Rules - February 2024

Replace reference to Director of Licensing with the Executive Director or the director's designee.

Rule 4729:1-5-03 | Veteran and military family provisions related to continuing education.
... documentation, the board's **director** of **licensing** shall extend the continuing education reporting period by an amount of time equal to the total number of months that the licensee or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month. (3) The licensee shall submit...

Rule 4729:2-1-01 | Definitions - pharmacy interns.
...erience in the area approved by the **director** of **licensing** pursuant to rule 4729:2-2-05 of the Administrative Code. (2) A person may serve as the preceptor for more than one intern. (3) Except as provided in paragraph (O)(4) of this rule, the number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty, unless otherwise approved...

Rule 4729:2-2-05 | Internship credit.
...formal request must be submitted to the **director** of **licensing** for approval prior to beginning the experience in these areas. The request shall include a detailed description of the internship with respect to time, place, duties, responsibilities, professional supervision, and the person supervising the experience. The request must be signed by both the intern and the person supervising the experience and returned wit...

Rule 4729:3-5-03 | Veteran and military family provisions related to continuing education.

... documentation, the board's **director** of **licensing** shall extend the continuing education reporting period by an amount of time equal to the total number of months that the registrant or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month. (3) The registrant shall su...

Rule 4729:5-1-01 | Definitions - terminal distributors of dangerous drugs.
...submit a request to the **director** of **licensing** for a one-time, ninety-day extension. (c) An applicant for a terminal distributor of dangerous drugs that fails to demonstrate compliance with appropriate security and control rules pursuant to this division of the Administrative Code. The applicant may submit a request to the **director** of **licensing** for a one-time, ninety-day extension. (2) An applica...

Rule 4729:6-1-01 | Definitions - distributors of dangerous drugs.

...e applicant may submit a request to the **director** of **licensing** for a one-time, ninety-day extension. (b) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board. (c) An applicant that fails to demonstrate compliance with appropriate security and control rules pursuant to this division of the Administrative Code...

Rule 4729-4-01 | Definitions - confidential personal information. (AMEND)

For the purposes of administrative rules promulgated in accordance with section 1347.15 of the Revised Code, the following definitions apply:

(A) "Access," as a noun, means an opportunity to copy, view, or otherwise perceive whereas "access" as a verb means to copy, view, or otherwise perceive.

(B) "Acquisition of a new computer system" means the purchase of a "computer system,"**[INSERT SPACE]**as defined in this rule, that is not a computer system currently in place nor one for which the acquisition process has been initiated as of the effective date of the board rule addressing requirements of section 1347.15 of the Revised Code.

(C) "Board" means the state of Ohio board of pharmacy.

(D) "Computer system" means a "system," as defined by section 1347.01 of the Revised Code, that stores, maintains, or retrieves personal information using electronic data processing equipment.

(E) "Confidential personal information" (CPI) has the **same** meaning as defined by division (A)(1) of section 1347.15 of the Revised Code and identified by rules promulgated by the board in accordance with division (B)(3) of section 1347.15 of the Revised Code that reference the federal or state statutes or administrative rules that make personal information maintained by the board confidential.

(F) "Employee of the board" means each employee of the board regardless of whether the employee holds an elected or appointed office or position within the board. "Employee of the board" is limited to the board of pharmacy.

(G) "Incidental contact" means contact with the information that is secondary or tangential to the primary purpose of the activity that resulted in the contact.

(H) "Individual" means natural person or the natural person's authorized representative, legal counsel, legal custodian, or legal guardian.

(I) "Information owner" means the individual appointed in accordance with division (A) of section 1347.05 of the Revised Code to be directly responsible for a system.

(J) "Person" means natural person.

(K) "Personal information" has the same meaning as defined in division (E) of section 1347.01 of the Revised Code.

(L) "Personal information system" means a "system" that "maintains" "personal information" as those terms are defined in section 1347.01 of the Revised Code.

(M) "Research" means a methodical investigation into a subject.

(N) "Routine" means **commonplace**, regular, habitual, or ordinary.

(O) "Routine information that is maintained for the purpose of internal office administration, the use of which would not adversely affect a person" as that phrase is used in division (F) of

section 1347.01 of the Revised Code means personal information relating to the board's employees that is maintained by the board for administrative and human resource purposes.

(P) "System" has the same meaning as defined by division (F) of section 1347.01 of the Revised Code.

(Q) "Upgrade" means a substantial redesign of an existing system for the purpose of providing a substantial amount of new application functionality, or application modifications that would involve substantial administrative or fiscal resources to implement, but would not include maintenance, minor updates and patches, or modifications that entail a limited addition of functionality due to changes in business or legal requirements.

Rule 4729-4-02 | Confidential personal information. (AMEND)

(A) Procedures for accessing confidential personal information.

For personal information systems, whether manual or computer systems, that contain confidential personal information, the board shall do the following:

(1) Criteria for accessing confidential personal information. Personal information systems of the board are managed on a "need-to-know" basis whereby the information owner determines the level of access required for an employee of the board to fulfill the employee's job duties. The determination of access to confidential personal information shall be approved by the employee's supervisor and the information owner prior to providing the employee with access to confidential personal information within a personal information system. The board shall establish procedures for determining a revision to an employee's access to confidential personal information upon a change to that employee's job duties including, but not limited to, transfer or termination. Whenever an employee's job duties no longer require access to confidential personal information in a personal information system, the employee's access to confidential personal information shall be removed.

(2) Individual's request for a list of confidential personal information. Upon the signed written request of any individual for a list of confidential personal information about the individual maintained by the board, the board shall do the following:

(a) Verify the identity of the individual by a method that provides safeguards commensurate with the risk associated with the confidential personal information;

(b) Provide to the individual the list of confidential personal information that does not relate to an investigation about the individual or is otherwise not excluded from the scope of Chapter 1347. of the Revised Code; and

(c) If all information relates to an investigation about that individual, inform the individual that the board has no confidential personal information about the individual that is responsive to the individual's request.

