



Rules for Stakeholder Feedback – Non-Limited Facilities

Date Issued: 3/28/2025
Comments Due: 4/25/2025

The Ohio Board of Pharmacy is required to review all administrative rules every five years. In accordance with Chapter 119. of the Revised Code, the Ohio Board Pharmacy proposes amendments, in track changes, to the following rules:

- Rule 4729:5-22-01 | Non-Limited Facilities - Definitions. (AMEND)
- Rule 4729:5-22-02 | Security, control, and storage of dangerous drugs. (AMEND)
- Rule 4729:5-22-03 | Record keeping. (AMEND)

These rules only apply to those holding a terminal distributor of dangerous drugs license with a facility license and meets the definition of a non-limited facility which includes:

- ***Blood banks;***
- ***Custodial care or residential care facilities;***
- ***Pediatric respite care programs;***
- ***Group homes;***
- ***Freestanding dialysis centers;***
- ***Infusion centers; and***
- ***Imaging centers.***

IMPORTANT: Hospice programs licensed in accordance with ORC 3712.04 are being proposed to be removed from the definition of a non-limited facility and added to the institutional facility rules (OAC 4729:5-9-01). The Board will have more guidance on this change next month following the April Board meeting.

Comments on the proposed rules will be accepted until the close of business on Friday, April 25, 2025. Please send all comments to the following email address:

RuleComments@pharmacy.ohio.gov.

Rule 4729:5-22-01 | Non-Limited Facilities - Definitions. (AMEND)

As used in Chapter 4729:5-22 of the Administrative Code:

(A) "Non-limited facility" or "unlimited facility" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section [4729.54](#) of the Revised Code where drugs are possessed on-site for administration, dispensing, or personally furnishing. The facility shall comply with all requirements set forth in this chapter.

(1) Non-limited facilities include any of the following:

(a) Blood banks;

(b) Custodial care or residential care facilities;

(c) Pediatric respite care programs;

(d) Group homes;

(e) Freestanding dialysis centers;

~~(f) Hospice care facilities, except those facilities that obtain dangerous drugs using pharmacy-supplied contingency stock;~~

~~(fg) Infusion centers;~~

~~(hg) Imaging centers; or~~

~~(ih) Any other facility as determined by the board.~~

(2) Non-limited facilities do not include any of the following:

(a) Limited facilities as defined in Chapter 4729:5-23 of the Administrative Code; or

(b) Any other person or facility licensed as a terminal distributor of dangerous [drugs](#) that is specifically defined and required to comply with security, control, and record keeping requirements of another chapter of this division (EMS organization, pain management clinic, animal shelter, etc.).

(B) "Controlled substance" has the same meaning as in section [3719.01](#) of the Revised Code.

(C) "Dangerous drug" has the same meaning as in section [4729.01](#) of the Revised Code.

(D) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule [4729:5-1-02](#) of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(E) "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.

(F) "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. A prescriber at a non-limited facility who personally furnishes a dangerous drug shall comply with the requirements of rule [4729:5-19-02](#) of the Administrative Code.

(G)

(1) "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 such as the following:

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

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

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

(g) 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

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

(2) ~~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.~~

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.

(H) "Readily retrievable" means that records maintained in accordance with this chapter 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.

(I) "Responsible person" has the same meaning as defined in rule [4729:5-2-01](#) of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section [4729.55](#) of the Revised Code, adequate safeguards as required in division (C) of section [4729.55](#) of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

Rule 4729:5-22-02 | Security, control, and storage of dangerous drugs. (AMEND)

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs.

(B) Except as provided in paragraphs (F) and (G) of this rule, controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access.

(1) The cabinet or safe shall be placed in an area that is not readily accessible to the public.

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a prescriber or pharmacist if not being used by a prescriber, pharmacist, or a licensed health care professional in accordance with paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.

(5) During non-business hours, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(6) Except as provided in paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only a prescriber or pharmacist shall be able to access the cabinet or safe.

(a) A prescriber or pharmacist may provide a licensed health care professional with a temporary key for the purposes of accessing the cabinet or safe. A licensed health care professional shall return the key provided in accordance with this rule to the prescriber or pharmacist or to a secured location with restricted access (such as a lockbox) no later than the end of the provider's shift or if there is no longer a prescriber or pharmacist available to provide personal supervision.

