June 2025 – Rules and Resolutions

Resolutions

NOTE: All resolutions that are starred (*) were initially authorized by the Board President pursuant to resolution R-2022-0128.

1) Pharmacy Technician Positions on the 2025 Rules Review Committee*

The Board hereby authorizes the addition of two registered or certified pharmacy technicians to the 2025 Rules Review Committee.

2) Waiver of Expiration Dates on Intracompany Transfer Records*

The Board hereby waives the requirement to include the expiration of a drug on all records of sale or transfer conducted in accordance with OAC 4729:5-3-09. This resolution shall remain in effect until such corresponding rule changes have been adopted.

Rules for Filing with CSI and JCARR

Rule 4729:5-18-01 – Definitions – remote dispensing pharmacies.

As used in Chapter 4729:5-18 of the Administrative Code:

(A) "Remote dispensing pharmacy" means a pharmacy where the dispensing of drugs, patient counseling, and other pharmacist care is provided through a telepharmacy system. The dispensing of drugs at a remote dispensing pharmacy may include the dispensing of drug therapy-related devices.

(B) "Telepharmacy system" means a system that monitors the dispensing of drugs and provides for related drug utilization review and patient counseling services by an electronic method, that complies with the requirements of Chapter 4729: 5-18-06. The telepharmacy system shall include the following technologies:

(1) Audio and video;

(2) Still image capture; and

(3) Store and forward.

(C) “Surveillance system” means a system providing continuous video footage of the remote dispensing pharmacy that is recorded and stored for at least sixty days, and that complies with the requirements of Chapter 4729: 5-18-07.

(D) “Supervising pharmacy” means a pharmacy licensed as a terminal distributor of dangerous drugs that exclusively oversees the operations of a remote dispensing pharmacy.

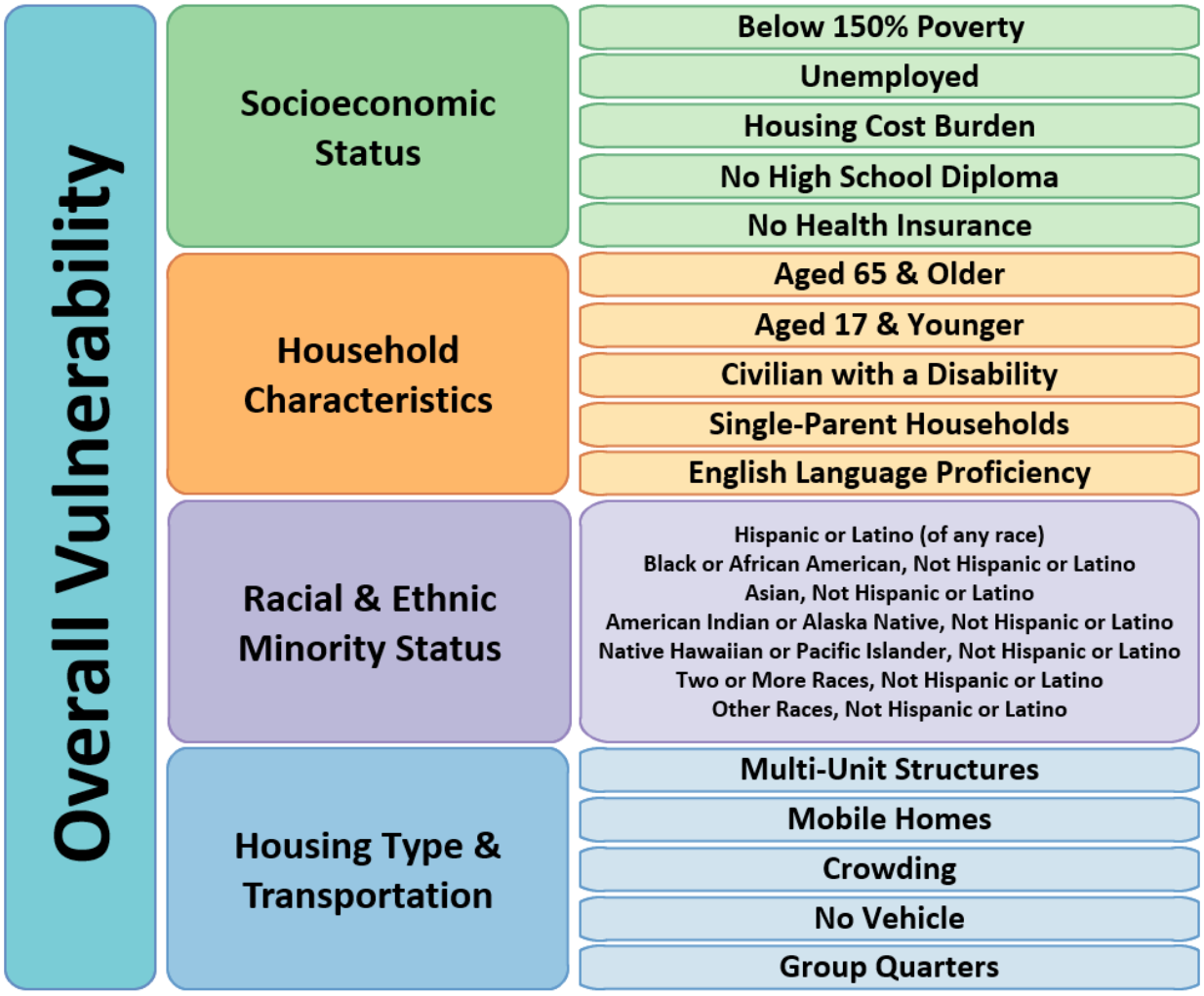
(E) “Supervising pharmacist” means a pharmacist holding a current Ohio license to practice pharmacy who has met the requirements to supervise a remote dispensing pharmacy as described in this chapter.

(F) “Responsible person” means the same as in Chapter 4729:5-2-01 of the Administrative Code.

(G) “Social vulnerability” means the demographic and socioeconomic factors that contribute to communities being more adversely affected by external hazards and stressors that cause disease and injury.

(H) “Social vulnerability index” or “SVI” means a risk score assigned to communities using U.S. Census data. These data are grouped into four themes that cover four major areas of social vulnerability (household characteristics, house type & transportation, racial & ethnic minority status, and socioeconomic status) and then combined into a single measure of overall social vulnerability. The overall SVI score ranges from 0 (least vulnerable) to 1 (most vulnerable).

Components of SVI:



Rule 4729:5-18-02 – Licensure of remote dispensing pharmacies.

(A) A remote dispensing pharmacy shall apply for and obtain a terminal distributor of dangerous drugs license with a remote dispensing classification.

(B) The remote dispensing pharmacy shall comply with the licensing requirements of Chapter 4729:5-2 of the Administrative Code.

(C) Remote dispensing pharmacies shall have a pharmacist designated as the responsible person in accordance with Chapter 4729:5-2-01 of the Administrative Code.

(D) The responsible person designated for a remote dispensing pharmacy shall be the same responsible person as is designated for the supervising pharmacy. The responsible person may, but is not required to, act as a supervising pharmacist.

(E) If the supervising pharmacy and remote dispensing pharmacy are not under common ownership and control, the supervising pharmacy and remote dispensing pharmacy shall enter into a contract that specifies the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes, rules, and regulations. The contract shall be maintained in a readily retrievable format.

Rule 4729:5-18-03 – Demonstration of need.

(A) Except as provided in this rule, a remote dispensing pharmacy shall not be located within a ten-mile radius of a pharmacy that serves the public as an outpatient pharmacy as defined in Chapter 4729:5-5 of the Administrative Code.

(B) A remote dispensing pharmacy may be located within the ten-mile radius of an outpatient pharmacy if either of the following apply:

(1) The remote dispensing pharmacy is part of a federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code, and the remote dispensing pharmacy is located on the same property as, or on a campus contiguous to, the health center or look-alike.

(2) The board approves a request, based on a demonstration of need, that meets the standards established in paragraph (C) of this rule.

(C) A person may submit a request to the board, in a manner determined by board, to allow a remote dispensing pharmacy located within a ten-mile radius of an outpatient pharmacy if the proposed remote dispensing pharmacy is located in census block that is medium-high (0.5-0.75) or high (greater than 0.75) based upon the social vulnerability index (SVI) as designated by the board's Ohio Pharmacy Access Dashboard (accessible via www.pharmacy.ohio.gov).

(D) Persons may register to receive notice from the board (accessible via www.pharmacy.ohio.gov) of requests received pursuant to paragraph (C) of this rule. The board shall notify any person who has registered to be notified and allow for the submission of public comments on the proposed request.

(E) During the sixty-day period that begins on the date that the board sends the electronic notice, a pharmacy currently operating in the state may submit a request to the board for approval as a location for operation of a remote dispensing pharmacy.

(F) At the board's next regularly scheduled meeting that occurs on or after the date that is ninety days after the electronic notices are sent, the board shall review all the requests received and make its determination of whether any should be approved. As part of the board's determination, the board shall consider the following:

(1) Any comments received from the public;

(2) The geographic proximity of a supervising pharmacy to a proposed remote dispensing pharmacy;

(3) The supervising pharmacy has not been disciplined for violation of rule 4729:5-5-02 and all subsequent rules thereunder within the preceding twelve months;

(4) The supervising pharmacy has not been disciplined for any significant theft or loss of dangerous drugs within the preceding twelve months; and

(5) The supervising pharmacy is not currently on probation or has other restrictions placed upon its terminal distributor of dangerous drugs license pursuant to a settlement agreement or order of the board.

Rule 4729:5-18-04 – Operation of a remote dispensing pharmacy.

(A) The remote dispensing pharmacy must be located within this state in a building that is zoned for commercial or industrial use and not out of a personal residence.

(B) Remote dispensing pharmacies shall display a sign visible to the public indicating that the facility is a remote dispensing pharmacy, that the facility is under continuous video surveillance, and that the video is recorded and retained.

(C) The supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing pharmacy and its employees.

(D) There shall be one supervising pharmacist at all times when the remote dispensing pharmacy is operational, who shall be located in this state while serving as the supervising pharmacist.

(E) A supervising pharmacist shall not be more than fifty miles from a remote dispensing pharmacy under that pharmacist's supervision.

(F) To avoid disruption in pharmacy services, the supervising pharmacy shall have a process in place to ensure there is a pharmacist who meets the training requirements of this chapter if the regularly scheduled supervising pharmacist is unable to provide supervision in accordance with this chapter.

(G) The remote dispensing pharmacy shall be staffed by at least two certified pharmacy technicians and/or pharmacy interns physically present in the remote dispensing pharmacy for the pharmacy to be open to the public.

(H) There shall be no more than a total of three certified pharmacy technicians and/or pharmacy interns working within a remote dispensing pharmacy location unless a pharmacist is physically located on-site.

(I) Unless approved by the board, a supervising pharmacist shall not simultaneously oversee the activities of more than one remote dispensing pharmacy. The board may consider expanding this limit to up to two remote dispensing pharmacies per one supervising pharmacist. For the board to consider a waiver of this limitation, the supervising pharmacy shall submit documentation, in a manner determined by the Board, that sufficiently demonstrates the following:

(1) The prescription volume and workload at the supervising pharmacy allows the supervising pharmacist to safely and effectively oversee more than one remote dispensing pharmacy;

(2) The prescription volume and workload at the remote dispensing pharmacies allows the supervising pharmacist to safely and effectively oversee more than one remote dispensing pharmacy; and

(3) Failure to grant this waiver may negatively impact patient health and access to pharmacy services.

(J) Certified pharmacy technicians, pharmacy interns, and pharmacists shall complete a training program to ensure that the telepharmacy system can be operated in a safe and effective manner. Training documentation shall be maintained and immediately retrievable at the remote dispensing pharmacy. Remote dispensing pharmacies must conduct additional training for their employees if any of the following occur:

(1) The telepharmacy system used by the remote dispensing pharmacy has changed;

(2) The existing telepharmacy system used by the remote dispensing pharmacy has undergone significant updates.