(3) Notice of invalid access:

(a) Upon discovery of or notification that confidential personal information of a person has been accessed by an employee for an invalid reason, the board shall notify the person whose information was invalidly accessed as soon as practical and to the extent known at the time. However, the board shall delay notification for a period of time necessary to ensure that the notification would not delay or impede an investigation or jeopardize homeland or national security. Additionally, the board may delay the notification consistent with any measures necessary to determine the scope of the invalid access, including which individuals' confidential personal information was invalidly accessed, and to restore the reasonable integrity of the system.

"Investigation" as used in this paragraph means the investigation of the circumstances and involvement of an employee surrounding the invalid access of the confidential personal information. Once the board determines that notification would not delay or impede an investigation, the board shall disclose the access to confidential personal information made for an invalid reason to the person.

(b) Notification provided by the board shall inform the person of the type of confidential personal information accessed and the date(s) of the invalid access.

(c) Notification may be made by any method reasonably designed to accurately inform the person of the invalid access, including written, electronic, or telephone notice.

(4) Appointment of a data privacy point of contact. The ~~**board**~~ **board's** executive director shall designate an employee of the board to serve as the data privacy point of contact. The data privacy point of contact shall work with the chief privacy officer within the office of information technology to assist the board with both the implementation of privacy protections for the confidential personal information that the board maintains **in** compliance~~**s**~~ with section 1347.15 of the Revised Code and the rules adopted pursuant to the authority provided by that chapter.

(5) Completion of a privacy impact assessment. The board executive director shall designate an employee of the board to serve as the data privacy point of contact who shall**, in a** timely **manner,** complete the privacy impact assessment form developed by the office of information technology.

(B) Valid reasons for accessing confidential personal information.

Pursuant to the requirements of division (B)(2) of section 1347.15 of the Revised Code, this rule contains a list of valid reasons, directly related to the board's exercise of its powers or duties, for which only authorized employees of the board or board members may access confidential personal information (CPI) regardless of whether the personal information system is a manual system or a computer system.

(1) Performing the following functions constitute valid reasons for authorized employees or members of the board to access confidential personal information:

(a) Responding to a public records request;

(b) Responding to a request from an individual for the list of CPI the board maintains on that individual;

(c) Administering a constitutional provision or duty;

(d) Administering a statutory provision or duty;

(e) Administering an administrative provision or duty;

(f) Complying with any state or federal program requirements;

(g) Processing or payment of claims or otherwise administering a program with individual participants or beneficiaries;

(h) Auditing purposes;

(i) Licensure processes;

(j) Investigation or law enforcement purposes;

(k) Administrative hearings;

(l) Litigation, complying with an order of the court, or subpoena;

(m) Human resource matters, including hiring, promotion, demotion, discharge, salary or compensation issues, processing leave requests or issues, **timecard** approvals or issues, and payroll processing;

(n) Complying with an executive order or policy;

(o) Complying with a board policy or a state administrative policy issued by the department of administrative services, the office of budget and management or other similar state agency; or

(p) Complying with a collective bargaining agreement provision.

(2) To the extent that the general processes described in paragraph (A) of this rule do not cover the following circumstances, for the purpose of carrying out specific duties of the board, authorized employees, contractors, and board members would also have valid reasons for accessing CPI in these following circumstances:

(a) Conducting a review of individuals who may be potential witnesses or other sources of information in a criminal or administrative proceeding;

(b) Administering the dangerous drug database also known as the "Ohio Automated Rx Reporting System" or "OARRS";

(c) Inspection purposes;

(d) Administering board orders; or

(e) Research performed for official duties.

(C) Confidentiality statutes, regulations, and rules.

The following federal statutes or regulations or state statutes or administrative rules make personal information maintained by the board confidential and identify the confidential personal information within the scope of rules promulgated by this board in accordance with section 1347.15 of the Revised Code:

(1) Social security numbers: 5 U.S.C. 552a (12/19/2014), unless the individual was told that the number would be disclosed.

(2) "Bureau of Criminal Identification and Investigation" criminal records check results: section 4776.04 of the Revised Code.

(3) Student education records: 20 U.S.C. 1232g (1/14/2013).

(4) Dangerous drug database information: division (C) of section 4729.79 of the Revised Code.

(5) Personal health information: 45 C.F.R. 164.502 (1/25/2013) from the federal "Health Insurance Portability and Accountability Act of 1996 (HIPAA)."

(6) Substance abuse treatment records: section 5119.27 of the Revised Code and 42 U.S.C. 290dd-2 (~~**7/20/2016**~~ **3/27/2020**).

(7) Records of dangerous drugs and controlled substances: section 3719.13 of the Revised Code.

(8) Security or infrastructure records: division (B) of section 149.433 of the Revised Code.

(9) Information or records that are **attorney-client** privileged: division (A)(1) of section 2317.02 of the Revised Code.

(10) Mediation communications or records: section 2710.03 of the Revised Code.

(11) Trial preparation records: division (A)(1)(g) of section 149.43 of the Revised Code.

(12) Court filings: Rule 45(D)(1) of the rules of superintendence for the courts of Ohio.

(13) Section 4729.23 of the Revised Code.

(D) Restricting and logging access to confidential personal information in computerized personal information systems.

For personal information systems that are computer systems and contain confidential personal information, the board shall do the following:

(1) Access restrictions. Access to confidential personal information that is kept electronically shall require a password or other authentication measure.

(2) Acquisition of a new computer system. When the board acquires a new computer system that stores, manages, or contains confidential personal information, the board shall include a mechanism for recording specific access by employees of the board to confidential personal information in the system.

(3) Upgrading existing computer systems. When the board modifies an existing computer system that stores, manages, or contains confidential personal information, the board shall make a determination whether the modification constitutes an upgrade. Any upgrades to a computer system shall include a mechanism for recording specific access by employees of the board to confidential personal information in the system.

(4) Logging requirements regarding confidential personal information in existing computer systems.

