3) Outsourcing facilities.

  (4) Third-party logistics providers.

  (5) Repackagers of dangerous drugs.

- **"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.

- **"Personal supervision"** means the person specified in rule shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

- **"Personally furnish"** or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting.

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OAC = Ohio Administrative Code / ORC = Ohio Revised Code / CFR = Code of Federal Regulations

Licensing and Responsible Person

Question	Description / Guidance	Law/Rule
Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?	Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.	OAC 4729:5-2-03
Does the responsible person match what is indicated in eLicense?	A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified within ten days of the effective date of the appointment of the new responsible person. A change of responsible person form is available on the Board's website: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.	OAC 4729:5-2-01

Personnel

Question	Guidance	Law/Rule
Have any licensed/registered employees at the facility with access to drug stock ever been disciplined by an Ohio licensing agency?	"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, IT or other staff that may need limited supervised access to areas where dangerous drugs or D.E.A. controlled substance order forms are kept. Disciplinary action means any of the following, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement: (1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification; (2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action; (3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation; (4) An action to reprimand or place the license, registration, or certification holder on probation; (5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender; (6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;	OAC 4729:5-1-01 OAC 4729:5-4-01

	(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation; (8) The surrender or other relinquishment of a license, registration or certification in lieu of a formal sanction against a person's license, registration or certificate, whether permanent or temporary; (9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future; (10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation. **NOTE:** Licensee will be asked to provide the names of Ohio licensed/registered employees with access to drug stock to assist Board staff with verification.	

Patient Records and Drug Administration

Question	Guidance	Law/Rule
Does this site use a manual, computerized or combination of both to maintain drug records?	Describe what type of system (manual, electronic or both).	
If using a computerized record keeping system, does the system have effective security controls to prevent unauthorized access?	All computerized systems must contain security features to prevent unauthorized access. Such features may include unique user names and passwords, biometrics (i.e. fingerprint), or any other method that ensures only authorized users may obtain access. All methods for accessing electronic records must be user-specific (i.e. no shared user names or passwords).	OAC 4729:5-16-03
If using a computerized system, are records backed up daily to prevent against record loss?	Licensee should provide documentation demonstrating that computerized records are backed up daily.	OAC 4729:5-16-03
If using computerized record keeping system, is it stand-alone or able to be shared or accessed by another location?	If shared access, confirm that security features are in place to prevent unauthorized access from other locations.	OAC 4729:5-16-03
HUMAN DRUG ADMINISTRATION ONLY: Does the licensee maintain records of drug administration containing the required information?	**APPLIES TO HUMAN DRUG ADMINISTRATION ONLY** Records of drug administration must be maintained for at least three years from the date of last administration. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either: (1) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug.	OAC 4729:5-16-03

	(2) For controlled substance dangerous drugs: the positive identification of the health care professional administering the drug. Records of dangerous drugs administered which become a permanent part of the patient's medical record meet the requirements of the rule. **NOTE:** Board staff will review drug records to determine compliance.	
HUMAN DRUG ADMINISTRATION ONLY: Are orders for the administration of dangerous drugs properly documented?	**APPLIES TO HUMAN DRUG ADMINISTRATION ONLY** Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber must include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification. **NOTE:** Board staff will review drug records to determine compliance.	OAC 4729:5-16-03
HUMAN DRUG ADMINISTRATION ONLY: Are medical assistants being used to administer drugs?	**APPLIES TO HUMAN DRUG ADMINISTRATION ONLY** If yes, Board staff will confirm that medical assistants are not administering anesthesia, controlled substances, or drugs administered intravenously.	OAC 4731-23-03
ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY: Does the licensee maintain records of drug administration containing the required information?	**APPLIES TO ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY** Records of drug administration must be maintained for at least three years from the date of last administration. Records of administration for animal use shall contain the name, strength, dosage form, and quantity of the drugs administered, the name or identification number of the animal to whom or for whose use the drugs were administered, the identification of the person administering the drug, the date of administration, and either:	OAC 4729:5-16-03

	(1) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug. (2) For controlled substance dangerous drugs: the positive identification of the health care professional administering the drug. NOTE: Records of dangerous drugs administered which become a permanent part of the patient's medical record meet the requirements of the rule. **NOTE:** Board staff will review drug records to determine compliance.	
ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY: Are orders for the administration of dangerous drugs properly documented?	**APPLIES TO ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY** Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber must include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification. **NOTE:** Board staff will review drug records to determine compliance.	OAC 4729:5-16-03
HUMAN AND ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY: Are protocols being used to administer dangerous drugs?	**APPLIES TO HUMAN AND ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY** Protocols may only be used as follows: (1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate	OAC 4729:5-3-12

	medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks; (2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases; (3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns; (4) The administration of erythromycin for prevention of ophthalmia neonatorum; and (5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729 of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention. If yes, Board staff will review protocols to ensure they meet the allowed uses and comply with the following: (1) Includes a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification; and date of signature. (2) Are maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.	
HUMAN AND ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY: Are pre-printed orders	**APPLIES TO HUMAN AND ANIMAL (NON-RESEARCH) DRUG ADMINISTRATION ONLY**	OAC 4729:5-3-12