(K) Unless approved by the Board, a remote dispensing pharmacy shall not dispense drugs pursuant to Chapter 4729:5-5 of the Administrative Code more than an average of one hundred fifty prescriptions per day during a ninety-day period. For the board to consider a waiver of this limitation, a remote dispensing pharmacy shall submit documentation, in a manner determined by the Board, that sufficiently demonstrates the following:

(1) The remote dispensing pharmacy is located in a census block that is medium-high (0.5-0.75) or high (greater than 0.75) based upon the social vulnerability index (SVI) as designated by the board's Ohio Pharmacy Access Dashboard (accessible via www.pharmacy.ohio.gov); and

(2) It is not economically feasible for the remote dispensing pharmacy to convert to an outpatient pharmacy as defined by Chapter 4729:5-5-01 of the Administrative Code.

(L) The responsible person shall perform on-site visits of the remote dispensing pharmacy at least once per quarter. The on-site visit shall be documented by the responsible person and such documentation shall be immediately retrievable at the location licensed as a remote dispensing pharmacy for three years from the date of the visit by the responsible person. As

part of this site visit, the responsible person shall conduct a controlled substance inventory in accordance with rule 4729:5-3-07 of the Administrative Code.

(M) In the event that the telepharmacy system is not in operation, the supervising pharmacist must be physically located on-site to dispense prescriptions.

(N) A remote dispensing pharmacy shall implement a continuous quality improvement program in accordance with rule 4729:5-3-22 of the Administrative Code.

(O) A remote dispensing pharmacy shall comply with all applicable requirements for the operation of an outpatient pharmacy in accordance with Chapter 4729:5-5 of the Administrative Code.

(P) A remote dispensing pharmacy that holds a category III terminal distributor of dangerous drugs license shall maintain a perpetual controlled substance inventory for all controlled substances stocked by the remote dispensing pharmacy. The inventory shall be established in a manner that will provide total accountability in all aspects of controlled substance distribution.

Rule 4729:5-18-05 – Personnel requirements.

(A) The supervising pharmacy is solely responsible for ensuring that the requirements of this rule are met.

(B) Before a pharmacist may act as the supervising pharmacist for a remote dispensing pharmacy, a pharmacist shall:

(1) Be licensed as a pharmacist under Chapter 4729. of the Revised Code;

(2) Be physically located in this state when acting as the supervising pharmacist; and

(3) Be employed by or under contract with the supervising pharmacy.

(C) In serving as a supervising pharmacist, the supervising pharmacist shall do all of the following:

(1) Supervise no more than three certified pharmacy technicians and pharmacy interns per remote dispensing pharmacy.

(2) Be in full and actual charge of the remote dispensing pharmacy by using the pharmacy's telepharmacy system and by using a surveillance system that meets standards established in this Chapter of the Administrative Code.

(3) Through the telepharmacy system and surveillance system, oversee the pharmacy interns and certified pharmacy technicians who are staffing the remote dispensing pharmacy.

(4) Verify each prescription and drug dispensed pursuant to the prescription before the drug leaves the remote dispensing pharmacy and provide the verification through visual review and the use of barcoding and any other technology as specified in rule 4729:5-18-06 of the Administrative Code. Documentation of verification shall capture the positive identification of the supervising pharmacist.

(5) Offer to provide the service of counseling for each drug dispensed pursuant to a new or refill prescription in accordance with rule 4729:5-5-09 of the Administrative Code.

(6) Have completed a training program on the proper use of the telepharmacy system used at the remote dispensing pharmacy.

(7) Have completed a training program on the proper use of the surveillance system used at the remote dispensing pharmacy.

(D) Before a certified pharmacy technician may work in a remote dispensing pharmacy, the certified pharmacy technician shall:

(1) Hold an active registration as a certified pharmacy technician under Chapter 4729. of the Revised Code;

(2) Hold a national certification as a pharmacy technician from an organization approved by the board, in accordance with rule 4729:3-1-01 of the Administrative Code.

(3) Have completed a training program on the proper use of the telepharmacy system used at the remote dispensing pharmacy.

(4) Have at least one thousand hours of practical experience working as a certified pharmacy technician in a pharmacy setting under the direct supervision of a pharmacist.

(5) Have worked at least one year in a pharmacy setting during the three years preceding the date the certified pharmacy technician begins working at the remote dispensing pharmacy.

(E) The supervising pharmacy must attest that all certified pharmacy technicians meet the requirements of paragraph (D) of this rule, and a record of such attestation must be immediately retrievable at the remote dispensing pharmacy.

(F) Before a pharmacy intern may work in a remote dispensing pharmacy, the pharmacy intern shall:

(1) Hold an active license as a pharmacy intern under Chapter 4729. of the Revised Code;

(2) Have at least one thousand hours of experience working as a certified pharmacy technician or pharmacy intern under the direct supervision of a pharmacist;

(3) Only five hundred hours of experience earned as part of the intern's introductory pharmacy practice experience or advanced pharmacy practice experience may count towards the one thousand hour requirement as described in paragraph (F)(2) of this rule.

(4) Have worked at least one thousand hours in a pharmacy setting during the three years preceding the date the pharmacy intern begins working at the remote dispensing pharmacy;

(5) Have completed a training program on the proper use of the telepharmacy system used at the remote dispensing pharmacy.

(G) The supervising pharmacy must attest that all working pharmacy interns meet the requirements of paragraph (F) of this rule, and a record of such attestation must be immediately retrievable at the remote dispensing pharmacy.

(H) Certified pharmacy technicians or pharmacy interns are not permitted to do any of the following while working at a remote dispensing pharmacy:

(1) Counsel an individual regarding drugs that are dispensed, recommend drugs and drug therapy-related devices or otherwise provide advice regarding drug therapy, or assist with selecting drugs and drug therapy related devices for treatment of common diseases and injuries or assist with providing instruction on their use;

(2) Perform compounding of sterile or nonsterile drugs, except for the reconstitution of prepackaged dangerous drugs;

(3) Engage in the repackaging of dangerous drugs;

(4) Administer immunizations or perform diagnostic testing, unless a pharmacist is physically onsite to provide direct supervision;

(I) Technicians-in-training, registered pharmacy technicians, or any other pharmacy personnel who do not meet the requirements of this chapter shall not engage in the practice of pharmacy or work at a remote dispensing pharmacy.

Rule 4729:5-18-06 – Technology requirements for a telepharmacy system.

(A) There shall be a fully functioning telepharmacy system in the remote dispensing pharmacy that is operational at all times that pharmacy personnel are working in the pharmacy.

(1) The telepharmacy system shall utilize positive identification and comply with the record keeping requirements for outpatient pharmacies in accordance with Chapter 4729:5-5 of the Administrative Code.

(2) All pharmacy personnel must complete a training program on proper use of the telepharmacy system and documentation of this completion must be maintained and immediately retrievable at the remote dispensing pharmacy.

(3) In the event that the telepharmacy system is not functional for more than one-business day, the supervising pharmacist or another pharmacist employed by the supervising pharmacy shall be required to be physically on-site to allow for prescriptions to be dispensed during normal business hours of the remote dispensing pharmacy.

(4) The supervising pharmacy shall have backup procedures to ensure prescriptions may be dispensed in the event of a telepharmacy system outage that is greater than one business day.

(5) In the event of a temporary telepharmacy system outage of less than the duration of one business day, the supervising pharmacist may direct the certified pharmacy technicians and/or pharmacy interns at the remote dispensing pharmacy to complete activities not requiring pharmacist verification or use of the telepharmacy system. Staff at the remote dispensing pharmacy may continue to sell prescriptions that have already been dispensed by the pharmacist. In this case, patients shall be provided with a phone number where they can obtain patient counseling in accordance with rule 4729:5-5-09 of the Administrative Code.

(6) The telepharmacy system shall comply with all the following:

(a) Chapter 3798. of the Revised Code;

(b) 42 U.S.C. 1320d et. seq.; and

(c) 45 C.F.R. parts 160, 162, and 164 for individually identifiable health information (HIPAA).

(C) The telepharmacy system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a dangerous drug or drug device, and sufficient data retention capabilities to investigate any quality-related events.

(1) The telepharmacy system must produce images that are high definition in that the image resolution is at least 300 pixels per inch.

(2) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing:

(a) A clear copy of the prescription label and the medication or device;

(b) The full quantity of the filled prescription;

(c) The medication stock bottle used to fill the prescription, if applicable; and

(d) Clear markings present on the pill or capsule, if applicable.

(3) Images associated with the verification of the prescription will be retained and become part of the patient's profile and maintained in accordance with rule 4729:5-5-07 of the Administrative Code.

(D) There shall be a working computer link, video link and audio link to the supervising pharmacist at a supervising pharmacy whenever the remote dispensing pharmacy is open to the public. The required technology must allow the supervising pharmacist to provide the personal assistance, direction, and approval needed to verify and ensure remote tasks are safely and properly performed.

(E) Written prescriptions presented to the remote dispensing pharmacy shall be scanned into the telepharmacy system to ensure initial dispensing and each refill and the original prescription may be viewed at both the remote dispensing pharmacy and the supervising pharmacy.

(1) All information in the prescription shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user.

(2) A prescription record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(F) Certified pharmacy technicians and/or pharmacy interns shall use barcoding technology when filling prescriptions at the remote dispensing pharmacy to ensure the accuracy of prescriptions dispensed in accordance with this chapter.

(G) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing pharmacy and shall be maintained for three years after the filling of the prescription.

Rule 4729:5-18-07 – Security requirements for a remote dispensing pharmacy.

(A) There shall be a fully functioning surveillance system in the remote dispensing pharmacy that is operational at all times.

(1) No operations of the remote dispensing pharmacy shall commence if the surveillance system is not functional.

(2) The video produced by the surveillance system must be stored for sixty days in a readily retrievable manner.

(3) The surveillance system shall be capable of providing not less than four simultaneous camera views of the pharmacy operation at the remote dispensing pharmacy.

(B) The surveillance system must allow the supervising pharmacist to determine who has accessed the pharmacy. A supervising pharmacist shall complete a training program on proper use of the surveillance system and documentation of this completion must be maintained and immediately retrievable at the remote dispensing pharmacy.

(C) The supervising pharmacist shall supervise the remote dispensing pharmacy via the pharmacy surveillance system to deter and detect theft or diversion.

(D) The supervising pharmacist shall ensure that all dangerous drugs, drug devices, controlled substances, and hypodermics that are delivered onto the premises of the remote dispensing pharmacy are immediately placed and secured in the pharmacy.

(E) Pharmacy technicians and pharmacy interns who meet the qualifications of rule 4729:5-18-05 and are employed by the remote dispensing pharmacy may only access the pharmacy if the supervising pharmacist is providing regular supervision via the pharmacy's surveillance system.

(F) An unlicensed person is permitted to enter the remote dispensing pharmacy if all the following apply:

(1) The person is performing maintenance or repair of the pharmacy;

(2) The supervising pharmacist provides supervision of the unlicensed person via the pharmacy's surveillance system; and

(3) There are two certified pharmacy technicians or pharmacy interns present in the pharmacy to provide on-site supervision of the unlicensed person.

(G) All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous drugs. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs.

(H) A remote dispensing pharmacy shall be secured by both:

(1) A physical barrier (i.e. barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(2) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation.

(I) The remote dispensing pharmacy shall contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist.

(J) Only the supervising pharmacist, certified pharmacy technicians, and pharmacy interns employed by the remote dispensing pharmacy may have access to keys or other methods of gaining access to the pharmacy.

(I) All keys, combinations, or access codes, including alarm codes, shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(K) No prescription, dangerous drug, hypodermic, nor any other item or product that requires the supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the pharmacy is closed or the surveillance system is inoperable.

(L) New or refill prescription orders may be deposited into a secure area within the building where the pharmacy is located when the pharmacy is closed.

(M) If a remote dispensing pharmacy provides services by means of a drive-through facility, the drive-through facility shall be constructed and maintained in a manner, and with materials, that secures the premises of the pharmacy from unauthorized access.