(a) The board shall require employees of the board who access confidential personal information within computer systems to maintain a log that records that access.

(b) Access to confidential information is not required to be entered into the log under the following circumstances:

(i) The employee or contractor of the board is accessing confidential personal information for official board purposes, including research, and the access is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(ii) The employee of the board is accessing confidential personal information for routine office procedures and the access is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(iii) The employee of the board comes into incidental contact with confidential personal information and the access of the information is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(c) The employee of the board accesses confidential personal information about an individual based upon a request made under either of the following circumstances:

(i) The individual requests confidential personal information about **the individual** ~~**himself or herself**~~.

(ii) The individual makes a request that the board take some action on that individual's behalf and accessing the confidential personal information is required in order to consider or process the request.

(d) For purposes of this paragraph, the board may choose the form or forms of logging, whether in electronic or paper formats.

(5) Log management. The board shall issue a policy that specifies the following:

(a) Who shall maintain the log;

(b) What information shall be captured in the log;

(c) How the log is to be stored;

(d) How long information kept in this log is to be retained.

(6) Nothing in this rule limits the board from requiring logging in any circumstance that it deems necessary.

Rule 4729-7-01 | Severability. (NO CHANGE)

If any provision of the rules in agency 4729 of the Administrative Code or if the application of any provision of the rules in agency 4729 of the Administrative Code is held or found to be invalid, unconstitutional, void, or ineffective, the invalidity shall not affect any other provision of the rules in this agency, or the application of any other provision of the rules in this agency, that can be given effect without the invalid provision or application, and, to this end, the provisions of the rules in this agency are hereby declared severable.

Rule 4729:1-3-05 | Therapeutic diabetic shoes. (NO CHANGE)

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacist may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacist shall not provide any other services that are authorized under Chapter 4779. of the Revised Code.

Rule 4729:2-3-01 | Practice as a pharmacy intern. (AMEND)

In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist:

(A) The sale of schedule V controlled substances pursuant to agency 4729 of the Administrative Code.

(B) The receipt of oral prescriptions pursuant to rule 4729:5-5-10 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code.

(C) The transfer and receipt of a non-controlled prescription copy pursuant to rule 4729:5-5-11 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code.

(D) The act of patient counseling pursuant to rule 4729:5-5-09 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code.

(E) The administration of immunizations pursuant to section 4729.41 of the Revised Code and agency 4729 of the Administrative Code.

(F) The documentation of informed consent to administer an immunization pursuant to section 4729.41 of the Revised Code.

(G) The dispensing of ~~**naloxone**~~ **overdose reversal drug** pursuant to section ~~**4729.44**~~ **3715.502** of the Revised Code and other dangerous drugs as authorized under Chapter 4729. of the Revised Code.

(H) Non-sterile compounding.

(I) Sterile compounding.

(J) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner.

(K) Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment.

(L) Performing diagnostic laboratory testing pursuant to agency 4729 of the Administrative Code.

(M) Requesting refill authorizations for dangerous drugs from a prescriber or the prescriber's agent.

(N) Notwithstanding the definition of direct supervision, a pharmacy intern may stock an automated drug dispensing unit and floor stock at a location licensed as a terminal distributor of dangerous drugs if a pharmacist is not physically present at the licensed location and all of the following apply:

(1) A pharmacist is readily available to answer questions of the intern;

(2) A pharmacist is responsible for conducting routine verifications of the activities of the intern to prevent the diversion of dangerous drugs;

(3) A pharmacist is fully responsible for all activities conducted by the intern at the licensed location.

Rule 4729:2-3-02 | Therapeutic diabetic shoes. (AMEND)

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacy intern, acting under the direct supervision of a pharmacist, may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacy intern, acting under the direct supervision of a pharmacist, shall not provide any other services that are authorized under Chapter 4779. of the Revised Code.

Rule 4729:5-1-02 | Licensed health professional authorized to prescribe drugs. (AMEND)

(A) The following persons licensed in accordance with Chapters 4715., 4723., 4725., 4729., 4730., 4731., and 4741. of the Revised Code are authorized by law to write prescriptions for drugs or dangerous drugs in the course of the person's professional practice:

(1) Chapter 4715. of the Revised Code: dentist.

(2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current therapeutic pharmaceutical agents certificate as defined in section 4725.01 of the Revised Code.

(3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.

(4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.

(5) Chapter 4723. of the Revised Code: advanced practice registered nurse in accordance with paragraph (D) of this rule.

(6) Chapter 4730. of the Revised Code: physician assistant in accordance with paragraph (E) of this rule.

(7) Chapter 4729. of the Revised Code: pharmacist in accordance with paragraph (F) of this rule.

(B) Those persons participating in an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within the person's scope of employment. Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)," "American Osteopathic Association (AOA)," or "Council of Podiatric Medical Education (CPME) of the American Podiatric Medical Association (APMA)." Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME, the AOA, or the APMA.

(C) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for dangerous drugs in the course of the prescriber's professional practice in a state other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio. The prescriber shall comply with the requirements of rule 4729:5-5-15 of the Administrative Code.

(D) An advanced practice registered nurse shall prescribe pursuant to the requirements set forth in section 4723.481 of the Revised Code and the rules adopted thereunder.

(E) A physician assistant who holds a valid prescriber number pursuant to section 4730.41 of the Revised Code issued by the state medical board is authorized to prescribe drugs and therapeutic devices in the exercise of physician-delegated prescriptive authority.

(F) A pharmacist who is either:

(1) Authorized to manage drug therapy pursuant **to** section 4729.39 of the Revised Code when authorized by a consult agreement and to the extent specified in the agreement; or

(2) Authorized to issue prescriptions for dangerous drugs pursuant to Chapter 4729. of the Revised Code.