(b) A prescriber or pharmacist may provide a licensed health care professional with a key, combination, or access code for the purposes of accessing the cabinet or safe, if all the following conditions apply:

(i) The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by a prescriber or pharmacist;

(ii) The room is locked during non-business hours or when there is no longer a prescriber or pharmacist available to provide personal supervision.

(c) Any other method approved by the board's executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion of controlled substances.

(C) Except as provided in paragraph (G) of this rule, a licensed health care professional, acting within the scope of the professional's practice may have access to controlled substances only under the personal supervision of a prescriber or pharmacist.

(D) Only a prescriber shall have access to uncompleted prescription blanks used for writing a prescription. Uncompleted prescription blanks shall be secured when not in use.

(E) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of a prescriber or a person delegated power of attorney in accordance with 21 CFR 1305.05 (9/30/2019). D.E.A. controlled substance order forms shall be secured when not in use.

(F) 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.

(1) There is no minimum size or weight requirement but if the cabinet or safe weighs less than seven hundred fifty pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.

(2) The cabinet or safe shall be placed in an area that is not readily accessible to the public.

(3) The cabinet or safe shall remain locked and secured when not in use.

(4) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access codes.

(5) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a prescriber or pharmacist if not being used by a prescriber or pharmacist. All locks shall be kept in good working order with keys removed therefrom.

(6) During non-business hours, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(7) Only a prescriber or pharmacist shall have possession of the key, combination, or access code to the safe or cabinet.

(G) A ~~registered~~ nurse licensed under Chapter 4723. of the Revised Code may have unsupervised access to controlled substances only under the following conditions:

(1) The drugs have been personally furnished by a prescriber or dispensed by a pharmacy for direct administration to a patient.

(2) The drugs must be stored in a securely locked, substantially constructed cabinet or safe with access that is limited to prescribers, pharmacists, and ~~registered~~ nurses. The cabinet or safe must be separate from those required in paragraphs (B) and (F) of this rule.

(a) The cabinet or safe shall be placed in an area that is not readily accessible to the public.

(b) The cabinet or safe shall remain locked and secured when not in use.

(c) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(d) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a prescriber, pharmacist, or ~~registered~~ nurse.

(e) During non-business hours, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(3) A record of drug administration shall be maintained in accordance with paragraph (E) of rule [4729:5-22-03](#) of the Administrative Code and shall also include the date and time the drugs are accessed from the cabinet or safe.

(4) The responsible person shall report the theft or significant loss of drugs maintained pursuant to this paragraph in accordance with rule [4729:5-3-02](#) of the Administrative Code.

(H) During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections.

(I) During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs.

(J) All records relating to the receipt, administration, distribution, personal furnishing, and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(K) All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall 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.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs.

(L) 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.

(M) Adulterated drugs, including expired drugs, shall be stored in accordance with rule [4729:5-3-06](#) of the Administrative Code.

(N) Disposal of controlled substances shall be conducted in accordance with rule [4729:5-3-01](#) of the Administrative Code.

(O) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule [4729:5-3-06](#) of the Administrative Code.

Rule 4729:5-22-03 | Record keeping. (AMEND)

(A) A non-limited facility shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold, or transferred.

(B) 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.

(C) Records of temperature control monitoring described in paragraph (K) of rule [4729:5-22-02](#) of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(D) 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 drug were personally furnished; the positive identification of the prescriber or delegated pharmacist 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.

(E)

(1) 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 and the date of administration, and either:

(a) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug.

(b) For controlled substance dangerous drugs: the positive identification of the health care professional administering the drug.

(2) Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(3) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall 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.

(4) Paragraph (E)(3) of this rule does not apply to the administration of dangerous drugs pursuant to paragraph (G) of rule [4729:5-22-03](#) of the Administrative Code or non-controlled dangerous drugs for direct administration to a patient that have been dispensed by a pharmacy or personally furnished by a prescriber.

(F) 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.

(G) Records of controlled substance drug disposal shall comply with the requirements of rule [4729:5-3-01](#) of the Administrative Code.

(1) If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal.

(H) Records of transfer or sale conducted in accordance with rule [4729:5-3-09](#) of the Administrative Code shall contain the name, strength, dosage form, national drug code, ~~expiration date,~~ and quantity of the dangerous drug transferred or sold; the address of the location where the drugs were transferred or sold; and the date of transfer or sale.

(I) Controlled substance inventory records shall be maintained in accordance with rule [4729:5-3-07](#) of the Administrative Code.

(J) All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.

(1) 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 in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(K) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(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, such as unique user names and passwords, to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.