Comments Remote Dispensing Pharmacy Rules

Commenter / Rule	Comment	Suggested Response
Jeff Kimmell, RPh **Suggestion;** **4729: 5-18-04 Paragraph B**	With regards to rule 4729: 5-18-04 Paragraph B which requires remote dispensing pharmacies to display a sign advising the public that it is a remote dispensing pharmacy: I have been involved in the operation of remote dispensing pharmacies in three of the four states from where I maintain active licensure. I believe this to be a dangerous practice for both the public and pharmacy staff. Outward advertising of a closed door pharmacy is unnecessary and increases the likelihood of attracting nefarious individuals during open hours as well as closed hours. None of the states that I operated within had this requirement.	Recommend to edit language in Rule 4729:5-18-04 (B) to read: (B) Remote dispensing pharmacies shall display a sign ~~visible to the public~~ <u>at the point of sale</u> indicating that the facility is a remote dispensing pharmacy, that the facility is under continuous video surveillance, and that the video is recorded and retained.
Tara Hartman, BSPS, PharmD **Opposed**	After careful review and thought on the SB 95 rules, I have serious concerns that the rules do not go far enough to prevent pharmacy chains from restricting pharmacist access and the unique care that we provide as healthcare professionals. I respect the steps being taken to provide access to medications in pharmacy deserts and feel	Thank you for your comments. The rules include restrictions for proposed remote dispensing pharmacies on 1) the proximity from existing outpatient pharmacies and 2) average quantity of prescriptions dispensed daily.

	remote pharmacies are important in these situations. I would ask the board to consider additional rules to prevent large retail chains from misappropriation of the intended rules for financial gain. Let's protect our patients and the CARE that we provide as pharmacists. There is nothing to prohibit a chain pharmacy from converting multiple locations to remote pharmacy locations. In theory, a large chain could change half of all locations under the proposed rules simply to reduce the pharmacist payroll. This would cause an unfair burden on the supervising pharmacist overseeing two locations and could undermine the pharmacist workload rules implemented. Any change of a location to remote only could also cause the unintended consequence of reduced access to services such as vaccinations and counseling on self care. Vaccinations are to be administered under the direct supervision of a pharmacist. As a pharmacist, I would personally not be comfortable in vaccines being	These requirements address stated concerns about over-use of these remote dispensing locations. Counseling and vaccination services are not allowed to be provided at a remote dispensing pharmacy without a pharmacist physically on-site.

	administered under my license without my physical presence.	
Trevor Perkins, PharmD **Rule 4729:5-18-04 and** **Rule 4729:5-18-05**	The requirement for two nationally certified technicians (with the additional requirements of hours and years worked from Rule 4729:5-18-05 – Personnel requirements) will be extremely hard to staff in the areas that we are seeking to serve with this new rule. Purpose change to allow registered technicians the ability to work in remote dispensing pharmacies. Certainly should not need a national certification to ring patients out at the register and count prescriptions	Certified technician/intern requirement is stipulated by statute.
Trevor Perkins, PharmD **Rule 4729:5-18-06 – Technology requirements** **for a telepharmacy system**	A picture of the stock bottle should not be necessary if the qr code on each stock bottle used is scanned and the information from the qr code scanned is saved in the prescription record. The QR code has all of the information needed to be	**Discussion Item**

	verified; stock bottle picture not needed and will lead to increased filling times, patient wait times, etc.	
Mark Johnston, RPh (CVS) **Rule 4729:5-18-06 – Technology requirements for a telepharmacy system**	Requesting removal of requirement of a pharmacist to use images containing the medication stock bottle when verifying a prescription	**Discussion Item**
Jill McCormack (NACDS and OCRM) **4729:5-18-04 (H) and 4729:5-18-04 (C)(1)**	"Strike language that limits the number of certified pharmacy technicians that a supervising pharmacist can supervise via a telepharmacy system at a remote dispensing pharmacy."	Statute states that BOP must make rules about the number of interns/certified pharmacy technicians that a supervising pharmacist may supervise at any given time.
Jill McCormack (NACDS and OCRM) **4729:5-18-04 (H) and 4729:5-18-04 (C)(1)**	Change quarterly requirement for controlled substance inventory to once every year to be consistent with requirements for other outpatient pharmacies.	**Discussion Item**

4729:1-3-03 – Administration of Drugs by Injection (AMEND)

(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer by injection any of the following drugs as long as the drug that is to be administered has been prescribed by a physician, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner and the individual to whom the drug was prescribed has an ongoing physician-patient or nurse-patient relationship with the physician or nurse:

~~**(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer, by injection, any of the following dangerous drugs if the dangerous drug that is to be administered has been prescribed by a physician and the individual to whom the dangerous drug was prescribed has an ongoing relationship with the physician, an advanced practice registered nurse who has entered into a standard care arrangement with the physician, or a physician assistant who has entered into a supervision agreement with the physician:**~~

(1) An addiction treatment drug administered in a long-acting or extended-release form, which may include any medication indicated for relapse prevention; ~~**An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. An opioid antagonist may also be administered for the treatment of alcohol dependence in accordance with approved labeling by the United States food and drug administration.**~~

(2) An antipsychotic drug administered in a long-acting or extended-release form**;**

(3) A human immunodeficiency virus treatment or prevention drug administered in a long-acting or extended-release form;

(3) Hydroxyprogesterone caproate for pregnant women**;**

(4) Medroxyprogesterone acetate for non-pregnant women**;**

(5) Cobalamin, to include: cyanocobalamin, hydroxocobalamin or any other vitamin B12 injection approved by the United States food and drug administration**;**

(6) Antibiotics;

(7) Denosumab;

(8) Romosozumab;

(9) Methotrexate;

(10) Heparin, low molecular weight heparin, and factor Xa inhibitors; and

~~**(6)**~~ **(11)** Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.

(B) To be authorized to administer drugs pursuant to this rule, a pharmacist shall comply with all the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements pursuant to paragraph (L) of this rule.

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association**, American safety and health institute,** or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(3) Practice in accordance with a protocol that meets the requirements of paragraphs (F) and (G) of this rule.

(C) Each time a pharmacist administers a drug pursuant to this rule, the pharmacist shall comply with all the following:

(1) For each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain written permission from the individual.

(2) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain written permission from the individual's parent or other person having care or charge of the individual.

(3) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain written permission from the person authorized to make such decisions on the individual's behalf.

(4) Permission obtained in accordance with this paragraph shall also include notification of the patient's right to request a private area in accordance with paragraph (J) of this rule.

(5) In the case of an **addiction treatment drug described in paragraph (A)(1) of this rule** ~~**opioid antagonis**~~t, obtain, in accordance with paragraph (D) of this rule, test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(6) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug.

(7) Notify the physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** who prescribed the drug within seven days that the drug has been administered to the individual. Notification ~~**of the physician**~~ shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) A pharmacist may obtain the test results described in paragraph (C)(5) of this rule:

(1) From the prescribing physician**, certified nurse-midwife, clinical nurse specialist, certified nurse practitioner**; ~~**or the physician's agent; or**~~

(2) From an agent of the prescribing physician, certified nurse-midwife, clinical nurse specialist, certified nurse practitioner; or

(**3**) By ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered.

(E) If a pharmacist orders blood and urine tests pursuant to paragraph (D) of this rule, the pharmacist shall evaluate the results of the tests to determine whether they indicate that it is appropriate to administer the **addiction treatment drug** ~~**opioid antagonist**~~. A pharmacist's authority to evaluate test results pursuant to this rule does not authorize the pharmacist to make a diagnosis.

(F) A ~~**physician-established**~~ protocol for the administration of dangerous drugs in accordance with section 4729.45 of the Revised Code shall include the following:

(1) For the dangerous drugs listed in paragraph (A) of this rule:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration;

(g) Injection sites; and

(h) The type of tests that may be ordered in accordance with paragraph (E) of this rule.

(2) The length of time the pharmacist must observe an individual for adverse effects, which shall be based on standards of care established by the **authorizing** physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner**. The location of the observation shall be in the general vicinity of the administering pharmacist to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) The locations that a pharmacist shall engage in the administration of dangerous drugs in accordance with paragraph (J) of this rule.

(5) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to a drug administered by the pharmacist.

(G) All ~~**physician-established**~~ protocols pursuant to this rule and section 4729.45 of the Revised Code shall comply with the following:

(1) The protocol shall be signed and dated by the **authorizing** physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** prior to implementation and shall be readily available to the administering pharmacist. The protocol shall be renewed by ~~**the physician**~~ on a biennial basis.

(2) A physician**, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(3) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for **immediate** inspection by an agent, inspector**,** or employee of the state board of pharmacy.

(4) The protocol must be established by a physician**, <u>certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner</u>** who has a scope of practice that includes treatment of the condition for which the individual has been prescribed the drug to be administered.

(H) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for administration of drugs in accordance with this rule. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

(I) A pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.

(J) Dangerous drugs administered in accordance with this rule shall be administered in a location that ensures the privacy and dignity of the patient and is consistent with state and federal privacy laws and regulations. When necessary to protect patient privacy, or if requested by the patient, this shall include a private area located outside of the pharmacy.

(K) Administration records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(L) A course in the administration of dangerous drugs developed pursuant to section 4729.45 of the Revised Code shall meet the following requirements:

(1) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(2) The course must include the following components:

(a) A minimum of an hour and a half (0.15 C.E.U.s) of live or home study coursework for each category of dangerous drug listed in paragraph (A) of this rule that is covered by the course and shall include:

(i) A review of the conditions treated or prevented;

(ii) Mechanisms of action;

(iii) Routes of administration;

(iv) Injection sites and ensuring patient privacy;

(v) Dosages and administration schedules;

(vi) Monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(vii) Patient populations;

(viii) Precautions and contraindications; and

(ix) Proper storage requirements.

(b) A minimum of thirty minutes (0.05 C.E.U.s) of live or home study coursework that includes:

(i) A review of sterile technique in injectable dosage preparation and administration;

(ii) A review of the proper disposal procedures for contaminated needles and dangerous drugs; and

(iii) A review of the proper procedures for accidental needle sticks.

(c) A minimum of one hour (0.1 C.E.U.s) of live and supervised physical participation in administration techniques for the categories of drugs covered by the course.

(d) If the course includes instruction on administration of an opioid antagonist, a minimum of one hour (0.1 C.E.U.s) of live or home study coursework that includes a review of the tests necessary to comply with paragraph (C)(5) of this rule and the evaluation of such tests.

(3) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(b) of this rule if the pharmacist has met the training requirements in paragraphs (A)(4)(c), (A)(4)(e) and (A)(4)(f) of rule 4729:1-3-02 of the Administrative Code;

(4) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(c) of this rule if all of the following apply:

(a) The pharmacist has met the training requirements in paragraph (A)(4)(d) of rule 4729:1-3-02 of the Administrative Code; and

(b) The instruction on administration techniques provided in accordance with rule 4729:1-3-02 of the Administrative Code includes the same techniques necessary to administer each category of dangerous drug covered by the training.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the pharmacist has successfully completed the course.

(7) All live coursework shall be taught by an instructor that is a licensed health care professional who has the appropriate education and experience to teach a course in the administration of the dangerous drugs included in the categories listed in paragraph (A) of this rule.

(M) Courses may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(N) A pharmacist who has not successfully completed a course in drug administration that meets the requirements set forth in this rule must complete a course that meets the requirements specified in this rule prior to the administration of a dangerous drug listed in paragraph (A) of this rule.

(O) A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers dangerous drugs in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (L) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(2) of this rule.

(P) A pharmacist shall not intravenously administer any drug listed in paragraph (A) of this rule.