Rule 4729:5-3-01 | Disposal of controlled substances. (AMEND)

(A) As used in this rule:

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

(2) "Controlled substance proof-of-use sheet" means a record that captures, at a minimum, the following information:

(a) Date;

(b) Patient name;

(c) Drug name;

(d) Drug strength;

(e) Quantity; and

(f) The positive identification of the individuals authorized by this rule who are responsible for removing the dangerous drugs from the medication cart, or other storage area, and transferring the drugs to the secure storage area.

(3) "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(4)

(a) "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:

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

(ii) A magnetic card reader;

(iii) A bar code reader;

(iv) A biometric method;

(v) A proximity badge reader;

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

(vii) 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

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

(b) 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.

(5) "State or local correctional facility" means any of the following:

(a) A "state correctional institution," as defined in section 2967.01 of the Revised Code;

(b) A "local correctional facility," as defined in section 2903.13 of the Revised Code.

(B) A terminal distributor of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (~~**4/1/2019**~~ **9/25/2023**). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (~~**4/1/2019**~~ **9/25/2023**) shall be maintained for a minimum of three years and made readily retrievable.

(1) If a long-term care facility uses a method of destruction pursuant to 21 C.F.R. 1317 (~~**4/1/2019**~~ **9/25/2023**), the controlled substances transferred to a collection receptacle or mail-back envelope must be completed by the director of nursing and witnessed by a nurse licensed in accordance with Chapter 4723. of the Revised Code. The amount of controlled substances transferred to the receptacle or mail-back envelope and the method of disposal used must be documented with the positive identification of both individuals on the corresponding controlled substance proof-of-use sheet.

(C) If a pharmacy is servicing a long-term care facility or a consultant pharmacist is employed by a long-term care facility and is having a pharmacist engage in the on-site destruction of ultimate user (i.e.~~,~~ patient-owned) controlled substances in the custodial care of nursing staff, the pharmacy or consultant pharmacist shall have policies and procedures in place to ensure compliance with and shall comply with all the following:

(1) Upon discontinuation of a patient's **use of a** controlled substance medication, a nurse and director of nursing, or other pharmacy or pharmacist-approved supervisory nurse, must document the removal of the patient's medication from the medication cart or storage area and record the transfer of the drugs to a secure storage area for disposal.

(2) The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on a controlled substance proof-of-use sheet. The proof-of-use sheet shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of removal and made readily retrievable.

(3) An Ohio licensed pharmacist or the director of nursing and another pharmacy or pharmacist-approved supervisory level nurse~~,~~ may destroy **an** ultimate ~~**user**~~ **user's** controlled substances using an on-site method at the location licensed as a terminal distributor of dangerous drugs. Both

individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (C)(4) of this rule. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

(4) A record of controlled substances destroyed shall be made containing the date of destruction, patient name, drug name, drug strength, quantity, method of destruction and the positive identification of the two individuals listed in paragraph (C)(3) of this rule responsible for the destruction.

(5) The record of controlled substance destruction pursuant to paragraph (C)(4) of this rule shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of destruction and made readily retrievable.

(6) Controlled substances shall be destroyed pursuant to this paragraph no later than ten days from the date the patient's controlled substance medication is removed from the medication cart or storage area in accordance with paragraph (C)(1) of this rule.

(D) A state or local correctional facility may engage in the on-site destruction of ultimate user (i.e., patient-owned) controlled substances in the custodial care of nursing staff, as follows:

(1) The correctional facility shall be licensed as a category III terminal distributor of dangerous drugs.

(2) The responsible person shall have policies and procedures in place to ensure compliance with and shall comply with all the following:

(a) Upon discontinuation of a patient's **use of a** controlled substance medication, the responsible person, director of nursing or a licensed pharmacist and another responsible person-approved nurse or corrections officer, must document the removal of the patient's medication from the medication cart or storage area and record the transfer of the drugs to a secure storage area for disposal.

(b) The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on a controlled substance proof-of-use sheet. The proof-of-use sheet shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of removal and made readily retrievable.

(c) The responsible person, director of nursing, or a licensed pharmacist and another responsible person-approved nurse or corrections officer, may destroy ultimate user controlled substances using an on-site method at the location licensed as a terminal distributor of dangerous drugs. Both individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (D)(2)(d) of this rule. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

(d) A record of controlled substances destroyed shall be made containing the date of destruction, patient name, drug name, drug strength, quantity, method of destruction and the positive identification of the two individuals listed in the paragraph (D)(2)(c) of this rule responsible for the destruction. The record of controlled substance destruction shall be maintained on-site at the

location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of destruction and made readily retrievable.

(e) Controlled substances shall be destroyed no later than ten days from the date the patient's controlled substance medication is removed from the medication cart or storage area in accordance with paragraph (D)(2)(a) this rule.

(E) The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method by any person legally authorized under Chapters 3719. and 4729. of the Revised Code and this division of the Administrative Code to possess controlled substance dangerous drugs. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable. A record of such destruction shall be made in accordance with 21 C.F.R. 1304 (~~**4/1/2019**~~ **9/25/2023**) and shall be maintained for a minimum of three years from the date of destruction and made readily retrievable to the board of pharmacy upon request.

Rule 4729:5-3-03 | Inspections and corrective actions. (AMEND)

(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by the state board of pharmacy as a terminal distributor of dangerous drugs is subject to an on-site inspection by the board. An authorized board ~~**agent**~~ **employee** may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board **employee's** ~~**agent's**~~ credentials, the ~~**agent**~~ **employee** shall be permitted to enter the licensed entity.

(B) Submission of an application for a license as a terminal distributor of dangerous drugs with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board **employee** ~~**agent**~~.

(C) If an **employee** ~~**agent**~~ of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the **employee** ~~**agent**~~ may provide written notice, in a manner determined by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code and this ~~**divsion**~~ **division** of the Administrative Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, or Chapter 3715. of the Revised Code; **or**

(4) Violating any provision of the federal drug abuse control laws or regulations or Chapter 2925. or 3719. of the Revised Code.

(E) The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

Rule 4729:5-3-05 | Confidentiality of patient records. (AMEND)

(A) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

(1) The patient, or owner if the patient is an animal, for whom the prescription or medication order was issued.