used for the administration of dangerous drugs?	A "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. If yes, Board staff will confirm the following: (1) A prescriber completes an assessment and make a diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. (2) The order contains the following information: the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as calculations and patient physiologic data; signature of the prescriber or some other form of positive identification of the prescriber; and date of signature.	
ANIMAL RESEARCH DRUG ADMINISTRATION ONLY: Does the licensee maintain records of drug administration containing the required information?	**ANIMAL RESEARCH DRUG ADMINISTRATION ONLY** Records of drug administration must be maintained for at least three years from the date of last administration. Records of administration for non-human research purposes shall contain the name of the drugs administered, the name or identifier of the animal, group of animals, or group of cells for whose use the drugs were administered, and the date the research protocol began. Administration to an animal or group of animals shall be pursuant to an institutional animal care and use committee (IACUC) protocol which outlines the name, strength, dosage form, and quantity of the drug to be administered, and a timeline for subsequent administration(s). Documentation within a lab notebook or research record of shall be deemed to meet the requirements of this paragraph. **NOTE:** Board staff will review drug records to determine compliance.	OAC 4729:5-16-03

Drug and Hypodermic Security

Question	Guidance	Law/Rule
Are controlled substances stored in a securely locked, substantially constructed cabinet or safe?	The cabinet or safe must meet the following requirements: (1) The cabinet or safe shall be placed in an area that is not readily accessible to the public (ex. waiting areas or areas where the public are allowed without supervision by staff). (2) During non-business hours, the cabinet or safe is stored in an area secured by a physical barrier with suitable locks, which may include a locked room or secured facility. (3) The cabinet or safe is locked and secured when not in use. (4) In the case of a combination lock or access code, the combination or access code is changed upon termination of employment of an employee having knowledge of the combination or access code. **NOTE:** Controlled substances do not include exempt chemical preparations approved by the United States Drug Enforcement Administration pursuant to 21 CFR 1308.23. The most recent list of exempt chemical preparations is available here: https://www.deadiversion.usdoj.gov/schedules/	OAC 4729:5-16-02
Has the responsible person designated any person as a designee for the purpose of security and control of the licensee's controlled substance drug stock?	A responsible person may have more than one designee. All designees shall meet the requirements of the responsible person set forth in rule 4729:5-2-01 of the Administrative Code. A laboratory shall maintain a current list of all approved designees for immediate inspection by an agent, officer or inspector of the Board. If applicable, Board staff will review the list to determine compliance.	OAC 4729:5-16-02
Do the methods utilized for accessing the cabinet or safe containing controlled	Access to the cabinet or safe must comply with the following: (1) In the case of a key lock, all locks are kept in good working order with keys removed therefrom. All keys shall be maintained in a	OAC 4729:5-16-02

substances prevent unauthorized access?	secure place that is inaccessible to anyone other than the responsible person or the responsible person's designee if not being used by the responsible person or the responsible person's designee (or by a laboratory employee or researcher – see #2 below). (2) A laboratory employee or researcher may have access to the cabinet or safe containing controlled substances under any of the following circumstances: ▪ A responsible person or the responsible person's designee may provide a laboratory employee or researcher with a temporary key for the purposes of accessing the cabinet or safe. An employee or researcher shall return the key provided in accordance with this paragraph to the responsible person or responsible person's designee or a secured location with restricted access (such as a lockbox) no later than the end of the employee's shift, the end of the researcher's activity, or if there is no longer a responsible person or designee available to provide personal supervision. **-OR-** ▪ A responsible person or the responsible person's designee may provide an employee or researcher with a key, combination or access code for the purposes of accessing the cabinet or safe, if all the following conditions apply: o The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by the responsible person or the responsible person's designee; o The room is locked during non-business hours or when there is no longer a responsible person or responsible person's designee available to provide personal supervision. **NOTE:** If a licensee proposes an alternate security plan for accessing the controlled substance safe or cabinet, that plan must be	

	submitted and approved by the Director of Compliance and Enforcement [see OAC 4729:5-16-03 (B)(6)(c)]. **REMINDER:** An employee or researcher of the laboratory may have access to controlled substances only under the personal supervision of the laboratory's responsible person or the responsible person's designee.	
Does the licensee comply with the security requirements for storing thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine?	Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a separate safe or steel cabinet equivalent to a U.S. Government Class V security container from all other controlled substances. See OAC 4729:5-16-02 (H) for additional information on the storage of thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine. **NOTE:** This requirement does not apply to exempt chemical preparations approved by the United States Drug Enforcement Administration pursuant to 21 CFR 1308.23. The most recent list of exempt chemical preparations is available here: https://www.deadiversion.usdoj.gov/schedules/	OAC 4729:5-16-02
Are non-controlled dangerous drugs, exempt chemical preparations, and hypodermics maintained under appropriate supervision and control?	When the laboratory is not in use by authorized personnel, non-controlled dangerous drugs, exempt chemical preparations, and hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet or safe, drawer, locked room, or secured facility. **NOTE:** When the laboratory is closed, the goal is to ensure the facility can be secured to prevent unauthorized access. The most recent list of exempt chemical preparations is available here: https://www.deadiversion.usdoj.gov/schedules/ **REMINDER:** Ohio law (ORC 3719.172) requires reasonable precautions to prevent any hypodermic in the person's possession from theft or acquisition by any unauthorized person.	OAC 4729:5-16-02 OAC 4729:5-3-14 ORC 3719.172