Drugs for Possible Inclusion	Rationale
Cefriaxone and penicillin G benthazine (2 comments) These are the only two IM antibiotics used for STI treatment widely.	In considering which drugs are named in this expansion, I would like to request that IM antibiotics that are administered into the gluteus such as Ceftriaxone and Penicillin for indications such as sexually transmitted infections be considered for inclusion into the expanded list. The IM antibiotics requested have clear dosages for FDA-labeled indications and their injection sites and administration techniques are identical to drugs already present on the list of approved drugs. In ambulatory practice sites where access to a provider is limited, the ability for a prescriber to delegate the administration of an IM antibiotic to an LAI-certified pharmacist would increase the number of patients they are able to assess. It would also potentially decrease costs for third party payers and/or patients directly as pharmacists in Ohio do not usually collect the same level of reimbursement for an injection administration as other providers. Separately, if considering test-to-treat ramifications, the potential and opportunities for Ohioans to access care through models such as a mobile medication units and/or satellite services would only be possible if these drugs are included on the expanded list.
	I would like to make a suggestion that injectable antibiotics such as Ceftriaxone or Bicillin be added to the list. With an appropriately signed protocol this would be beneficial for clinic settings as we are consistently requested by our providers to administer to patients.
HIV PrEP (2 comments) No issues with widely allowing prevention drug class.	[See linked document for full rationale] Recommend modifying the proposed changes to long acting injectables that pharmacists can administer under protocol to include both HIV treatment and prevention.

	Proposed verbiage: “A human immunodeficiency virus treatment or prevention drug administered in a long-acting or extended-release form”.
	The National Association of Chain Drug Stores (NACDS) is writing in support of the proposed amendments to expand rule 4729:1-3-03, authorizing pharmacists to administer injectable drugs pursuant to a protocol and expanding the types of prescribers that can authorize protocols. NACDS supports the rule and suggests that the board consider amending the rule to include the administration of HIV prevention medications.
Select RANK-L inhibitors Prolia (denosumab) and Evenity _romosozumab-aqqg) (2 comments) Recommend against widely allowing RANKL inhibitor class, as there are many uses and not all would be appropriate for pharmacist admin.	Some insurances are requiring these meds to be brown bagged. Therefore, the patient has to pick up at pharmacy and bring them to office. It would be nice if they could just get them administered at the pharmacy where they pick up.
	Allowing pharmacists to administer Prolia in Ohio could be a significant move toward improving access to care, particularly for underserved populations. Here's an explanation of the need for this and its potential advantages: For underserved populations, particularly those in rural or remote areas, access to healthcare providers who can administer Prolia is limited. Many individuals in these communities face barriers like long travel distances, lack of transportation, or insufficient access to specialized care. Allowing pharmacists to administer Prolia would help alleviate these barriers by providing more convenient locations for patients to receive the treatment, often in the same pharmacies where they already fill their prescriptions. Pharmacists are typically more accessible than other healthcare providers, with many pharmacies offering extended hours, including evenings and weekends. This makes it easier for patients, particularly those who may have busy schedules or face difficulty accessing a doctor's office, to receive their injection in a timely manner.

	Pharmacists are also well-practiced at administration of injectables due to their accessibility, perhaps better qualifying them than other healthcare professionals to administer Prolia. By allowing pharmacists to administer Prolia, physicians and other healthcare providers can focus their time and resources on other aspects of patient care. This is especially important in areas where healthcare providers may be scarce or overburdened, such as in the underserved setting. The cost of healthcare is a significant concern for many underserved populations. Allowing pharmacists to administer Prolia could reduce healthcare costs for both patients and the healthcare system by lowering administrative overhead and reducing the need for hospital or clinic visits. This could help ensure that Prolia treatment remains affordable and accessible to those who need it most.
Methotrexate (2 comments)	Methotrexate injectable. For the same patient health care reasons as vitamin b12. Many patients are unable to give the infections themselves, or have access to qualified assistance. I have personally had patients coming in looking for shorter and shorter insulin syringes to give themselves their methotrexate shots because "the needles [they] use hurt too much" and have had to counsel that too short of a needle actually hurts more than a needle that delivers the medication to the muscle as intended.
	A great addition to this injectable list would be methotrexate, there's a lot of elderly patients on the injectable form that are somewhat clueless and could use a pharmacist's help.

Heparin, low molecular weight heparin (enoxaparin, dalteparin) factor Xa inhibitors (fondaparinux) all administered subcutaneously (1 comment)	These are medications that are commonly used for bridge therapy in patients currently being seen by a Pharmacist at an Anticoagulation Clinic. This would improve access to a qualified health Professional that can assist with administration when a patient has not been trained adequately or loses the desire/ability to self-administer. Retail Pharmacies dispense this product and Pharmacists are currently only teaching the patient how to "hypothetically" self-administer. If a patient returns to this location with concerns/questions, they are in the presence of a Provider that could ensure compliance with the administration. These medications also require an understanding of dose and timing adjustments. Daily contact or communication with a Pharmacist could result in better compliance, better outcomes, and safer dosing to avoid risks with overdose or underdosing complications.
Drugs Not Recommended	**Rationale**
Etomidate, rocuronium, succinylcholine (1 comment)	I have a suggestion that I believe can improve patient care and in addition extend the scope of pharmacy practice, and that is during a medical emergency situation to allow pharmacists to administer medications via injection under an organizational protocol and under direct supervision of a physician. For example, in a busy emergency room there may be occasions where there are multiple medical emergency situations occurring at one time, there is limited staff available, and sometimes the pharmacist is the only available person who could be in charge of administering medications such as epinephrine during a cardiac arrest, or administering sedatives/neuromuscular blockers during rapid sequence intubation, under the direct order and supervision of a physician. The most common induction agent for rapid sequence intubation is etominate and a couple common

	neuromuscular blockers are succinylcholine or rocuronium. I don't think this has to be the norm, but just allowing the process during a rare emergency situation with no other options available would be helpful for a couple reasons: 1. The situation does arise occasionally and pharmacist may take it upon themselves to do what they feel is necessary for patient care. 2. A pharmacist may refuse to administer one of these medications when asked which can cause delay in patient care and negatively impact patient outcomes.
Testosterone (1 comment)	Testosterone – unable to be administered by MA. Some provider offices only have MAs as support staff. It doesn't make sense to waste provider time to administer.
GLP-1 receptor agonists (1 comment)	We believe that pharmacists are highly and appropriately qualified to administer medications, especially any may also be self-injected by patients. In an effort to identify immediate priorities, we propose that pharmacists be permitted to administer GLP-1 Receptor Agonists due to their prominence in healthcare and importance to our community. The Ohio Department of Health indicates that in 2022 "more than 1 million (13.2%) Ohio adults were diagnosed with diabetes; In addition, approximately 1,085,000 Ohio adults (11.8%) had been diagnosed with prediabetes."1 The Centers for Disease Control National Diabetes Statistics Report indicates that the annual total costs attributable to diabetes in Ohio in 2021 was $25,619,100,000.2 In a recent study conducted by CVS Health, it was found that 81% of consumers trust their local pharmacist and 74% of pharmacists want to perform more clinical services; The same study found that 95% of pharmacist colleagues believe in-person interactions are important to health outcomes.3 According to a study by Harvard Medical

	School, 25% of adults are affected by needle anxiety, which leads to non-adherence of critical prescribed medications.4 Since all injectable GLP-1 Receptor Agonists require a subcutaneous injection and CVS Pharmacy has over 330 locations and more than 950 pharmacists in Ohio trained to administer injectable medications and vaccines, we can offer these patients a more comfortable experience, which may result in greater adherence. Giving patients the option to have easily accessible and highly trained health care providers administer GLP-1 Receptor Agonists to combat diabetes could have a significant impact on our community's health.

4729:5-3-24 – Dispensing Dangerous Drugs to an Alternate Location (NEW)

NOTE: This is intended to replace the current pick up station rule OAC 4729:5-5-14, which would be rescinded.

(A) As used in this rule, "alternate location" means a location other than a patient or caregiver's address on file with the pharmacy that complies with the requirements set forth in this rule.

(B) This rule does not apply to a central fill pharmacy as defined in rules 4729:5-5-19 and 4729:5-9-02.13 of the Administrative Code.

(C) A pharmacy licensed as a terminal distributor of dangerous drugs may dispense dangerous drugs to an alternate location in accordance with this rule. An alternate location may include either:

(1) A pharmacy as defined in section 4729.01 of the Revised Code; or

(2) A location licensed as a terminal distributor of dangerous drugs or who is exempted from licensure in accordance with section 4729.541 of the Revised Code and all the following apply:

(a) The dispensing pharmacy maintains a record keeping system that provides accountability for the delivery, return, and, if returned, the disposal of all dangerous drugs dispensed in accordance with this division of the administrative code.

(b) There is clear and convincing evidence that delivery of a dangerous drug directly to the patient would result in:

(i) Danger or harm to public health or safety; or

(ii) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

(c) The receipt, storage, control, and distribution of the dispensed dangerous drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code and in accordance with the professional's scope of practice.

(d) There is a documented method in place to ensure compliance with rule 4729:5-5-09 of the Administrative Code.

(e) The dispensing complies with federal law, rules, and regulations.

(D) A terminal distributor of dangerous drugs that serves as an alternate location shall comply with the following:

(1) Maintain a record keeping system that will provide accountability for the receipt, disposal, and return of all dangerous drugs dispensed by the pharmacy in accordance with this division of the administrative code.

(2) Unless donated to a drug repository program pursuant to section 3715.87 of the Revised Code, a dangerous drug that is not distributed or administered to a patient shall either:

(a) Be returned to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code.

(3) Only receive drugs from the dispensing pharmacy if there is clear and convincing evidence that the delivery of a dangerous drug directly to the patient would result in:

(a) Danger or harm to public health or safety; or

(b) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

(4) The location acknowledges that any patient specific dangerous drug dispensed by a pharmacy is the property of that patient, except that a dangerous drug that is not distributed or administered to a patient within six months shall be deemed abandoned. A terminal distributor of dangerous drugs may do any of the following with an abandoned drug:

(a) Return the drug to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code;

(c) Donate to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code. For the purposes of meeting the requirements under division (H) of section 3715.873 of the Revised Code and rule 4729:5-10-06 of the Administrative Code, a terminal distributor of dangerous drugs that possesses an abandoned drug shall be deemed

as the owner of the drug for the sole purpose of providing consent for the drug's donation to a drug repository program; **or**

(d) If dispensed by a pharmacy under common ownership and control as the receiving terminal distributor of dangerous drugs, the drug may be returned to stock in accordance with 4729:5-5-22 of the Administrative Code.

(5) Nothing shall authorize a terminal distributor of dangerous drugs to return to inventory or otherwise repurpose an abandoned drug for use on another patient, unless the terminal distributor:

(a) Operates a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code; or

(b) Returns the drug in accordance with paragraph (D)(4)(d) of this rule.

(E) The state board of pharmacy may restrict a site from acting as an alternate location if it has clear and convincing evidence that the activities of that location present the following:

(1) Danger or harm to public health or safety; or

(2) Danger or harm to the patient.

(F) No prescriber or pharmacy that provides a patient with a drug pursuant this rule shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(G) Paragraph (F) of this rule does not prohibit a prescriber or pharmacy from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber or pharmacy.