(2) The prescriber who issued the prescription or medication order, or a subsequent treating prescriber.

(3) Licensed health care personnel who are responsible for the care of the patient.

(4) A member, inspector, agent, or investigator of the state board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.

(5) An agent of an Ohio licensing agency that is responsible for the licensure or registration of a health professional authorized to prescribe drugs as defined in section 4729.01 of the Revised Code when enforcing that agency's chapter of the Revised Code.

(6) A state or federal agency charged with the responsibility of providing medical care (i.e., medicaid, medicare, workers' compensation, etc.) for the patient upon a written request by an authorized representative of the agency requesting such information.

(7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.

(8) An agent who contracts with the terminal distributor of dangerous drugs as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for privacy of individually identifiable health information.

(9) Any person, other than those listed in paragraphs (A)(1) to (A)(8) of this rule, only when the patient has given consent for such disclosure in writing. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient.

In an emergency, the terminal distributor of dangerous drugs may disclose the information when, in the professional judgment of the pharmacist or healthcare provider, it is deemed to be in the best interest of the patient. A pharmacist or healthcare provider making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.

(B) Testimonial privilege is not waived for any communication between a prescriber, a pharmacist, and a patient pursuant to section 2317.02 of the Revised Code.

(C) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released, upon request, to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:

(1) Prescription identification number; or, if an order for medication, the name of the patient;

(2) The drugs prescribed or ordered;

(3) Quantity of drugs prescribed, dispensed, administered or personally furnished;

(4) Name of the prescriber;

(5) Date, name of agency, and signature of person removing the records.

(D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(9) of this rule, shall be kept on file at the terminal distributor of dangerous drugs for a period of three years in a readily retrievable manner.

(E) All patient records maintained by a terminal distributor of dangerous drugs shall be maintained in accordance with the following:

(1) For human patients, the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and

(2) All state and federal laws, rules, and regulations.

Rule 4729:5-3-06 | Storage of adulterated drugs. (AMEND)

To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration.

(A) Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(B) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(C) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:5-3-01 of the Administrative Code.

Rule 4729:5-3-07 | Controlled substances inventory requirements. (NO CHANGE)

(A) Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014).

(B) All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date.

(C) The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs.

(D) All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable.

(E) When a drug or compound is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule.

(F) In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

Rule 4729:5-3-08 | Sales of dangerous drugs on-line. (AMEND)

(A) All persons selling or offering to sell dangerous drugs via the internet at retail, into, out of, or within Ohio must be properly licensed with the state board of pharmacy.

(B) All terminal distributors of dangerous drugs who sell or offer to sell dangerous drugs at retail on the internet to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws, rules**,** and regulations governing the legal distribution of dangerous drugs.

(C) Except as provided in paragraph (F) of this rule, all terminal distributors of dangerous drugs who sell or offer to sell dangerous drugs at retail on the internet to persons located in Ohio shall maintain **a digital pharmacy** accreditation ~~**as a verified internet pharmacy practice site**~~ from the national association of boards of pharmacy, **as approved by the board**.

(D) Websites owned and/or maintained by a terminal distributor of dangerous drugs who sell or offer to sell dangerous drugs at retail on the internet to persons located in Ohio or any other state must provide the following information to the public:

(1) Name under which the terminal distributor is licensed to do business as in Ohio.

(2) Full address of the licensed location.

(3) Telephone number where the terminal distributor may be contacted during regular business hours.

(4) A list of the states in which the terminal distributor may legally sell dangerous drugs.

(5) The name, address**,** and how the state licensing agency and the drug enforcement administration may be contacted in each state in which the person is authorized to do business. This may include a link to the agency's and the drug enforcement administration's website.

(E) Any Ohio licensed terminal distributor requesting personal information from the public by way of the internet (**e.g.,** questionnaire forms, e-mail, etc.) must provide for security and confidentiality of the information. This portion of the website must also provide information regarding how the personal information will be used, pursuant to all federal and state laws, rules, and regulations, and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

(F) A veterinarian, licensed under Chapter 4741. of the Revised Code, may sell or offer to sell dangerous drugs via the internet only when the internet pharmacy~~,~~ that fulfills the dangerous drug prescription or facilitates the sale of the dangerous drug maintains **a digital pharmacy** accreditation ~~**as a verified internet pharmacy practice site**~~ from the national association of boards of pharmacy.

Rule 4729:5-3-10 | Employment of individuals with felony convictions. (AMEND)

(A) Pursuant to 21 C.F.R. 1301.76 (~~**9/9/2014**~~ **6/22/2023**), a terminal distributor of dangerous drugs that is a United States drug enforcement administration registrant shall not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for drug enforcement administration registration denied, revoked, or surrendered for cause.

"For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

(B) Paragraph (A) of this rule does not apply if a waiver is obtained by a licensee pursuant to 21 C.F.R. 1307.03 (3/9/2010).

Rule 4729:5-7-01 | Definitions - Charitable pharmacies. (NO CHANGE)

As used in Chapter 4729:5-7 of the Administrative Code:

(A) "Charitable pharmacy" means a pharmacy that meets all of the following requirements:

(1) Holds a terminal distributor of dangerous drug license issued under section 4729.54 of the Revised Code;

(2) Is exempt from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3) (5/28/2015); and

(3) Is not a hospital as defined in section 3727.01 of the Revised Code.

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

(C) "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.

(D) "Sample drug" has the same meaning as in section 2925.01 of the Revised Code.

Rule 4729:5-7-02 | Licensure, compliance, and support personnel. (AMEND)

(A) A pharmacy seeking authorization to be a charitable pharmacy shall maintain a terminal distributor of dangerous drug license. An application for licensure shall include the following:

(1) A completed terminal distributor application requesting licensure as a charitable pharmacy;

(2) Documentation to support the exemption from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3) (5/28/2015);

(3) The fee for the appropriate category of licensure; and

(4) Any other requirements set forth in division 4729:5 of the Administrative Code.