Drug Storage and Temperature Control

Question	Guidance	Law/Rule
Are areas where dangerous drugs are stored dry, well-lit, well-ventilated, and maintained in a clean and orderly condition?	All areas where dangerous drugs are stored must be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition.	OAC 4729:5-16-02
Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Storage areas must be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. There is not a requirement for monitoring room temperature, however, Board staff may document temperature readings if storage areas are excessively hot or cold.	OAC 4729:5-16-02
Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?	The facility must maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained: (1) Temperature logs with, at a minimum, daily observations; or (2) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion. Records of temperature control monitoring for refrigerators and freezers used for the storage of drugs must include any of the following: (1) For temperature logs, either: (a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or (b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.	OAC 4729:5-16-02 OAC 4729:5-16-03

	(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion. **NOTE:** A licensee may select the appropriate method for monitoring temperature (i.e. electronic, manual, etc.). Temperature readings should be available for review by Board staff.	
Does the licensee have a policy to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs?	A licensee is required to develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs. The policy should be made available for review upon inspection and should describe, at a minimum, all the following: ▪ The actions to be taken in the event of temperature excursions outside the labelled storage conditions. ▪ The process for appropriately investigating, documenting, and assessing temperature excursions outside the labelled storage conditions to ensure the integrity of the drug stock (for example, stability data or technical justification).	OAC 4729:5-16-02
Are refrigerators and/or freezers use for the storage of drugs free of food or beverage products?	A licensee is required to develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs. The policy should be made available for review upon inspection and all refrigerators and freezers used for drug storage will be examined to ensure compliance. **NOTE:** Facilities may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures.	OAC 4729:5-16-02

Theft or Significant Loss of Drugs and Drug Documents

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

Orders for Schedule II Controlled Substances

Question	Guidance	Law/Rule
Are all executed DEA Forms 222 retained for at least three years?	21 CFR 1305.17 requires executed DEA Forms 222 must be maintained separately from all other records of the registrant. Ohio regulations require these records to be retained for at least three years.	OAC 4729:5-16-03
Are DEA Forms 222 secured when not in use?	Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms (DEA Form 222) under the personal supervision of the laboratory's responsible person. D.E.A. controlled substance order forms (DEA Form 222) must be secured when not in use. This may include the following: a locked drawer, filing cabinet, safe, lock box, lockable bag, or any other method that can be locked to prevent unauthorized access.	OAC 4729:5-16-02

Controlled Substance Inventory

Question	Guidance	Law/Rule
Does the licensee conduct an annual inventory of controlled substances?	All Category III licensees must complete an annual inventory **even if drugs are not on-site** (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory. Each inventory must contain a complete and accurate record of all controlled substances on hand the date the inventory is conducted. The inventory must have the names of the controlled substances, each finished form, the number of units, and/or the number of commercial containers of each finished form. If listed in Schedules I or II, make an exact count or measure of the contents. If listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case the licensee must make an exact count of the contents. **NOTE:** The annual inventory may be taken on any date which is within thirteen months of the previous inventory date. **REMINDER:** This requirement does not apply to exempt chemical preparations approved by the United States Drug Enforcement Administration pursuant to 21 CFR 1308.23. The most recent list of exempt chemical preparations is available here: https://www.deadiversion.usdoj.gov/schedules/ Board staff will review records to determine compliance.	OAC 4729:5-3-07
How does the licensee monitor its inventory of controlled substances?	Board staff will review and document how the licensee monitors its inventory of controlled substances (e.g. daily count, perpetual inventory, etc.).	

Drug Purchases

Question	Guidance	Law/Rule
Does the licensee maintain complete and accurate records of drugs purchased?	Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement. Records must be maintained for a period of three years. Board staff will review records of receipt to determine compliance.	OAC 4729:5-16-03
Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?	Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale (including samples), the terminal distributor shall query the Board's online roster to confirm any of the following: (1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code (i.e. wholesaler, manufacturer, repackager, outsourcing facility or 3PL); or (2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code (i.e. pharmacies or other terminal distributors). If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase. **NOTE:** Except for veterinary drugs (OAC 4729:7-2-05), compounded drugs used for office-stock can no longer be ordered from compounding pharmacies.	OAC 4729:5-3-04

	Documented queries must be maintained for three years. Board staff will review drug invoices and compare to documented queries of eLicense.	

Drug Disposal (For Dangerous Drugs in Schedules II – V)

REMINDER: *These requirements do not apply if the controlled substance or dangerous drug was consumed when conducting an analysis.*

Question	Guidance	Rule/Law
Does the licensee dispose of controlled substance dangerous drugs on-site using a method that renders the drug non-retrievable?	Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request. "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes. **NOTE:** Per the Drug Enforcement Administration, flushing (i.e. drain or toilet) does not meet the definition of non-retrievable. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable.	OAC 4729:5-3-01
Does the licensee use a reverse distributor for the	If yes, Board staff will document the name of the reverse distributor.	

