Rules for Stakeholder Feedback – Laboratories

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 4729:5-16-01 | Laboratories - definitions. (AMEND)
- Rule 4729:5-16-02 | Security, control, and storage of dangerous drugs. (AMEND)
- Rule 4729:5-16-03 | Record keeping. (AMEND)

These rules only apply to those holding a terminal distributor of dangerous drugs license with a laboratory classification.

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.

77 S. High Street, 17th Floor
Columbus, OH 43215 U.S.A.

Phone: 614 | 466 4143
Fax: 614 | 752 4836

Rule 4729:5-16-01 | Laboratories - definitions. (AMEND)

As used in Chapter 4729:5-16 of the Administrative Code:

(A) "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. The facility shall comply with all requirements set forth in this chapter. A laboratory does not include any of the following:

(1) A laboratory licensed under Chapter 3796. of the Revised Code; 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.).

(B) "Anonymous sample" means an unknown substance submitted to a laboratory for qualitative ~~and~~ and/or quantitative analysis.

(C) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code but shall not include exempt chemical preparations as defined in paragraph (E) of this rule.

(D) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(E) "Exempt chemical preparation" means a chemical or compound approved by the United States drug enforcement administration pursuant to 21 CFR 1308.23 (12/30/2016).

(F) "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.

(G) "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.

(H) "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 laboratory who personally furnishes a dangerous drug shall

comply with the requirements of rule 4729:5-19-02 or 4729:5-20-02 of the Administrative Code.

(I)

(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 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.

~~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.~~

(J) "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.

(K) "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

and controlled substances 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 controlled substances and maintaining all drug records otherwise required.

Rule 4729:5-16-02 | Security, control, and storage of dangerous drugs. (AMEND)

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

(B) Except as provided in paragraph (H) of this rule, controlled substances 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.

(4) In the case of a key lock, all keys shall be maintained in a 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, responsible person's designee, or a laboratory employee or researcher 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) When the laboratory is not in use by authorized personnel, 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 the responsible person or the responsible person's designee shall have possession of keys, combinations, or access codes to the cabinet or safe.

(a) 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.

(b) 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:

(i) 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;

(ii) 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.

(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.

(C) 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. 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.

(D) Only a prescriber shall ~~only~~ have access to uncompleted prescription blank(s) used for writing a prescription. Uncompleted prescription blank(s) 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 under the personal supervision of the laboratory's responsible person. D.E.A. controlled substance order forms shall be secured when not in use.

(F) Controlled substances in the process of testing, use, or research shall be returned to the required storage location upon completion of each such process.

(G) All samples containing, or suspected of containing, a dangerous drug or controlled substance shall be treated as schedule I and II controlled substances.

(H) 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 the responsible person or the responsible person's designee if not being used by the responsible person or the responsible person's designee. All locks shall be kept in good working order with keys removed therefrom.

(6) When the laboratory is not in use by authorized personnel, 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 the responsible person or the responsible person's designee shall have possession of the key, combination, or access code to the safe or cabinet.

(8) This paragraph does not apply to exempt chemical preparations as defined in rule 4729:5-16-01 of the Administrative Code.

(I) 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.

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

(K) All areas where dangerous drugs and controlled substances are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Unless otherwise required by a documented research study, 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 controlled substances 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 and controlled substances.

(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 drugs and controlled substances.

(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. This paragraph does not apply to drugs submitted to crime laboratories for analysis or laboratories conducting research using adulterated drugs.

(N) Laboratories shall comply with all state and federal laws, rules, and regulations governing the use of controlled substances for the purpose of research or chemical analysis.

(O) Unless consumed as part of an analysis, disposal of controlled substance dangerous drugs shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(P) Unless consumed as part of an analysis, disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

(Q) Unless consumed as part of an analysis, disposal of controlled substances that are not dangerous drugs or any unused portion of a submitted anonymous sample for scientific analysis shall be conducted as follows:

(1) The method of disposal shall render the drug or substance non-retrievable as defined in rule 4729:5-3-01 of the Administrative Code.

(2) Disposal shall be conducted by any of the following:

(a) The responsible person or the responsible person's designee and one other employee of the laboratory;

(b) Two employees of the laboratory designated by the responsible person; or

(c) A contracted waste disposal company in compliance with all federal, state, and local laws, rules, and regulations.

(3) Records for the disposal of the drug or substance 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 personnel conducting and witnessing the disposal.

Rule 4729:5-16-03 | Record keeping. (AMEND)

(A) A laboratory shall keep a record of all dangerous drugs and controlled substances received, administered, personally furnished, used (i.e. chemical analysis or research), disposed, destroyed, or transferred.

(B) The acts of administering, using (i.e. chemical analysis or research), and destroying or disposing controlled substances shall be documented with positive identification.

(C) Records of receipt shall contain a description of the drug or substance and all the following if obtained from a person licensed in accordance with section 4729.52 or 4729.54 of the Revised Code:

(1) The name, strength, dosage form, and quantity of the drug;

(2) The name and address of the seller;

(3) The name and address of the recipient; and

(4) The date of receipt.

(D) Except as provided in paragraph (E) of this rule, records of personally furnishing 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, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished~~,~~; the date the drug is personally furnished; and, if applicable, the date the drug is received by the patient or patient's caregiver.

(E) 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 or group of animals (e.g., herd, parliament, flock, flamboyance)~~,~~; the name and address of the ~~animal's~~ owner of the animal or animals~~,~~; the date the drug is personally furnished; and, if applicable, the date the drug is received by the patient or patient's caregiver.

(F) Except as provided in paragraphs (G) and (H) of this rule, records of administration shall contain the name, strength, dosage form, and quantity of the drugs administered~~,~~; the name

and date of birth of the person to whom or for whose use the drugs were administered~~,~~; the identification of the person administering the drug~~,~~; and the date of administration.

(1) Records of non-controlled substances administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(2) Records of controlled substances administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph if documented using positive identification.

(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 or protocol issued by a prescriber 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.

(G) Except as provided in paragraph (H) of this rule, 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~~,~~; and the date of administration.

(1) Records of non-controlled substances administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(2) Records of controlled substances administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph if documented using positive identification.

(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 or protocol issued by a prescriber 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.

(H) 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~~record shall be deemed to meet the requirements of this paragraph. The laboratory shall have the current IACUC protocol available for immediate inspection by an agent, inspector, or employee of the board.

(I) 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.

(5) This paragraph does not apply to records relating to known or suspected controlled substances or dangerous drugs received as evidentiary material.

(J) 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.

(K) Records of dangerous drug disposal, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed~~,~~; the date destroyed~~,~~; the method of disposal~~,~~; and the identification of the person that performed the disposal.

(L) Records of controlled substance dangerous drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance dangerous drug inventory is performed on-site, records shall also include the positive identification of two laboratory employees 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 dangerous drug, records shall also include the positive identification of two laboratory employees conducting and witnessing the disposal.

(M) Records of the disposal of controlled substances that are not dangerous drugs or any unused portion of a submitted anonymous sample shall be maintained in accordance with paragraph (Q) of rule 4729:5-16-02 of the Administrative Code.

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

(O) 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.

(P) Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-16-02 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.

(Q) 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.

(R) 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.