(B) A charitable pharmacy is considered to be a pharmacy pursuant to section 4729.01 of the Revised Code and shall comply with all federal and state laws, rules, and regulations that pertain to outpatient pharmacies and the practice of pharmacy, including Chapter 4729:5-5 of the Administrative Code.

(C) A charitable pharmacy may designate employees and volunteers as support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, for the purposes of sorting donations of non-controlled substance dangerous drugs.

(1) Drug sorting shall be conducted under the personal supervision of a licensed pharmacist.

(2) Support personnel are not permitted to label, package, repackage, or dispense dangerous drugs.

(3) The charitable pharmacy shall have written policies and procedures for drug sorting by support personnel. Such policies and procedures shall require documentation of all activities related to drug sorting, including participation logs, support personal information (name, address, contact phone, etc.), and a daily activity log to be signed by the licensed pharmacist or pharmacists providing supervision. All documents and records must be readily retrievable and shall be maintained on-site for a period of three years.

Rule 4729:5-7-03 | Persons eligible to transfer sample drugs to a charitable pharmacy. (AMEND)

(A) An eligible sample drug shall only be transferred directly to a charitable pharmacy by any of the following:

(1) A manufacturer licensed in accordance with section 4729.52 of the Revised Code, including a representative of the manufacturer;

(2) A person licensed in accordance with section 4729.52 of the Revised Code acting on behalf of a manufacturer; or

(3) A prescriber practicing at a location that is licensed as a terminal distributor of dangerous drugs, unless exempt from licensure pursuant to section 4729.541 of the Revised Code.

(B) If a sample drug is transferred by a prescriber:

(1) A record must be created by the prescriber documenting the transfer. The record shall contain the:

(a) Name and address of the supplying prescriber;

(b) Name, strength, and quantity of the sample drug being transferred;

(c) Date of the sample drug transfer; and

(d) Name and address of the charitable pharmacy receiving the sample drug.

(2) A copy of all required records documenting the transfer of a sample drug shall be kept by the prescriber and the charitable pharmacy for a minimum of three years and shall be stored in a readily retrievable manner.

(3) The prescriber shall not transfer a sample drug to a charitable pharmacy unless the sample drug was received directly from a manufacturer, a manufacturer's representative, or by a person licensed in accordance with section 4729.52 of the Revised Code acting on behalf of a manufacturer.

(4) The sample drug complies with the requirements of rule 4729:5-7-04 of the Administrative Code.

(5) The sample drug must not have any physical signs of tampering.

(6) The sample drug packaging must not have any physical signs of tampering.

(C) Nothing in this rule prohibits the donation of a sample drug to a charitable pharmacy operating as a drug repository in accordance with Chapter 4729:5-10 of the Administrative Code.

Rule 4729:5-7-04 | Eligibility requirements for sample drugs received by a charitable pharmacy. (NO CHANGE)

An eligible sample drug received by a charitable pharmacy shall meet all the following requirements:

(A) The sample drug is in the original manufacturer's container and the container is clearly marked as a sample.

(B) Prior to being transferred, the sample drug has been stored under the proper conditions to prevent deterioration or adulteration.

(C) The sample drug is clearly marked with an expiration date and lot number.

(D) The sample drug is not expired.

(E) The sample drug is not a controlled substance.

Rule 4729:5-7-05 | Dispensing a sample drug by a charitable pharmacy. (NO CHANGE)

(A) A pharmacist in a charitable pharmacy must have a valid prescription prior to dispensing a sample drug to a patient.

(B) The pharmacy shall comply with all requirements for the dispensing of drugs pursuant to Chapter 4729:5-5 of the Administrative Code.

(C) The charitable pharmacy shall determine the eligibility requirements for a patient to receive a sample drug.

(D) The sample drug shall be dispensed to the patient free of charge.

(E) The sample drug may be dispensed:

(1) In the manufacturer's original container where the container is clearly marked as a sample; or

(2) By removing the sample drug from the original container only if the prescription label on the appropriate container, pursuant to all state and federal requirements, clearly states that the drug dispensed is a sample drug.

Rule 4729:5-12-01 | Medication Therapy Management - Definitions. (AMEND)

As used in in Chapter 4729:5-12 of the Administrative Code:

(A) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(B) "Medication therapy management" or "MTM" means:

(1) A distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication therapy management can be an independent service provided by a pharmacist or pharmacy intern under the direct supervision of a pharmacist or can be in conjunction with the dispensing of a dangerous drug with the objectives of:

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between a prescriber and pharmacist; and

(e) Improving outcomes.

(2) Medication therapy management may only be performed by the following:

(a) An Ohio licensed pharmacist;

(b) An Ohio licensed pharmacy intern practicing in this state under the direct supervision of a pharmacist; and

(c) A pharmacist or pharmacy intern practicing in another state in accordance with that state's laws and rules.

(C) "Limited category II terminal distributor of dangerous drugs license with a medication therapy management classification" means a limited category II terminal distributor of dangerous drugs license issued by the state board of pharmacy in accordance with section 4729.54 of the Revised Code to a person solely engaged in the practice of medication therapy management.

A limited category II terminal distributor of dangerous drugs license with a medication therapy management classification does not entitle the holder to possess or sell dangerous drugs.

(D) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that they can be separated out from all other records and produced for review by an agent of the board within three business days.

(E) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

Rule 4729:5-12-02 | Medication Therapy Management. (AMEND)

(A) A pharmacist or pharmacy intern under the direct supervision of a pharmacist ~~**that**~~ **who** provides medication therapy management services shall practice at a location that complies with one of the following:

(1) If the person or entity solely performs medication therapy management in this state or to residents of this state, the location shall be licensed as a limited category II terminal distributor of dangerous drugs license with a medication therapy management classification; or

(2) If the person or entity engages in the sale of dangerous drugs, the location is appropriately licensed as a terminal distributor of dangerous drugs.