disposal of controlled substances?		
Does the licensee maintain complete and accurate records of the disposal of controlled substance dangerous drugs?	A licensee must use a DEA Form 41 to document the disposal of controlled substances. **NOTE:** Use of the DEA Form 41 does not apply to the disposal of an unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply. If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification on the DEA Form 41 of two laboratory employees conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	OAC 4729:5-3-01 OAC 4729:5-16-03
Does the licensee maintain complete and accurate records of the disposal of unused portions of controlled substances resulting from patient administration?	Records must include the name of the drug, the quantity disposed, the date and manner of disposal, and the positive identification of two laboratory employees conducting and witnessing the disposal. Documentation may be maintained in the patient record (i.e. with administration record). The disposal method does not have to render the unused portion of the drug non-retrievable. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	OAC 4729:5-3-01 OAC 4729:5-16-03
Does the licensee dispose of non-controlled drugs using a method that prevents the possession or	Methods of disposal of non-controlled dangerous drugs must prevent the possession or use of the drugs by unauthorized persons.	OAC 4729:5-3-06

use of the drugs by unauthorized persons?		
Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs?	Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal. NOTE: This does not apply to wastage from administration. For non-controlled drugs, such documentation is not required. All records must be maintained for a period of three years.	OAC 4729:5-16-03

Schedule I Controlled Substance Drug Disposal

REMINDER: *These requirements do not apply if the controlled substance or dangerous drug was consumed when conducting an analysis.*

Question	Guidance	Rule/Law
Does the licensee dispose of schedule I controlled substances on-site using a method that renders the drug non-retrievable?	Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request. "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes. **NOTE:** Per the Drug Enforcement Administration, flushing (i.e. drain or toilet) does not meet the definition of non-retrievable. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable.	OAC 4729:5-3-01
Does the licensee use a contracted waste disposal company in compliance	If yes, Board staff will document the name of the waste disposal company.	OAC 4729:5-16-02

with all federal, state, and local laws, rules, and regulations?	Disposal of controlled substances may be conducted by a contracted waste disposal company in compliance with all federal, state and local laws, rules, and regulations.	
Does the licensee maintain complete and accurate records of the disposal of schedule I controlled substances?	Records for the disposal of the drug shall contain the actual identification of the drug or substance, form, and quantity disposed, the date disposed, the method of disposal and, if disposal is conducted on-site, the positive identification of the two individuals conducting and witnessing the disposal. On-site disposal may be conducted by any of the following: 1) The responsible person or the responsible person's designee and one other employee of the laboratory; or 2) Two employees of the laboratory designated by the responsible person. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	OAC 4729:5-16-02

Personally Furnishing

Question	Guidance	Rule/Law
Does the licensee personally furnish any dangerous drugs to patients?	Are dangerous drugs, including any drug samples, personally furnished to patients? Board staff will document the types of drugs personally furnished by the licensee.	
If personally furnishing controlled substances, list the controlled substances the licensee has in stock with dosage forms.	If yes, Board staff will document the controlled substances that the licensee has on hand with dosage forms.	
Are non-sample drugs that are personally furnished to patients properly labeled?	Drugs personally furnished to a patient must be labelled and packaged in accordance with state and federal drug laws and rules and regulations adopted pursuant to those laws. A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, must affix to the container a label showing: (1) The name and address of the prescriber; (2) The name of the patient for whom the drug is intended; (3) Name and strength of the drug; (4) Directions for use; (5) Date furnished; and (6) If a compounded drug, the statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.	OAC 4729:5-19-02 [as required by OAC 4729:5-16-01 (G)]
Are sample drugs that are personally furnished to patients properly labeled?	A prescriber who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container must affix a label to the sample container or provide written documentation accompanying the sample that includes the following: (1) The name of the prescriber; (2) The name of the patient for whom the drug is intended; and	OAC 4729:5-19-02 [as required by OAC 4729:5-16-01 (G)]

	(3) Directions for use. Board staff will review labels to confirm compliance. "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Except as provided in paragraph (E) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code in accordance with paragraph (B) of this rule.	
Are medical assistants preparing and packaging drugs to be personally furnished?	A prescriber may designate an unlicensed person, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished. An unlicensed person shall not prepare and package any of the following dangerous drugs: (a) Anesthesia; (b) Controlled substances; or (c) Drugs administered intravenously.	OAC 4729:5-19-02 [as required by OAC 4729:5-16-01 (G)]
Are controlled substances being personally furnished in quantities that exceed a 72-hour supply?	A prescriber may not personally furnish to a patient an amount of a controlled substance that exceeds the amount necessary for the patient's use in a seventy-two-hour period. Board staff will review records to determine compliance.	ORC 4729.291
Is the licensee personally furnishing more than a total of 2,500 dosage units of controlled substances in a thirty-day period?	Is the licensee personally furnishing more than a total of 2,500 dosage units of controlled substances in a thirty-day period? A prescriber may not, in any thirty-day period, personally furnish to all patients, taken as a whole, controlled substances in an amount that exceeds a total of two thousand five hundred dosage units. "Dosage unit" means any of the following: (1) A single pill, capsule, ampule, tablet;	ORC 4729.291