Organization	Comment
Buderer Drug Company	Whereas we are a compounding pharmacy, we often desire to send a finished labeled prescription to one of our other pharmacies for patient pick up and counseling rather than mailing it directly to the patient. This would be most commonly done for a sterile product prepared at one facility and filled on the order of a prescription, but more conveniently picked up at one of our other locations. Will this process be allowed under the new rules? Would a compounded medication, filled on the order of a prescription and labeled as such, shipped to a surgery center or doctor's office for administration by the medical staff still be allowed under the new rules? It is understood that any place that would accept the medication would need to be licensed with an active TDDD.
OHC Blue Ash & OHC Pharmacy	I am the Director of Pharmacy at Oncology Hematology Care, Inc. (OHC), based in Cincinnati, Ohio. I have been administering oncology drugs to our patients for over 9 years. I am commenting on the proposed rule 4729:5-3-24, specifically the clause in paragraphs (D)(3) and (D)(4) on drug return and repurposing. The current provision restricts terminal distributors of dangerous drugs from returning abandoned drugs to inventory or repurposing them for use on another patient, except within a drug repository program as specified in Chapter 4729:5-10 of the Administrative Code. The existing regulation does not account for scenarios where drugs have never left the controlled delivery service or the custody, including the strict storage requirements, of another terminal distributor within the same organization. Permitting the return and repurposing of such drugs under these controlled conditions could yield significant benefits, as outlined below: 1. Waste Reduction - <u>Minimize Pharmaceutical Waste:</u> Allowing the return and repurposing of these drugs would substantially reduce the volume of pharmaceutical waste. This not only aligns with environmental

	sustainability goals but also ensures that valuable medications are utilized effectively. - Responsible Resource Utilization: Many returned drugs remain within their shelf life and are in pristine condition due to stringent storage and handling protocols. Repurposing these drugs ensures that resources are not wasted. 2. Economic Benefits - Cost Savings for Healthcare Providers and Patients: Oncology drugs, for example, can cost upwards of $30,000 or more. Allowing the return and repurposing of such high-cost medications can alleviate the financial burden on patients, insurance companies, Medicare, and pharmacies. - Reduction in Healthcare Expenditures: The cost savings from reduced drug waste can be redirected toward other critical areas of patient care, thereby enhancing overall healthcare quality and accessibility. 3. Minimizing Drug Shortages - Ensuring Drug Availability: By allowing the return and repurposing of drugs that have remained within controlled environments, we can mitigate the risk of drug shortages. This is particularly crucial for life-saving medications, including oncology drugs, where timely access is essential for patient outcomes. - Enhanced Inventory Management: Improved inventory turnover and management through the repurposing of returned drugs can contribute to a more resilient and responsive pharmaceutical supply chain. 4. Risk Management and Regulatory Oversight - Controlled Conditions: Drugs that have never left the controlled delivery service or the custody of another terminal distributor within the same organization are maintained under rigorous regulatory compliance and environmental controls. These conditions ensure that the drugs' integrity and efficacy are preserved.

	- Robust Verification Protocols: Implementing thorough inspection and verification processes before reintroducing returned drugs into inventory can address safety concerns. This includes checks for expiration dates, storage conditions, and tamper-evidence. 5. Precedence - Alignment with Best Practices: Other states and jurisdictions have successfully implemented similar return and repurposing programs with stringent oversight, demonstrating that it is feasible to balance safety with practical benefits. Aligning our regulations with these best practices can enhance operational efficiency while maintaining safety standards. - Example - Virginia: https://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section275/ In conclusion, I strongly advocate for the reconsideration of the current restriction in paragraphs (D)(3) and (D)(4) to permit the return and repurposing of drugs that have remained within a controlled environment. By doing so, we can achieve significant reductions in waste, healthcare costs, and the risk of drug shortages, ultimately benefiting our patients and the broader healthcare system. Thank you for your consideration. I am available to discuss this proposal further and collaborate on developing detailed protocols to ensure its successful implementation.
OHC Blue Ash	I am a clinical pharmacist for Oncology Hematology Care Pharmacy, based in Cincinnati. I am commenting on the proposed rule 4729:5-3-24, specifically relating to its items on drug return and repurposing. I worry that not being able to return abandoned prescriptions/drugs to inventory would result in great harm to the healthcare system. The proposed rule should take into account scenarios where drugs have never left the controlled delivery service, or instances where prescriptions have never left the strict storage requirements of a terminal distributor within the same organization. Permitting the return and repurposing of these drugs would yield significant benefit

	to: minimizing waste, reducing risk of drug shortages, and economic benefit to healthcare providers, patients, pharmacies, and insurance companies. I strongly encourage reconsideration for inclusion of scenarios where drugs/prescriptions that have remained in a controlled environment would be permitted for return and repurposing.
Nationwide Children's Hospital	**4729:5-3-24 – Dispensing Dangerous Drugs to an Alternate Location** **Suggested changes:** - Due to the various benefits of this service to patients and our communities, we propose to change C(2)(c) to: There is clear and convincing evidence that delivery of a dangerous drug directly to the patient would result in: (i) Danger or harm to public health or safety; (ii) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy; or **(iii) Improving access to therapy and decreasing prescription abandonment.**
N/a	I tried to read the new rule but in typical government fashion, it looks like the responsible party that drafted it got paid by the word. I am assuming this is a continuation of the current rule allowing delivery to Physician offices & Clinics. I am vehemently opposed to the fact that local pharmacies are not being supported by the board of pharmacy. The true battle is grappling with the PBMs and making sure local pharmacies get their fair dispensing fee, allowing them to remain viable businesses. This would insure that a local pharmacist is on hand for counseling and available to the patient. I worry that this is the first step in ending all local retail pharmacy as it exists today. The local pharmacist, due to their being readily assessable to the public as a heath care provider & often the first step in a patient's health care journey. I am opposed to any drop off regulations that remove the pharmacist from this important function.

4729:5-14-04 – Record keeping (EMS)

Summary of Changes:

- **Paragraph H:** Removes requirement that exempts EMS that conduct 1:1 exchanges from having to conduct an annual controlled substance inventory.
- **Paragraph I:** Added new paragraph that incorporates standardized record keeping langauge for occasional wholesale sales (OAC 4729:5-3-09).

4729:5-14-04 **Record keeping.**

(A) All EMS organizations shall keep a record of all dangerous drugs received, administered, sold, transferred, destroyed, or disposed ~~or used~~.

(B) ~~Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.~~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) All records of receipt, distribution, administration, selling, disposing, destroying or using dangerous drugs shall be maintained for a period of three years at the place where the dangerous drugs are located.

Records from satellites may be stored at the EMS organization headquarters if prior approval, in a manner determined by the board, is obtained by the EMS organization.

(D) Records of administering dangerous drugs shall be legible and shall contain the first and last name of the EMS personnel who administered the drug, name of the EMS organization, name and strength of the drug administered, date of administration, time of administration, amount of the ~~dose~~drug administered, the name or other means of identifying the patient, such as medical record number or run number, and the identification of the individual administering the drug using either of the following methods:

(1) An electronic signature in a computerized recordkeeping system; or

(2) Any form of positive identification.

(E) ~~Records of the disposal or destruction of non-controlled dangerous drugs shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and, if disposal is performed on-site, the positive identification of the EMS personnel who disposed of the 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 positive identification of the EMS personnel that performed the disposal.

(F) Records for the disposal of controlled substance drugs shall be maintained in accordance with rule 4729:5-3-01 of the Administrative Code and, if disposal is performed on-

site, the positive identification of the two EMS personnel who disposed of the drugs in accordance with rule 4729:5-14-03 of the Administrative Code.

Records for the disposal or destruction of the unused portion of a controlled substance resulting from administration to a patient from a licensee~~'~~'s stock or emergency supply shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date disposed, the method of disposal, and the positive identification of the two EMS personnel who disposed of the drugs.

(G) All records maintained in accordance with this rule shall be uniformly maintained and readily retrievable.

(H) An EMS organization shall conduct an annual inventory of all controlled substances in accordance with ~~agency 4729.~~rule 4729:5-3-07 of the Administrative Code.

~~Notwithstanding any other provision of the Administrative Code, this paragraph does not apply to an EMS utilizing a 1:1 exchange system with a hospital acting as its responsible DEA registrant.~~

(I) 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, 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)~~(J) 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) 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;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;

(3) Contains security features to prevent unauthorized access to the records; and

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

~~(J)~~(K) Records of oxygen transfilling shall include the manufacturer's lot number of the oxygen used for transfilling the portable oxygen tanks.

4729:9-3-01 – Sale or Distribution of Ephedrine-Containing Products

Summary of Changes:

Paragraph (C): Correct a typo in paragraph (C) and clarified that a seller of ephedrine products must hold a license rather than just apply for a license by the Board:

> Previous: (1) Submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54.
>
> Proposed: (1) Hold a category III license in accordance with section 4729.52 of the Revised Code or section 4729.54 of the Revised Code.

(A) As used in this rule, "ephedrine" is alpha-[-(Methylamino)ethyl]benzene-methanol; alpha-[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; alpha- hydroxy-beta-methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae) and in several other Ephedra spp. Isomeric forms include d- and l-ephedrine as well as d-and l-pseudoephedrine with l-ephedrine and d-pseudoephedrine as the naturally occurring isomers.

(B) Each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is excepted from classification as a schedule V controlled substance:

(1) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.

(2) "Breathe Easy" herb tea.

(3) "Bronkaid Dual Action" caplets.

(4) "Hydrosal" hemorrhoidal ointment.

(5) "Primatene Dual Action Formula" tablets.

(6) "Primatene" tablets.

(7) "SnoreStop" tablets.

(8) Drug products listed in division (K)(1) of section 3719.44 of the Revised Code.

(C) Except for products listed in paragraph (B) of this rule or products excepted in accordance within paragraph (D) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall:

(1) Hold a category III license in accordance with section 4729.52 of the Revised Code or section 4729.54 of the Revised Code.

(2) Comply with all applicable security and storage requirements in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(3) Conduct an inventory of all products containing ephedrine pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(4) Maintain all records required in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(5) The requirements listed in this paragraph do not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

(D) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the corporation's stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging of the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product including the following:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of

other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (D)(6) of this rule.

(E) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the United States food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:

(1) The package size and the manner of packaging;

(2) Distribution, advertising, and promotion of the product;

(3) Labeling and the name of the product;

(4) The potential, duration, scope, and significance of inappropriate use and/or abuse;

(5) Other facts as may be relevant to and consistent with public health and safety.

(F) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

Five Year Review - Terminal Distributors of Dangerous Drugs

Applies to the following TDDD license types:

- 4729:5-11 – Pain Management Clinics
- 4729:5-13 – First Aid Departments
- 4729:5-16 – Laboratories
- 4729:5-19 – Clinics and Prescriber Offices
- 4729:5-20 – Veterinary Clinics
- 4729:5-21 – Opioid Treatment Programs
- 4729:5-22 – Non-Limited Facilities
- 4729:5-23 – Limited Facilities

Summary of Significant Changes

Rules	Type of Change	Proposed Change(s)
4729:5-11-01 **4729:5-13-01** **4729:5-16-01** **4729:5-19-01** **4729:5-20-01** **4729:5-21-01** **4729:5-22-01** **4729:5-23-01**	Positive Identification	Updates definition of positive identification to clarify that it applies not just for "entry into a secure mechanical or electronic system."
4729:5-11-02	BCI Title	Updates reference to BCI from BCI&I.
4729:5-11-03 **4729:5-13-03** **4729:5-19-03** **4729:5-21-03** **4729:5-22-02** **4729:5-23-02**	LPN Access to Dispensed Controlled Substances	Permits LPNs to access personally furnished or dispensed controlled substance medications.
4729:5-11-04 **4729:5-13-04** **4729:5-19-04** **4729:5-20-04**	Expiration Date on Transfer/Sale Records	Removes requirement to have expiration date on sale or transfer records.

4729:5-21-04 **4729:5-22-03** **4729:5-23-03**		
4729:5-16-03	Institutional Animal Care and Use Committee (IACUC) protocol	Requires the laboratory to have the current Institutional Animal Care and Use Committee (IACUC) protocol available for immediate inspection by an agent, inspector, or employee of the board.
4729:5-16-03	Group of animals on personally furnishing records	If personally furnishing to group of animals, laboratory is required to notate this on records of personally furnishing dangerous drugs.
4729:5-19-02 **4729:5-21-02**	Personally Furnishing (Human)	Restricts unlicensed personnel from preparing any controlled substances that are to be personally furnished. Restricts personal furnishing of immediate use compounded medications. Removes references to naloxone and refers to ORC 3715. Specifies the requirements for prescriber mailing of prescriptions that were personally furnished, including record keeping and return to stock requirements.
4729:5-20-02	Personally Furnishing (Animal)	Includes record keeping requirements for personally furnishing dangerous drugs via mail and includes record keeping and return to stock requirements.
4729:5-22-01	Hospice as a Non-Limited Facility	Removes hospice from the definition of non-limited facility. The Board is proposing to incorporate hospice into the institutional facility definition.

Rule 4729:5-11-01 | Pain Management Clinics - Definitions. (AMEND)

As used in Chapter 4729:5-11 of the Administrative Code:

(A) "Pain management clinic" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.552 of the Revised Code. The facility shall comply with all requirements set forth in this chapter.