(B) A non-resident provider of medication therapy management shall obtain the appropriate licensure in accordance with paragraph (A) of this rule.

(C) The number of interns engaged in the practice of medication therapy management at any time is limited to not more than two for each pharmacist on duty unless otherwise approved by the board.

(D) A pharmacist or pharmacy intern under the direct supervision of a pharmacist that provides medication therapy management services shall ensure that they are provided according to the individual needs of a patient and may include the following:

(1) Performing or otherwise obtaining a patient's health status assessment;

(2) Developing a medication treatment plan for monitoring and evaluating a patient's response to therapy;

(3) Monitoring the safety and effectiveness of the medication therapy;

(4) Performing a medication review to identify, prevent, or resolve medication related problems;

(5) Providing education and training to a patient or a patient's agent on the use or administration of the medication;

(6) Documenting the delivery of care, communications with other involved healthcare providers, and other appropriate documentation and records pursuant to paragraph (E) of this rule;

(7) Providing necessary services to enhance a patient's adherence with the therapeutic regimen;

(8) Integrating medication therapy management services within the overall health management plan for a patient;

(9) Providing for the safe custody and security of all records and compliance with all applicable federal and state laws, rules, and regulations concerning the security and privacy of patient information; and

(10) Any other activity as determined by the board.

(E) All records relating to medication therapy management service shall:

(1) Provide accountability and an audit trail; and

(2) Be uniformly maintained for a period of three years and shall be made readily retrievable.

4729:6-2-03 – Criminal Records Checks. (AMEND)

(A) **Unless otherwise approved by the board, a** new distributor of dangerous drug license will not be issued until the following persons submit fingerprints to the Ohio bureau of criminal ~~**identification and**~~ investigation (BCI~~**&I**~~) for a criminal records check in accordance with paragraph (C) of this rule:

(1) The responsible person on the application for licensure; and

(2) The following persons based upon the drug distributor's business type:

(a) All partners of a partnership.

(b) The sole proprietor of a sole proprietorship.

(c) All members of a limited-liability company.

(i) If the limited liability company has a member which is not a natural person, the limited liability company's president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position.

(ii) If the limited liability company's sole member is a publicly traded corporation, the limited-liability company may seek a waiver pursuant to paragraph (A)(3) of this rule.

(~~**c**~~ **d**) Except as provided in paragraph (A)(3) of this rule, the president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and, if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation.

If the director or the director's designee determines other person(s) in the organizational structure have substantial control, such as the power to influence management and operational decision-making over the distribution of dangerous drugs, the director or designee may require a criminal records check of those with substantial control in addition to or in place of those persons set forth in this paragraph.

~~**(d) The agency director of a government agency.**~~

(e) The executive director or any equivalent position of a nonprofit organization.

(3) For publicly traded corporations, the board's executive director or the ~~**directors**~~ **director's** designee may waive the criminal records checks required in paragraph (A)(2)(c) of this rule under the following circumstances:

(a) The ~~**public**~~ **publicly** traded corporation submits a request to the executive director and includes the organizational structure of the corporation, including all corporate officer positions responsible for directing the distribution of dangerous drugs. The director or the ~~**directors**~~ **director's** designee may request additional information about the corporation's organizational structure.

(b) The executive director or the director's designee approves an alternate list of corporate officers ~~**that**~~ **who** are required to submit a criminal records check. If approval is not provided, the publicly traded corporation shall comply with paragraph (A)(2)(c) of this rule.

(B) The persons listed in paragraph (A)(2) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to a criminal records check in accordance with this rule.

(C) All criminal records checks conducted in accordance with this rule shall consist of both a BCI~~**&I**~~ criminal records check and a federal bureau of investigations records check (FBI) and shall comply with the following:

(1) Be based on electronic fingerprint impressions that are submitted directly to BCI~~**&I**~~ from a WebCheck provider agency or ink impressions. The state board of pharmacy may accept the results of a criminal records check based on ink impressions only in the following circumstances:

(a) Readable electronic fingerprint impressions cannot be obtained or are rejected by either BCI~~**&I**~~ or FBI;

(b) The person or persons listed in paragraph (A) of this rule reside outside of the state of Ohio; or

(c) The person or persons listed in paragraph (A) of this rule have a home address that is seventy-five miles or more from the nearest WebCheck location.

(2) Results will only be considered valid if the fingerprint impressions were obtained within one year of the date the application is received by the board.

(3) The results of the criminal records check must be sent directly to the state board of pharmacy from BCI~~**&I**~~.

(D) Only new persons listed in paragraphs (A)(1) and (A)(2) of this rule shall be required to submit to a criminal records check for a new application resulting from a change in the description of a distributor of dangerous drugs pursuant to rule 4729:6-2-05 of the Administrative Code.

4729:6-2-04 – Drug Distributor Applications. (AMEND)

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a distributor of dangerous drugs:

(1) The name, full physical business address (not a post office box), and telephone number.

(2) All trade, fictitious, or business names used by the licensee (e.g.**,** "doing business as" or "formerly known as"). ~~**Trade or business names shall not be identical to the name used by another, unrelated drug distributor permitted to purchase or sell drugs in this state.**~~

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs located in this state or used to distribute drugs into this state.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, **limited liability company,** corporation, ~~**or**~~ government agency**, or nonprofit organization**).

(5) The following information for the owner(s) and/or operator(s) of the drug distributor:

(a) For a partnership:

(i) The full name, business address, social security number, and date of birth of each partner. If the partner is not a natural person, each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(ii) The name of the partnership.

(iii) The partnership's federal employer identification number.

(b) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.

(c) For a limited lability company: the full name, business address, social security number, and date of birth of each member. If the member(s) is not a natural person, each business entity that is a member having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(~~**b**~~ **d**) For a corporation:

(i) The full name, business address, social security number**,** and date of birth of the corporation's president, vice-president, secretary, treasurer**,** and chief executive officer, or any equivalent position. For a publicly traded corporation that obtains a criminal records check waiver pursuant to paragraph (A)(3) of rule 4729:6-2-03 of the Administrative Code, the full name, business address, social security number**,** and date of birth of the corporate officers subject to a criminal records check as determined by the board**'**s executive director or director**'**s designee.