	(2) In the case of a liquid solution, one (1) milliliter; (3) In the case of a cream, lotion or gel, one (1) gram; or (4) Any other form of administration available as a single unit. Board staff will review records to determine compliance.	
If personally furnishing controlled substances or gabapentin, is the licensee reporting to OARRS?	All controlled substances and gabapentin personally furnished to patients must be reported to OARRS with 24-hours of being personally furnished.	OAC 4729:8-3-04 OAC 4729:8-3-01
Does the licensee maintain complete and accurate records of drugs personally furnished?	**FOR HUMAN USE:** Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver. **FOR ANIMAL USE:** Records of personally furnishing for animal use shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the identification of the person personally furnishing the drug, the name of the animal, the name and address of the animal's owner, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver. Records of personally furnishing must be maintained for at least three years. Board staff will review records to determine compliance.	OAC 4729:5-16-03
Is counseling offered to patients/caregivers when drugs are personally furnished?	A licensee must personally offer to provide, or may provide in writing, the service of counseling to a patient or caregiver whenever any dangerous drug is personally furnished. A prescriber or pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.	OAC 4729:5-19-02 [as required by OAC 4729:5-16-01 (G)]

Are drugs that are personally furnished distributed under appropriate supervision and control?	A prescriber may delegate an individual or individuals to distribute dangerous drugs that are personally furnished: (1) A prescriber or pharmacist provides personal supervision (i.e. is on-site). Personal supervision is not required for non-controlled drugs if the drugs are provided by a licensed health care professional (i.e. nurse) and a prescriber or pharmacist is available for counseling by means of electronic communication during normal hours of operation. (2) Counseling is offered. **NOTE:** This requirement does not apply to naloxone that is personally furnished via a physician protocol.	OAC 4729:5-19-02 [as required by OAC 4729:5-16-01 (G)]
Are physician assistants personally furnishing drugs in accordance with applicable state laws?	**FOR SAMPLES:** A physician assistant can furnish sample drugs subject to the following limitations: (1) The amount of the sample furnished shall not exceed a seventy-two-hour supply, except when the minimum available quantity of the sample is packaged in an amount that is greater than a seventy-two-hour supply, in which case the physician assistant may furnish the sample in the package amount. (2) Samples of controlled substances may not be personally furnished. **FOR NON-SAMPLES:** A physician assistant can furnish non-sample drugs subject to the following limitations: (1) The physician assistant shall personally furnish only antibiotics, antifungals, scabicides, contraceptives, prenatal vitamins, antihypertensives, drugs and devices used in the treatment of diabetes, drugs and devices used in the treatment of asthma, and drugs used in the treatment of dyslipidemia.	ORC 4730.43

	NOTE: Because of these drug categories, a physician assistant is not permitted to personally furnish controlled substances. (2) The physician assistant shall not furnish the drugs and devices in locations other than a health department operated by the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code, a federally funded comprehensive primary care clinic, or a nonprofit health care clinic or program. **REMINDER:** Nurse practitioners are prohibited from personally furnishing any drug listed on the Ohio Board of Nursing's exclusionary formulary. Currently, the formulary does not contain any drugs. If drugs are added to the formulary, the Board will add a question regarding personally furnishing by a nurse practitioner.	
Is naloxone being personally furnished at the location in accordance with Ohio laws and rules?	A physician established protocol for personally furnishing naloxone must include all of the following in writing: (1) A description of the clinical pharmacology of naloxone; (2) Precautions and contraindications concerning furnishing naloxone; (3) Any limitations the physician specifies concerning the individuals to whom naloxone may be furnished; (4) The naloxone dosage that may be furnished and any variation in the dosage based on circumstances specified in the protocol; (5) Labeling, storage, record-keeping, and administrative requirements; (6) Training requirements that must be met before an individual will be authorized to furnish naloxone; (7) Any instructions or training that the authorized individual must provide to an individual to whom naloxone is furnished. An authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with sections 4731.941 and 3707.561 of the Revised Code, shall do all the following:	ORC 4731.941 OAC 4729:5-19-02 [as required by OAC 4729:5-16-01 (G)]

	(1) Prepare, package, and label the naloxone in accordance with the requirements of this rule. (2) Conduct the final association of the naloxone to the patient. (3) Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol. (4) Maintain records for personally furnishing as required by the record keeping **REMINDER:** By law, the authorized individual must instruct the individual to whom naloxone is furnished to summon emergency services as soon as practicable either before or after administering naloxone. Board staff will review protocol to ensure it meets the requirements of the law/rule and confirm the labeling requirements meet the requirements of the OAC.	

Drug Samples

Question	Guidance	Rule/Law
Does the licensee distribute samples to patients?	Board staff will document the types of drugs received as samples.	
Does the licensee receive samples at the request of a prescriber?	Prescribers must request samples. Samples cannot be dropped off at a facility without permission. No drug distributor or distributor's representative, including sales representatives, may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber.	OAC 4729:6-3-08
Are sample drugs personally furnished free of charge, in the original container, and prior to the drug's expiration date?	Licensees cannot open sample packages and distribute them in alternate containers or partial quantities. Samples must be provided free of charge. Expired samples must be disposed of in the same manner as all other drug inventory and may not be dispensed or donated, unless they are donated to a pharmacy school under ORC 3715.89.	ORC 3719.81

OARRS

Question	Guidance	Rule/Law
Are any of the prescribers using delegates to request OARRS reports?	Delegates are required to have their own OARRS accounts. A delegate is not permitted to use the username and login for a prescriber or another delegate.	4729.80

Drug Compounding

Question	Guidance	Rule/Law
Is the licensee engaged in either sterile or non-sterile drug compounding on site?	If engaged in drug compounding, the licensee may be subject to an additional inspection by a Board Specialist (i.e. pharmacist). A separate compounding guide will be made available for licensees engaged in drug compounding.	