(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 pain management clinic 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 that includes any of 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.**

~~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.~~

(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 4729:5-11-02 | Criminal records checks for pain management clinics. (AMEND)

(A) As used in this rule, "physician" means a person authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(B) All criminal records checks conducted in accordance with this rule shall consist of both an Ohio bureau of criminal identification ~~**and investigation**~~ (BCI~~**&I**~~) records check and a federal bureau of investigations (FBI) records check.

(C) Pursuant to section 4729.552 of the Revised Code, a terminal distributor of dangerous drug license with a pain management clinic classification will not be issued until the physician owner(s) or, if incorporated, the physician officers of the pain management clinic submit fingerprints to BCI~~**&I**~~ for a criminal records check, **which shall also include an FBI records check.** The results of the criminal records check must be sent directly to the state board of pharmacy from BCI~~**&I**~~. To be considered valid, the criminal records check must have been performed within the past twelve months.

(D) If there is a change in any of the persons listed in paragraph (C) of this rule, only the new persons shall submit to a criminal records check as part of the change of ownership requirements pursuant to rule 4729:5-2-03 of the Administrative Code.

(E) Physician owner(s) or physician officers are required to have all employees submit to a BCI~~**&I**~~ and FBI criminal records check to ensure that no person has been previously convicted of, or pleaded guilty to, a theft offense that would constitute a felony as described in division (K)(3) of section 2913.01 of the Revised Code or a felony drug abuse offense as defined in section 2925.01 of the Revised Code.

(1) BCI~~**&I**~~ shall send the results of the BCI~~**&I**~~ criminal records check directly to the employer or potential employer. BCI~~**&I**~~ shall provide a letter regarding the FBI criminal records check to the employer or potential employer stating that there is either no record of any conviction or a letter stating that the request may not meet the criteria.

(2) When an employer or potential employer receives a letter stating that the request may not meet the criteria, they may share this information with the employee or potential employee.

(3) In order to complete the criminal records check, the employee or potential employee must then complete a "Request for Release-FBI Rapsheet" and send it to BCI~~**&I**~~ to request a copy of

the FBI criminal records check results be sent directly to the employee or potential employee. The employee or potential employee must provide the results to the employer or potential employer in the original sealed envelope received from BCI**&I**.

(4) The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI**&I** from a WebCheck provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a WebCheck provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

Rule 4729:5-11-03 | 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 paragraph 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; and

(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.

(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. During non-business hours, the cabinet or safe shall be 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 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 be able to access 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 4729:5-11-04 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, noncontrolled 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 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 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 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 4729:5-11-04 | Record keeping. (AMEND)

(A) A pain management clinic 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)(1) of rule 4729:5-11-03 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 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.

(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;~~,~~ 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 4729:5-11-03 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; and

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

Rule 4729:5-13-01 | First aid departments - definitions. (AMEND)

As used in Chapter 4729:5-13 of the Administrative Code:

(A) "First aid department" means a facility licensed as a limited terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code that stocks or administers dangerous drugs in conjunction with the treatment of medical emergencies. The facility shall comply with all requirements set forth in this chapter.

(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 first aid department 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 that includes any of 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. (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 4729:5-13-02 | Licensure and drug list. (NO CHANGE)

(A) An application for licensure shall include all the following:

(1) A completed application;

(2) A list of the dangerous drugs, known as a drug list, that may be possessed and administered or personally furnished by a first aid department, expressed in standard dose units, signed by the responsible person; and

(3) The fee for the appropriate category of licensure.

(B) A first aid department may only possess those dangerous drugs that are on the drug list submitted to the board pursuant to paragraph (A)(2) of this rule and only at locations licensed by the state board of pharmacy. The responsible person may modify the drugs that may be possessed and administered by a first aid department by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(C) Except as authorized pursuant to rule 4729:5-3-09 of the Administrative Code, a first-aid department that purchases dangerous drugs for first-aid departments in other locations and redistributes them shall obtain a license as a wholesale distributor of dangerous drugs.

Rule 4729:5-13-03 | Security, control, and storage of dangerous drugs.

(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 paragraph 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; and

(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.

(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 be able to access the safe or cabinet.

(G) A 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 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 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 4729:5-13-04 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 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 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 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) Dangerous drugs shall only be administered by a licensed health care professional, acting within the scope of the professional's practice, in accordance with a prescriber's order or protocols authorized by a prescriber pursuant to agency 4729 of the Administrative Code. A copy of the protocols shall be maintained on-site for immediate inspection by an agent, officer, or inspector of the board.

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

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

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

Rule 4729:5-13-04 | Record keeping.

(A) A first aid department 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)(1) of rule 4729:5-13-03 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 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.

(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; 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 4729:5-13-03 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, 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; and

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

(L) All purchase orders or requisitions for dangerous drugs must be signed by the first aid department's responsible person.

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/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.

(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 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 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 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, 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.

Rule 4729:5-19-01 | Clinics and Prescriber Offices - Definitions. (AMEND)

As used in Chapter 4729:5-19 of the Administrative Code:

(A) "Clinic" or "prescriber office" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where a licensed prescriber, as specified in rule 4729:5-2-01 of the Administrative Code, or pharmacist serves as the responsible person on the license and drugs are possessed on-site for administration or to personally furnish. The facility shall comply with all requirements set forth in this chapter. A clinic or prescriber office does not include a veterinary clinic as defined in rule 4729:5-20-01 of the Administrative Code.

(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) "Dosage unit" means any of the following:

(1) A single pill, capsule, ampule, or tablet;

(2) In the case of a liquid solution, one milliliter;

(3) In the case of a cream, lotion, or gel, one gram; or

(4) Any other form of administration available as a single unit.

(E) "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.

(F) "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.

(G) "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.
(H)

(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 that includes any of 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.**

~~**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.**~~

(I) "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.
(J) "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.

(K) "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.

Rule 4729:5-19-02 | Personally furnishing dangerous drugs. (AMEND)

(A) A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall 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.

(B) 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 shall 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

(3) Directions for use.

(C) For controlled substances, quantities personally furnished to a patient are limited to a seventy-two-hour supply and quantities personally furnished to all patients shall not exceed two thousand five hundred dosage units in any thirty day period pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in paragraph (C) of this rule have been exceeded:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07 (**8/8/2023** ~~**6/23/2005);**~~**).**

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program licensed under section 5119.37 of the Revised Code.

(3) Controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(E)

(1) Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification.

(2) A prescriber may delegate the act of personally furnishing to a licensed Ohio pharmacist practicing at a free clinic, as defined in section 3701.071 of the Revised Code. The act of personally furnishing shall be documented using positive identification.

(F)

(1) A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (E)(2) of this rule.

(2) 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 by the prescriber or a pharmacist in accordance with paragraph (E)(2) of this rule. An unlicensed person shall not prepare and package **controlled substances**. ~~**any of the following dangerous drugs:**~~

~~**(a) Anesthesia;**~~

~~**(b) Controlled substances; or**~~

~~**(c) Drugs administered intravenously.**~~

(3) Pursuant to rule 4729:7-3-04 of the Administrative Code, a prescriber shall not personally furnish immediate-use compounded drug preparations.

(G) Counseling.

(1) A prescriber, pharmacist**,** or a delegate in accordance with paragraph (H)(1) of this rule shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (G)(2) of this rule 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, either verbally or in writing, the offer of counseling or does not respond to the written offer to counsel.

(2) Prescriber or pharmacist counseling may include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage and disposal;

(h) Action to be taken in the event of a missed dose; and

(i) The prescriber or pharmacist's comments relevant to the patient's drug therapy, including

other necessary information unique to the specific patient or drug.

(H) Provision of dangerous drugs.

(1) A prescriber may delegate an individual or individuals to distribute dangerous drugs personally furnished by a prescriber or pharmacist if all the following apply:

(a) A prescriber or pharmacist provides personal supervision;

(b) Counseling is offered in accordance with paragraph (G) of this rule; and

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraph (H)(1)(a) of this rule does not apply if a non-controlled substance dangerous drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and a prescriber or pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(I) No prescriber or pharmacist acting in accordance with paragraph (E)(2) of this rule may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(J) **Naloxone and other overdose reversal drugs may be personally furnished or otherwise distributed in accordance with Chapter 3715. of the Revised Code. A terminal distributor of dangerous drugs shall not be required to maintain any patient-specific records for the distribution of naloxone or other overdose reversal drug.**

~~**Personally furnishing naloxone.**~~

~~**(1) Except as provided in paragraph (J)(3) of this rule, 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 of the following:**~~

~~**(a) Prepare, package, and appropriately label the naloxone.**~~

~~(b) Conduct the final association of the naloxone to the patient.~~

~~(c) Keep and maintain all records in accordance with this chapter.~~

~~(d) Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol.~~

~~(2) 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 may personally furnish the drug to themselves in order to assist an individual who there is reason to believe is experiencing an opioid-related overdose if all of the following conditions are met:~~

~~(a) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.~~

~~(b) The authorized individual has received training instructing them to summon emergency services as soon as practicable either before or after administering naloxone.~~

~~(c) Such practice is authorized in the physician approved protocol.~~

~~(3) An authorized individual personally furnishing naloxone pursuant to paragraph (J)(2) of this rule shall not be required to comply with paragraphs (J)(1)(a), (J)(1)(b), and (J)(1)(d) of this rule.~~

~~(4) A terminal distributor of dangerous drugs may also administer naloxone in accordance with section 4729.514 of the Revised Code.~~

(K) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(L) Paragraph (K) of this rule does not prohibit a prescriber from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber.

(M) A prescriber personally furnishing dangerous drugs shall comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and division 4729:8 of the Administrative Code.

(N) Except as provided in paragraph (O) of this rule, a prescriber may only mail or provide delivery of a dangerous drug that has been personally furnished if all the following apply:

(1) The prescriber does not routinely mail or deliver the drug to the patient;

(2) The drug is unavailable at a local pharmacy or the patient cannot afford the drug;

(3) Failure to mail or deliver the drug would result in harm to the patient; and

(4) The prescriber includes in the records required for personally furnishing the name of the common carrier (including the United State Postal Service), contract carrier, or employee of the terminal distributor who performed, or attempted to perform, the delivery.

(O) The restrictions listed of paragraph (N) of this rule do not apply if the drug that has been personally furnished is either:

(1) Part of a clinical trial approved by the United States food and drug administration. A prescriber that mails or delivers a drug that is part of a clinical trial shall comply with the requirements of paragraph (N)(4) of this rule; or

(2) Delivered or otherwise provided by a mobile clinic or medication unit in accordance with rule 4729:5-3-23 of the Administrative Code.

(P) Any drug that has left the possession of the terminal distributor of dangerous drugs shall comply with the requirements of rule 4729:5-3-16 of the Administrative Code.

Rule 4729:5-19-03 | 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 paragraph 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; and

(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.

(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 be able to access 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 4729:5-19-04 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, noncontrolled
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 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 4729:5-19-04 | Record Keeping. (AMEND)

(A) A clinic or prescriber office 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)(1) of rule 4729:5-19-03 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 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.

(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~~,~~; 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 4729:5-19-03 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 or the disposal of patient owned drug stock maintained in

accordance with paragraph (G) of rule 4729:5-19-03 of the Administrative Code, 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 and rule 4729:5-19-03 of the Administrative Code 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.

Rule 4729:5-20-01 | Veterinary Clinics - Definitions. (AMEND)

As used in Chapter 4729:5-20 of the Administrative Code:

(A) "Veterinary clinic" or "clinic" means a facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where a licensed veterinarian serves as the responsible person on the license and drugs are possessed on-site for administration or to personally furnish. The facility shall comply with all requirements set forth in this chapter.

(B) "Animal aide" has the same meaning as in section 4741.01 of the Revised Code.

(C) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

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

(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 distribution of dangerous drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. For the purposes of this chapter, the prescriber shall be a veterinarian.

(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 that includes any of 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.

(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) "Registered veterinary technician" has the same meaning as in section 4741.01 of the Revised Code.

(J) "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.

(K) "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.

(L) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

Rule 4729:5-20-02 | Personally furnishing dangerous drugs. (AMEND)

(A) A veterinarian who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall affix to the container a label showing:

(1) The name and address of the veterinarian;

(2) The name of the patient for whom the drug is intended, which shall include the name of the owner and identification of the animal or animals;

(3) Name and strength of the dangerous 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.