Prescriptions

For more information on the Board's requirements for issuing a valid prescription, visit: www.pharmacy.ohio.gov/Rx.

Question	Guidance	Rule/Law
Does the facility use pre-printed prescriptions for non-hospice patients?	Board staff will review prescription blanks to ensure that any pre-printed prescriptions with multiple drug names or strength combinations do not contain any controlled substances among the choices. **NOTE:** There are different requirements for outpatient hospice patients (see next question).	OAC 4729:5-5-05
Does the facility use pre-printed prescriptions for hospice care program outpatients?	For purposes of pre-printed prescription forms for hospice care program outpatients, the following conditions apply: (1) Pre-printed prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to this sheet. (2) Pre-printed forms may not contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber. (3) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either: (a) Manually indicating the total drug orders authorized on the form; or (b) Manually initialing each drug order. (4) All written drug orders must be signed by the prescriber. (5) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy. (6) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II drug orders.	OAC 4729:5-5-05

	Board staff will review prescription blanks to ensure compliance.	
How does the licensee issue prescription?	Board staff will document the methods used for transmitting prescriptions (written, oral, fax, or electronic transmission). If the licensee faxes hard copy prescriptions, Board staff will confirm the original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the location where it was issued for three years from the date of issuance. Following the successful transmission of the prescription, the word "VOID" or "FAXED" shall be written or stamped on the face of the original prescription in a manner that does not destroy any of the original information contained on the prescription.	OAC 4729:5-3-11
Are uncompleted prescription blanks secured when not in use?	Only a prescriber may have access to uncompleted prescription blanks used for writing a prescription. Uncompleted prescription blanks must be secured when not in use. Prescription blanks must be secured when not on the prescriber's person. This may include the following: a locked drawer, filing cabinet, safe, lock box, lockable bag, or any other method that can be locked to prevent unauthorized access.	OAC 4729:5-16-02

Expired/Adulterated Drugs

Question	Guidance	Rule/Law
Are multi-dose vials properly labeled?	Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.	OAC 4729:5-16-02
Are there expired/adulterated drugs present in the licensee's active drug stock?	Board staff will conduct a check for expired drugs/adulterated drugs, including, but not limited to, the following: ▪ Expired drugs in common stock areas. ▪ Multidose vials that have been opened/punctured and exceed twenty-eight days from the date of puncture, unless otherwise specified by the manufacturer. ▪ Adulterated drugs in common stock areas (partial vials of single-dose injectable drugs). If the vial says single use, and it has been punctured/used, it must be discarded and may not be used again. ▪ **NOTE:** The following are also considered expired or adulterated and should not be present in a licensee's active drug stock: ○ A device containing dangerous drugs must be used by the date/time indicated on the manufacturer's labeling or, if no such date exists, may only be used up to six hours following preparation. ○ A conventionally manufactured sterile dangerous drug product that is reconstituted must be used by the date/time indicated on the manufacturer's labeling or, if no such date exists, may only be used up to six hours following preparation.	OAC 4729:5-3-06 OAC 4729:5-16-02

	○ A conventionally manufactured sterile dangerous drug product that is diluted (i.e. diluting or mixing into a syringe to administer directly to a patient) must be used within six hours of preparation. **IMPORTANT:** This requirement does not apply to drugs submitted to crime laboratories for analysis or laboratories conducting research using adulterated drugs.	
Are expired/adulterated drugs appropriately segregated from the licensee's active drug stock?	Expired/adulterated drugs must be stored separately from active drug stock in a manner that prohibits access by unauthorized persons. Expired/adulterated controlled substances that are segregated must be secured in the same manner as active controlled substance stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored where active controlled substance stock is maintained but segregated in a manner that is clear to all who see it that the drugs may not be used. Expired/adulterated non-controlled substance drugs must be segregated from the active drug stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored in common stock areas but segregated in a manner that is clear to all who see it that the drugs may not be used. Expired/adulterated non-controlled substance drugs must be maintained under the same supervision requirements as active non-controlled substance drug stock. **IMPORTANT:** This requirement does not apply to drugs submitted to crime laboratories for analysis or laboratories conducting research using adulterated drugs.	OAC 4729:5-3-06 OAC 4729:5-16-02
Are expired/adulterated drugs stored no longer than one year from the date of expiration/adulteration?	Expired/adulterated drugs shall be stored no longer than one year from the date of expiration/adulteration by those holding a terminal distributor of dangerous drugs license. Board staff will review expired/adulterated drugs to confirm.	OAC 4729:5-3-06 OAC 4729:5-16-02

	IMPORTANT: This requirement does not apply to drugs submitted to crime laboratories for analysis or laboratories conducting research using adulterated drugs.	

General Record Keeping

Question	Guidance	Rule/Law
Does the licensee maintain all required records on-site for a period of three years in a readily retrievable manner?	All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years. If stored off-site, Board staff will document the off-site location and confirm the licensee submitted proper notification to the Board.	OAC 4729:5-16-03
Are records maintained under appropriate supervision and control to restrict unauthorized access?	All records relating to the receipt, administration, distribution, personally furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access. Generally, a licensee should avoid having any required records easily accessible to the general public (i.e. waiting rooms, unsecured storage facilities, or any other place where the public could easily access drug records).	OAC 4729:5-16-02
Are records electronically created and maintained?	Such records may be created and maintained electronically in accordance with the following: (1) Complies with the requirements of the record keeping rule (including positive identification requirements); (2) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user; (3) Contains security features to prevent unauthorized access; and (4) Contains daily back-up functionality to protect against record loss. Board staff will ask the licensee to provide documentation demonstrating daily back-up functionality to protect against record loss.	OAC 4729:5-16-03
Does the licensee engage in the transfer or sale of dangerous drugs?	If yes, records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code must contain the name, strength, dosage form, national drug code, expiration date and quantity of the dangerous drug transferred or sold, the address of	OAC 4729:5-16-03 OAC 4729:5-3-09

	the location where the drugs were transferred or sold, and the date of transfer or sale. **NOTE:** This includes intracompany transfers/sales and occasional sales. Occasional sales by non-pharmacies (i.e. sales outside of a commonly owned company) are limited to naloxone and drugs that are in shortage. "Drug shortage," with respect to an occasional sale, means a drug on the United States Food and Drug Administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler. Board staff will review records to determine compliance.	
Does the licensee maintain required records for conducting chemical analysis or research using a dangerous drug or controlled substance?	**NOTE:** For anonymous samples, there are different requirements. See next question. A laboratory conducting chemical analysis or research with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug or controlled substance: (1) The name of the drug or controlled substance. (2) The form (e.g., powder, granulation, tablet, capsule, or solution) and the concentration in such form (e.g., "C.P.," "U.S.P.," "N.F.," ten-milligram tablet, or ten-milligram concentration per milliliter). (3) The quantity utilized in any manner by the laboratory including the date and manner of utilization. (4) The identification of the person or persons conducting the chemical analysis or research. If a controlled substance, the positive identification of the person or persons conducting the chemical analysis or research.	OAC 4729:5-16-03

	(5) This paragraph does not apply to records relating to known or suspected controlled substances or dangerous drugs received as evidentiary material. Board staff will review records to determine compliance.	
Does the licensee maintain required records for conducting chemical analysis of anonymous samples of suspected controlled substances or dangerous drugs?	A laboratory conducting chemical analysis of anonymous samples of suspected controlled substances or dangerous drugs shall maintain records, to the extent known and reasonably ascertainable by the person conducting the analysis, containing the following information: (1) Date the sample is received; (2) Purported contents and actual identification; (3) Quantity received; (4) Form of sample (i.e., powder, liquid, tablets, etc.); (5) Description of sample; (6) Quantity utilized in analysis; and (7) The identification of the person or persons conducting the analysis. Board staff will review records to determine compliance.	OAC 4729:5-16-03

Prescription Pick-Up Station

Question	Guidance	Rule/Law
Does the licensee act as a pick-up station by receiving patient-specific prescriptions from pharmacies for final distribution/administration to ultimate users?	A pick-up station is a facility that receives patient-specific prescriptions from the pharmacy and then distributes/administers the drugs to the patient. Board staff will document the types of prescriptions that are received by licensee.	OAC 4729:5-5-14
Is there clear and convincing evidence that the facility acts as a pick-up station in the interest of the patient or public health?	To serve as a pick-up station, there must be clear and convincing evidence that delivery of a prescription medication directly to the patient would result in: (a) Danger to public health or safety, or (b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy. A pick-up station only valid for those situations where there is evidence it is in the best interest of the patient or the public to have the drug be provided by the prescriber. Examples include: ▪ Injectable drugs the prescriber will administer on-site. ▪ Distribution of specialty medications which require specialized storage or administration education, medications for patients in a mental health clinic, who should not (for safety reasons) have possession of large quantities of their medications without increased medical supervision. **NOTE:** Non-self-injectable cancer drugs are generally required by law (ORC 4729.43) to be sent from a pharmacy directly to a prescriber for administration.	OAC 4729:5-5-14
Is the receipt, storage, control and distribution of	The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional	OAC 4729:5-5-14

prescriptions or drugs in the full and actual charge of a licensed health care professional at the pick-up station location?	licensed pursuant to Chapter 4715. (Dental Practice Act), 4723. (Nurse Practice Act), 4729. (Pharmacy Practice Act), 4730. (Physician Assistant Practice Act), 4731. (Medical Practice Act), or 4741. (Veterinary Medical Practice Act) of the Revised Code. Board staff will inspect the location to ensure a licensed health care professional overseeing the delivery and distribution of drugs received by the pharmacy. Drugs must be maintained under the same security and storage conditions as regular inventory.	
Is there a record keeping system in place to provide accountability for the proper receipt delivery and return of all prescription medications?	Record keeping systems must include a record of patient specific prescriptions delivered to the facility, a record of distribution or administration of the drugs to the individual patient, and a record of all medications returned to the pharmacy. Receipt of prescriptions should be an invoice such that each patient specific prescription is identifiable, including a date of delivery, and documentation of receipt. Any medications returned to the pharmacy (patient failed to pick up, etc.) should also be documented with an invoice/log that is maintained on file at the facility and provided to the pharmacy. Documentation must include patient name, prescription information, and date returned (or date disposed). **NOTE:** A prescription delivered to the facility that is abandoned by the patient (i.e. never picked up by the patient) must be destroyed on-site or returned to the dispensing pharmacy for destruction. Prescriptions which are abandoned by the patient may not be re-dispensed to another patient, unless the facility is acting as a drug repository (see Drug Repository section).	OAC 4729:5-5-14