(B) A veterinarian 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, the veterinarian shall affix a label to the sample container or provide written documentation accompanying the sample that includes the following:

(1) The name and address of the veterinarian;

(2) The name of the patient for whom the drug is intended, which shall include the name of the owner and identification of the animal or animals; and

(3) Directions for use.

(C) A veterinarian may delegate to a registered veterinary technician or animal aide, acting within the scope of the professional's practice, the act of preparing and packaging a dangerous drug that will be personally furnished. Unless otherwise authorized under Chapter 4741. of the Revised Code and the rules adopted thereunder, animal aides shall not prepare and package dangerous drugs that are anesthetic agents or controlled substances.

(D) A veterinarian shall conduct the final association of a controlled substance dangerous drug with a patient prior to personally furnishing the drug to the patient's owner or caregiver.

(E) Counseling.

(1) A veterinarian or the veterinarian's designee shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (E)(2) of this rule to an owner or caregiver whenever any dangerous drug is personally furnished. A veterinarian shall not be required to counsel an owner or caregiver when the owner or caregiver refuses, either verbally or in writing, the offer of counseling or does not respond to the written offer to counsel.

(2) Veterinarian counseling may include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for monitoring drug therapy;

(g) Proper storage and disposal;

(h) Action to be taken in the event of a missed dose; and

(i) The veterinarian's comments relevant to the patient's drug therapy, including other necessary information unique to the specific patient or drug.

(F) Provision of dangerous drugs.

(1) A veterinarian may delegate an individual or individuals to distribute dangerous drugs that are personally furnished if all the following apply:

(a) A veterinarian provides personal supervision;

(b) Counseling is offered in accordance with paragraph (E) of this rule;

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraph (F)(1)(a) of this rule does not apply if a non-controlled dangerous drug is provided to the owner or caregiver by a registered veterinary technician or animal aide and a

veterinarian is available for counseling by means of electronic communication during normal hours of operation.

(G) No veterinarian may personally furnish to an owner or caregiver to whom there is no veterinary-client-patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(H) Any patient specific dangerous drug dispensed by a pharmacy that is provided to an owner or caregiver by a veterinarian pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that owner or caregiver and is not considered personally furnishing. No veterinarian that provides an owner or caregiver with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(I) Paragraph (H) of this rule does not prohibit a veterinarian from charging an owner or caregiver for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the veterinarian.

(J) A veterinarian may mail or provide delivery of a dangerous drug that has been personally furnished if the prescriber includes in the records required for personally furnishing the name of the common carrier (including the United State Postal Service), contract carrier, or employee of the terminal distributor who performed, or attempted to perform, the delivery.

(K) Any drug that has left the possession of the terminal distributor of dangerous drugs shall comply with the requirements of rule 4729:5-3-16 of the Administrative Code.

Rule 4729:5-20-03 | Security and control 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 substances shall be stored in a securely locked, substantially constructed cabinet or safe.

(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 veterinarian if not being used by a veterinarian or a veterinary technician 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 veterinarian shall be able to access the cabinet or safe.

(a) A veterinarian may provide a veterinary technician with a temporary key for the purposes of accessing the cabinet or safe. A veterinary technician shall return the key provided in accordance with this paragraph to the veterinarian or a secured location with restricted access (such as a lockbox) no later than the end of the technician's shift or if there is no longer a veterinarian available to provide personal supervision.

(b) A veterinarian may provide a veterinary technician 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 veterinarian;

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

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

(C) A registered veterinary technician may have access to controlled substances only under the personal supervision of a veterinarian.

(D) Only a veterinarian 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 veterinarian 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) Except as provided for in this paragraph, the cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, patients, business guests, or visitors to be present in or pass through areas containing the cabinet or safe, a veterinarian or veterinary technician shall provide for adequate observation of the area.

(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 code.

(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 veterinarian if not being used by a veterinarian. 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 veterinarian shall be able to access the safe or cabinet.

(G) A registered veterinary technician may have unsupervised access to controlled substances in accordance with the following:

(1) The drugs have been personally furnished by a veterinarian and are intended for administration to patients undergoing treatment and/or boarding within the veterinary clinic.

(2) The drugs must be stored in a securely locked, substantially constructed cabinet or safe with access that is limited to veterinarians and veterinary technicians. 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 veterinarian and veterinary technician.

(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 4729:5-20-04 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, personally furnishing, and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(K) All areas where dangerous drugs 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 shall comply with the following:

(1) Maintain either 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 drugs.

(L) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a date opened. Multiple-dose vials shall be examined prior to use for evidence of physical

or chemical contamination. Vials that have any of the following characteristics shall be deemed adulterated:

(1) Contain particulate matter, precipitates, turbidity, or discoloration;

(2) Mislabeled; or

(3) Noticeable coring (damage to the rubber stopper).

(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 4729:5-20-04 | Record keeping. (AMEND)

(A) A veterinary clinic 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 (J) of rule 4729:5-20-03 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 or identification of the animal or animals; name and address of the animal's or animals' owner or caregiver; the date the drug is personally furnished; and, if applicable, the date the drug is received by the animal's or animals' owner or caregiver. A veterinarian shall be required to document the final association of a controlled substance dangerous drug with a patient using positive identification.

If dangerous drugs are personally furnished for administration at an animal shelter as defined in rule 4729:5-15-01 of the Administrative Code, the records shall include the name of the employee who was provided the drugs and the name and address of the animal shelter in lieu of the owner or caregiver's name and address.

(E)

(1) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered; the name or identification of the animal or animals to whom or for whose use the dangerous drugs were administered; and the date of administration. For controlled substance dangerous drugs, the administration record shall also include the positive identification of the licensed or registered 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) Orders for the administration of controlled substances shall be documented using positive identification. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(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 health care professional or animal aide 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 or registered 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 or registered healthcare professionals conducting and witnessing the disposal.

(3) A veterinarian may use an animal aide in lieu of one of the licensed or registered healthcare professionals required to conduct and witness the disposal of controlled substances pursuant to paragraphs (G)(1) and (G)(2) of this rule.

(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, 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; and

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

Rule 4729:5-21-01 | Opioid Treatment Programs - Definitions. (AMEND)

As used in Chapter 4729:5-21 of the Administrative Code:

(A) "Opioid Treatment Program" or "OTP" means a facility that is licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code and holds, or is in the process of applying for, a valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 CFR 8.11 (3/17/2025). The facility shall comply with all requirements set forth in this chapter. An OTP does not include office-based opioid treatment performed in accordance with rule 4731-33-03 of the Administrative Code.

(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) "Dosage unit" means any of the following:

(1) A single pill, capsule, ampule, tablet;

(2) In the case of a liquid solution, one milliliter;

(3) In the case of a cream, lotion, or gel, one gram; or

(4) Any other form of administration available as a single unit.

(E) "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.

(F) "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.

(G) "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.

(H)

(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 that includes any of 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.

(I) "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.

(J) "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.

(K) "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.

Rule 4729:5-21-02 | Personally furnishing dangerous drugs from an opioid treatment program. (AMEND)

(A) A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall 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 dangerous 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.

(B) 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, the prescriber shall affix a label to the sample container or provide written documentation accompanying the sample that includes the following:

(1) Name of the prescriber;

(2) The name of the patient for whom the drug is intended; and

(3) Directions for use.

(C) For controlled substances, quantities personally furnished to a patient are limited to a seventy-two-hour supply and in any thirty day period quantities personally furnished to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in paragraph (C) of this rule have been exceeded:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 CFR 1306.07 (8/8/2023);

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program licensed under section 5119.37 of the Revised Code.

(3) Controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(E)

(1) A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber, a pharmacist, or a nurse in accordance with paragraph (F) of this rule.

(2) The personal supervision requirement listed in paragraph (E)(1) of this rule does not apply if a licensed health care professional acting within the scope of the professional's practice is preparing and packaging either of the following:

(a) Methadone for the purpose of treating drug dependence or addiction; or

(b) Buprenorphine for the purpose of treating drug dependence or addiction.

(3) 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 by the prescriber or a pharmacist in accordance with paragraph (F) of this rule. An unlicensed person shall not prepare and package any of the following dangerous drugs:

(a) Anesthesia;

(b) Controlled substances; or

(c) Drugs administered intravenously.

(F) Only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification.

A prescriber may delegate the act of personally furnishing pursuant to the following:

(1) A prescriber may delegate the act of personally furnishing to a licensed pharmacist. The delegated pharmacist shall document the act of personally furnishing using positive identification.

(2) A prescriber may delegate the act of personally furnishing methadone for the purpose of treating drug dependence or addiction to a nurse practicing in accordance with Chapter 4723. of the Revised Code pursuant to the following:

(a) The opioid treatment program utilizes an automated methadone dispensing system that is routinely calibrated to ensure the accuracy of the methadone personally furnished.

(b) The nurse shall document the act of personally furnishing using positive identification.

(3) A prescriber may delegate the act of personally furnishing buprenorphine for the purpose of treating drug dependence or addiction to a nurse practicing in accordance with Chapter 4723. of the Revised Code. The nurse shall document the act of personally furnishing using positive identification.

(G) Counseling.

(1) A prescriber, pharmacist, or a delegate in accordance with paragraph (H)(1) of this rule shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (G)(2) of this rule 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, either verbally or in writing, the offer of counseling or does not respond to the written offer to counsel.

(2) Prescriber or pharmacist counseling may include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage and disposal;

(h) Action to be taken in the event of a missed dose; and

(i) The prescriber or pharmacist's comments relevant to the patient's drug therapy, including other necessary information unique to the specific patient or drug.

(H) Provision of dangerous drugs.

(1) A prescriber may delegate a licensed healthcare professional acting within the scope of the professional's practice to distribute dangerous drugs personally furnished by a prescriber or pharmacist if all the following apply:

(a) A prescriber or pharmacist provides personal supervision;

(b) Counseling is offered in accordance with paragraph (G) of this rule; and

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraph (H)(1)(a) of this rule does not apply under any of the following circumstances:

(a) The drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and the drug provided is either:

(i) Methadone for the purpose of treating drug dependence or addiction and a prescriber or licensed pharmacist is available for counseling by means of electronic communication during normal hours of operation; or

(ii) Buprenorphine for the purpose of treating drug dependence or addiction as part of an opioid treatment program and a prescriber or licensed pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(b) The drug is being provided to a patient by a licensed pharmacist.

(c) A non-controlled dangerous drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and a prescriber or pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(I) No prescriber or pharmacist may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(J) Naloxone and other overdose reversal drugs may be personally furnished or otherwise distributed in accordance with Chapter 3715. of the Revised Code. A terminal distributor of dangerous drugs shall not be required to maintain any patient-specific records for the distribution of naloxone or other overdose reversal drug. (K) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(L) Paragraph (K) of this rule does not prohibit a prescriber from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber.

(M) Except as provided in paragraph (N) of this rule, a prescriber may only mail or provide delivery of a dangerous drug that has been personally furnished if all the following apply:

(1) The prescriber does not routinely mail or deliver the drug to the patient;

(2) The drug is unavailable at a local pharmacy or the patient cannot afford the drug;

(3) Failure to mail or deliver the drug would result in harm to the patient; and

(4) The prescriber includes in the records required for personally furnishing the name of the common carrier (including the United State Postal Service), contract carrier, or employee of the terminal distributor who performed, or attempted to perform, the delivery.

(N) The restrictions listed of paragraph (M) of this rule do not apply if the drug that has been personally furnished is either:

(1) Part of a clinical trial approved by the United States food and drug administration. A prescriber that mails or delivers a drug that is part of a clinical trial shall comply with the requirements of paragraph (N)(4) of this rule; or

(2) Delivered or otherwise provided by a mobile opioid treatment program in accordance with rule 4729:5-21-05 of the Administrative Code or a mobile clinic or medication unit in accordance with rule 4729:5-3-23 of the Administrative Code.

(O) Any drug that has left the possession of the terminal distributor of dangerous drugs shall comply with the requirements of rule 4729:5-3-16 of the Administrative Code.