Drug Repository Program

Question	Guidance	Rule/Law
Does this facility operate a drug repository program in accordance with Ohio law?	If yes, Board staff should verify the licensee meets the eligibility requirements. **NOTE:** Only a pharmacy, hospital, or nonprofit clinic may elect to participate in a drug repository program. "Nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons as defined in section 2305.234 of the Revised Code. "Nonprofit clinic" does not include a hospital as defined in section 3727.01 of the Revised Code, a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit. "Hospital" means an institution classified as a hospital under section 3701.07 of the Revised Code in which are provided to inpatients diagnostic, medical, surgical, obstetrical, psychiatric, or rehabilitation care for a continuous period longer than twenty-four hours or a hospital operated by a health maintenance organization. "Hospital" does not include a facility licensed under Chapter 3721. of the Revised Code, a health care facility operated by the department of mental health and addiction services or the department of developmental disabilities, a health maintenance organization that does not operate a hospital, the office of any private licensed health care professional, whether organized for individual or group practice, or a clinic that provides ambulatory patient services and where patients are not regularly admitted as inpatients. "Hospital" also does not include an institution for the sick that is operated exclusively for patients who use spiritual means for healing and for whom the acceptance of medical care is inconsistent with their religious beliefs, accredited by a national accrediting organization, exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986, 100 Stat. 2085, 26 U.S.C.A. 1, as amended, and providing twenty-four hour nursing care pursuant to the exemption in division (E) of section 4723.32 of the Revised Code	ORC 3715.871

	from the licensing requirements of Chapter 4723. of the Revised Code.	
Do the donated drugs comply with the applicable requirements of Ohio law and rules?	**GENERAL REQUIREMENTS (DOES NOT APPLY TO ORALLY ADMINISTERED CANCER DRUGS):** ▪ The drugs are in their original sealed and tamper-evident unit dose packaging. ▪ The packaging must be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. ▪ If the drugs were packaged by a pharmacy, the name of the pharmacy and any other pharmacy identifiers must be removed from the packaging prior to dispensing or personally furnishing to a recipient patient. This may be accomplished by removing the drug from the pharmacy packaging or by removing the name from the outside packaging of a multiple dose, unit dose packaging system. ▪ The drugs have been in the possession of a licensed healthcare professional, terminal distributor of dangerous drugs, or drug distributor and not in the possession of the ultimate user. ▪ The drugs must have an expiration date of six months or greater. ▪ The packaging must list the expiration date of the drug. ▪ The drugs must not have any physical signs of tampering or adulteration. ▪ The drug packaging must not have any physical signs of tampering ▪ All confidential patient information must have been removed from the drug packaging.	OAC 4729:5-10-04

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

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

	responsible for the care and wellbeing of a patient, or the signature of the responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor. (3) The date the form was signed. **NOTE:** A licensee may opt to have a patient sign a donor form in advance of receiving treatment in the event the patient discontinues treatment. Additionally, the following donor information must be documented on the donor form or an alternate record. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph. (1) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#). (2) The strength of the drug donated. (3) The quantity of the drug donated. (4) The date the drug was donated.	
Do the recipient forms comply with the requirements of Ohio law?	Prior to receiving donated drugs from a drug repository program, each recipient must sign a form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code. ORC 3715.872 (B) states: For matters related to donating, giving, accepting, or dispensing drugs under the drug repository program, all of the following apply: (1) Any person, including a pharmacy, drug manufacturer, or health care facility, or any government entity that donates or gives drugs to the drug repository program shall not be subject to liability in tort or other civil action for injury, death, or loss to person or property.	OAC 4729:5-10-06

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

	(1) The name and address of the donor location. (2) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#). (3) The strength of the drug. (4) The quantity of the drug. (5) The date the drug was sent to the pharmacy, hospital, or nonprofit clinic. (6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic. Records of personally furnishing and administration are maintained in accordance with OAC 4729:5-11-04. Board staff will review records to verify compliance.	

Temporary Removal of Drugs

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

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

Pharmacist Consult Agreements

Question	Guidance	Law/Rule
Does the licensee utilize consult agreements with pharmacists?	If yes, Board staff will review copies of the agreement. **REMINDER:** A pharmacist, as part of an opioid treatment program licensed by the state, may administer controlled substance narcotics pursuant to a consult agreement in accordance with this division of the Administrative Code for the maintenance or detoxification treatment of opioid addiction. [OAC 4729:1-6-03 (D)]	OAC 4729:1-6
Does the consult agreement contain all the required information?	A consult agreement must contain all the following: (1) Identification of the Ohio-licensed physician(s) and pharmacist(s) authorized to enter into the agreement. This may include: (a) Individual names of physicians and pharmacists; (b) Physician or pharmacist practice groups; or (c) Identification based on institutional credentialing or privileging. (2) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid. (3) A description of the drugs or drug categories managed as part of the agreement. (4) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement. (5) A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.	OAC 4729:1-6-02

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

	qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs. Board staff will ask the licensee to review current agreements to determine compliance.	

Laboratory - Update History

Update Date	Section Update	Update
3/10/2022	Prescriptions	Updated rule reference for the Board's prescription formatting rule.
3/10/2022	Prescription Pick-Up Station	Updated rule reference for the Board's pick-up station rule.