Rule 4729:5-21-03 | Security and control 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) All schedule II controlled substances shall be maintained in accordance with 21 CFR 1301.72 (3/17/2025). Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to schedule II controlled substances maintained in accordance with this paragraph.

(C) All schedule III through V controlled substances shall be maintained in accordance with 21 CFR 1301.72 (3/17/2025). Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to controlled substances maintained in accordance with this paragraph.

(D) When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through storage areas maintained in accordance with paragraphs (B) and (C) of this rule, the opioid treatment program shall provide for adequate observation of the area by a prescriber, pharmacist, or nurse specifically authorized in writing.

(E) Controlled substances administered for the treatment of opioid dependence or addiction may be administered directly to the patient by any of the following:

(1) A licensed prescriber, in accordance with the prescriber's scope of practice and as authorized by federal or state law.

(2) A nurse licensed under Chapter 4723. of the Revised Code pursuant to a valid order issued by a licensed prescriber.

(3) A pharmacist in accordance with a consult agreement pursuant to section 4729.39 of the Revised Code. The pharmacist shall only administer the drug pursuant to a valid order by the consulting physician.

(F) Persons enrolled in an opioid treatment program will be required to wait in an area physically separated from the drug storage and preparation areas. This requirement shall be enforced by the responsible person and program employees.

(G) 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.

(H) 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.

(I) 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.

(J) 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.

(K) 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.

(L) All areas where dangerous drugs 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 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 drugs.

(M) 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.

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

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

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

Rule 4729:5-21-04 | Record Keeping. (AMEND)

(A) An OTP 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 (L)(1) of rule 4729:5-21-03 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 drugs were personally furnished; the positive identification of the prescriber, delegated pharmacist, or delegated nurse 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; 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.

(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, 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; and

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

Rule 4729:5-21-05 | Mobile opioid treatment programs. (AMEND)

(A) As used in this rule, "mobile opioid treatment program" has the same meaning as "mobile narcotic treatment program" as used in 21 CFR part 1301 (3/17/2025).

(B) For any opioid treatment program intending to operate a mobile opioid treatment program, the licensee shall notify the local drug enforcement administration (DEA) office, in writing, its intent to do so, and the opioid treatment program must receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program. The mobile opioid treatment program may only operate in the same state in which the opioid treatment program is registered with the DEA.

(1) Licensees are not required to obtain a separate terminal distributor of dangerous drugs license for conveyances (mobile components) utilized by the licensee to transport dangerous drugs away from licensed locations for use as part of a mobile opioid treatment program. Vehicles must possess valid county/city and state information (e.g., a vehicle identification number (VIN) or license plate number) on file at the licensed location of the opioid treatment program licensed by the board.

(2) A mobile opioid treatment program is not permitted to reverse distribute, share, or transfer dangerous drugs from one mobile component to another mobile component while deployed outside of the licensed location. These mobile components of opioid treatment programs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and shall not transport patients.

(C) For any conveyance operated as a mobile opioid treatment program, a securely locked safe must be installed and used to store dangerous drugs in schedules II-V for the purpose of maintenance or detoxification treatment when not located at the licensee's licensed location.

(1) The safe must conform to the requirements set forth in paragraph (a)(1) of 21 CFR 1301.72 (3/17/2025).

(2) The mobile component shall also be equipped with an alarm system that conforms to the requirements set forth paragraph (a)(1)(iii) of 21 CFR 1301.72 (3/17/2025).

(3) The storage area of the mobile component must conform to the accessibility requirements in paragraph (d) of 21 CFR 1301.72 (3/17/2025).

(4) The storage area for controlled substances in a mobile component of an opioid treatment program must not be accessible from outside of the vehicle.

(a) Authorized personnel transporting the controlled substances on behalf of the mobile opioid treatment program are required to retain control over the controlled substances when transferring controlled substances between the licensed location and the conveyance, from the conveyance to the location where medication will be administered or personally furnished, and when administering or personally furnishing medication. At all other times during transportation, all controlled substances must be properly secured in the safe.

(b) Upon completion of the operation of the conveyance on a given day, the conveyance must be immediately returned to the licensed location, and all controlled substances must be removed from the conveyance and secured within the licensed opioid treatment program. After the conveyance has returned to the registered location and the controlled substances have been removed, the conveyance may be parked until its next use at the licensed location or any secure, fenced-in area, once the local DEA office has been notified of the location of this secure, fenced-in area.

(c) A mobile opioid treatment program may apply to the DEA for an exception to the requirements in paragraph (C)(4)(b) of this rule.

(i) The application for such an exception shall be submitted in accordance with 21 CFR 1301.72 (3/17/2025).

(ii) If an exception is granted, the licensee shall comply with the security conditions set forth in the approval granted by the DEA. Any conveyance maintained in accordance with an exception granted under this rule shall be subject to inspection by a board of pharmacy agent.

(iii) If an exception is revoked or otherwise rescinded by the DEA, the licensee shall comply with the requirements in paragraph (C)(4)(b) of this rule.

(iv) All approvals from the DEA shall be maintained at the licensed location and made immediately available for inspection by an agent of the state board of pharmacy.

(d) All opioid treatment programs with mobile components shall be required to establish a standard operating procedure to ensure, if the mobile component becomes inoperable

(mechanical failure, accidents, fire, etc.), that the controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the licensed location.

(5) Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to controlled substances maintained by the mobile opioid treatment program.

(D) Persons enrolled in any opioid treatment program, including those receiving treatment at a mobile opioid treatment program, will be required to wait in an area that is physically separated from the medication storage area and areas used for administration or personally furnishing by a physical entrance such as a door or other entryway. Patients will need to wait outside of a mobile opioid treatment program if that unit does not have seating or a reception area that is separated from the medication storage area and areas used for administration or personally furnishing. This requirement shall be enforced by the terminal distributor of dangerous drugs and the licensee's employees.

(E) Any controlled substances being transported for disposal from the location where the drugs are administered or personally furnished shall be secured and disposed of in compliance with 21 CFR 1317 (3/17/2025) and rule 4729:5-3-01 of the Administrative Code.

(F) A conveyance used as part of a mobile opioid treatment program may only be supplied with controlled substance dangerous drugs by the licensed opioid treatment program that operates such conveyance. Persons permitted to administer or personally furnish controlled substances from mobile opioid treatment programs shall not:

(1) Receive controlled substances from other mobile opioid treatment program or any other entity;

(2) Deliver controlled substances to other mobile opioid treatment program or any other entity; or

(3) Conduct reverse distribution of controlled substances on a mobile opioid treatment program.

(G) A mobile opioid treatment program shall maintain records with the following information for each dangerous drug:

(1) Name of drug;

(2) Strength of drug;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of patient (consumer);

(6) Amount consumed;

(7) Amount and dosage form taken home by patient; and

(8) Initials of the employee personally furnishing or administering a drug.

(H) The records required by paragraph (G) of this rule shall be maintained in a log at the licensed opioid treatment program.

(1) As an alternative to maintaining a paper log, an opioid treatment program may also use an automated/computerized data processing system for the storage and retrieval of the program's records, if the following conditions are met:

(a) The automated system maintains the information required in paragraph (G) if this rule;

(b) The automated system has the capability of producing a hard copy printout of the records required in paragraph (G) of this rule;

(c) The opioid treatment program or its mobile component prints a hard copy of each day's log, which is then initialed appropriately by each person who personally furnished/administered the medication to the program's patients;

(d) The automated system is approved by DEA;

(e) The opioid treatment program or its mobile component maintains an off-site back-up of all computer generated program information; and

(f) The automated system is capable of producing accurate summary reports for both the licensed site of the opioid treatment program and any mobile component, for any time-frame selected by DEA personnel during an investigation. If these summary reports are maintained

in hard copy form, they must be kept in a systematically organized file located at the licensed opioid treatment program.

(2) The opioid treatment program must retain all records for any mobile component three years from the date of execution.

(l) A mobile opioid treatment program shall comply with all other applicable requirements of 21 CFR 1301 (3/17/2025).

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) Infusion centers;

(g) Imaging centers; or

(h) 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.

(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 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 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 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, 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.

Rule 4729:5-23-01 | Limited Facilities - Definitions. (AMEND)

As used in Chapter 4729:5-23 of the Administrative Code:

(A) "Limited facility" means a facility licensed as a limited category II or limited category III 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) A limited facility includes any of the following:

(a) Dog trainers affiliated with an Ohio law enforcement agency;

(b) Home health care providers, including those offering in-home services;

(c) Hospice care providers of in-home services;

(d) Physical therapy providers;

(e) Teaching institutions; and

(f) Any other facility as determined by the board.

(2) A limited facility does not include any of the following:

(a) Non-limited facilities as defined in Chapter 4729:22 of the Administrative Code; or

(b) Any other person or facility licensed as a terminal distributor of dangerous 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.).

(3) A limited facility shall submit an application for licensure that includes all the following:

(a) A completed application;

(b) A list of the controlled substances and dangerous drugs, known as a drug list, that may be possessed and administered by a limited facility, expressed in standard dose units, signed by the responsible person; and

(c) The fee for the appropriate category of licensure.

(4) A limited facility may only possess those controlled substances and dangerous drugs that are on the drug list submitted to the board pursuant to paragraph (A)(3)(b) of this rule and only at locations licensed by the state board of pharmacy. The responsible person may modify the drugs that may be possessed and administered by the limited facility by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(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) "Law enforcement officer" has the same meaning as 21 CFR 1300.05 (10/09/2014).

(E) "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.

(F) "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.

(G) "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 limited facility who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-19-02 of the Administrative Code.

(H)

(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.

(I) "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.

(J) "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 4729:5-23-02 | Security, control, and storage of dangerous drugs. (AMEND)

(A) The security and control of controlled substances and 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 (G) and (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 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 the responsible person, a prescriber, or a pharmacist if not being used by a prescriber, pharmacist, responsible person, or a licensed health care professional or employee of a dog training facility 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, pharmacist, or responsible person shall have possession of the keys or access codes to the cabinet or safe.

(a) A prescriber, pharmacist, or responsible person may provide a licensed health care professional or an employee of a dog training facility with a temporary key for the purposes of accessing the cabinet or safe. A licensed health care professional or employee shall return the key provided in accordance with this rule to the responsible person, a prescriber, or a pharmacist or to a secured location with restricted access (such as a lockbox) no later than

the end of the person's shift or if there is no longer a prescriber, pharmacist, or the responsible person available to provide personal supervision.

(b) A prescriber, pharmacist, or the responsible person may provide a licensed health care professional or an employee of a dog training facility 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, pharmacist, or responsible person;

(ii) The room is locked during non-business hours or when there is no longer a prescriber, pharmacist, or the responsible person 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 paragraphs (D) and (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) A limited facility that is a dog trainer affiliated with an Ohio law enforcement agency may permit access to controlled substances to those engaged in the training of canines only under the personal supervision of the responsible person.

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

(F) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of the responsible person, 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.

(G) A 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 nurses. The cabinet or safe must be separate from those required in paragraphs (B) and (H) 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 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 4729:5-23-03 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) 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, pharmacist, or responsible person if not being used by a prescriber, pharmacist, or the responsible person. 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, pharmacist, or the responsible person shall have possession of the key, combination, or access code to the safe or cabinet specified in this paragraph.

(I) 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 or possess hypodermics.

(J) 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 or employees of a dog training facility.

(K) 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.

(L) 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.

(M) 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.

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

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

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

(Q) Disposal of controlled substances by a dog training facility that are not dangerous drugs 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 and one other employee of the dog training facility;

(b) A law enforcement officer; 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 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 person or persons conducting and witnessing the disposal.

Rule 4729:5-23-03 | Record keeping. (AMEND)

(A) A limited facility shall keep a record of all dangerous drugs and controlled substances 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 or controlled substances 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 (L) of rule 4729:5-23-02 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 4729:5-23-03 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 disposal of controlled substances that are not dangerous drugs shall comply with the requirements of paragraph (P) of rule 4729:5-23-02 of the Administrative Code.

(H) 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 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.

(I) 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, 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.

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

(K) 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.

(L) 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.