(ii) The name or names of the corporation.

(iii) The state of incorporation.

(iv) The corporation's federal employer identification number.

(v) The name of the parent company, if applicable.

(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.

~~**(c) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.**~~

(~~**d**~~ **e**) For a government agency: the full name, business address, social security number, and date of birth of the agency director.

(f) For a nonprofit organization: the full name, business address, social security number, and date of birth of the executive director or any equivalent position.

(6) If the entity submitting an application for a distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, the licensing process shall include an inquiry to the licensing authority of the state ~~**or jurisdiction**~~ **where located** to determine if the entity possesses a current and valid license **or registration** to distribute dangerous drugs in that state ~~**or jurisdiction**~~ and any disciplinary action, including actions pending, the licensing authority is taking or may have taken against the entity. This information may be used to determine if the business entity should be granted a license by the state board of pharmacy. An entity located outside the boundaries of the state of Ohio that is making application for licensure as a third~~-~~party logistics provider or virtual wholesaler shall maintain **an applicable** ~~**verified-accredited wholesale distributors (VAWD)**~~ accreditation from the national association of boards of pharmacy if the state where the entity resides does not license such entities.

(7) If applicable, proof of the ~~**entitys**~~ **entity's** valid registration with the United States food and drug administration and/or the United States drug enforcement administration.

(8) Any information required on the application as determined by the board.

(9) Any follow-up information as deemed necessary by the board's executive director or the director's designee upon receipt of the application materials.

(B) Prior to the end of the licensing period established in rule 4729:6-2-02 of the Administrative Code, a renewal application requesting such information as the state board of pharmacy may require will be sent to the email or physical address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the date established in rule 4729:6-2-02 of the Administrative Code.

(C) The Board shall not license an entity located outside of the United States.

(D) Except as provided in (D)(1) of this rule, an applicant or licensee engaged in the distribution of dangerous drugs shall obtain all applicable licenses issued in accordance with this division of the Administrative Code.

(1) This provision does not apply to a manufacturer who is also engaged in the wholesale distribution of dangerous drugs.

(2) An applicant or licensee engaged in activities requiring multiple licenses shall ensure that all requirements for each license can be maintained and all applicable drug records are segregated by license type.

4729:6-2-06 – Procedure for discontinuing business as a distributor of dangerous drugs. (AMEND)

(A) A distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the state board of pharmacy. The notice shall be submitted, in a manner determined by the board, **within thirty days of discontinuation of business as a distributor of dangerous drugs.** ~~**at least thirty days in advance of the proposed date of discontinuing business, unless waived by the board's executive director or the director's designee due to extraordinary circumstances beyond the licensee's control.**~~ This notice shall include the following information:

(1) The name, address, and license number of the drug distributor discontinuing business.

(2) If applicable, the name, address, and license number of the drug distributor or other authorized entity where the dangerous drugs will be transferred.

(3) The name and address of the secured location where the records required to be maintained in accordance with this division will be stored.

(4) The proposed date of discontinuing business.

(B) Unless the licensee is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the licensee discontinuing business may transfer the dangerous drugs and **drug** records**.** ~~**in accordance with the following:**~~

~~**(1)**~~ **(C)** On the date of discontinuing business, a complete inventory~~.~~ of all controlled substances being transferred or disposed of, in accordance with rule 4729:6-3-01 of the Administrative Code, shall be made. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred or disposed.

~~**(2)**~~ This inventory shall serve as the final inventory of the licensee discontinuing business and the initial inventory of the licensee to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer.

Rule 4729:6-3-01 | Disposal of controlled substances. (AMEND)

(A) As used in this rule:

"Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(B) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (~~**1/1/2016**~~ **9/25/2023**). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (~~**1/1/2016**~~ **9/25/2023**) shall be maintained for a minimum of ~~**three**~~ **five** years and made readily retrievable to the board of pharmacy upon request.

Rule 4729:6-3-03 | Inspections and corrective actions. (AMEND)

(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by state board of pharmacy in accordance with section 4729.52 of the Revised Code or this ~~divsion~~ **division** of the Administrative Code is subject to an on-site inspection by the board. An authorized board ~~agent~~ **employee** may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board ~~agent's~~ **employee's** credentials, the agent shall be permitted to enter the licensed entity.

(B) Submission of an application for a license, in accordance with section 4729.52 of the Revised Code or this ~~divsion~~ **division** of the Administrative Code, with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board **employee** ~~agent~~.

(C) If an **employee** ~~agent~~ of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the **employee** ~~agent~~ may provide written notice, in a manner determined by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code and this division of the Administrative Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, or Chapter 3715. of the Revised Code; **or**

(4) Violating any provision of the federal drug abuse control laws or regulations or Chapter 2925. or 3719. of the Revised Code.

(E) The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

Rule 4729:6-3-04 | Verification of licensure prior to sale or purchase. (AMEND)

(A) As used in section 4729.60 of the Revised Code and in this rule, "roster" means any of the following:

(1) The online roster maintained as part of the board's ~~**elicensing**~~ **electronic licensing** system (available on the board's website: www.pharmacy.ohio.gov);

(2) An electronic list of licensees and registrants if maintained by the board; and

(3) Any other format capable of meeting the requirements of section 4729.60 of the Revised Code and this rule that has been approved by the board.

(B) Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the board to determine if the purchaser is licensed as either:

(1) A terminal distributor of dangerous drugs. For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drugs ordered.

(2) A distributor of dangerous drugs.

(C) Paragraph (B) of this rule does not apply when a drug distributor sells or distributes dangerous drugs to any of the following:

(1) A person specified in division (B)(4) of section 4729.51 of the Revised Code; or

(2) Any of the exempted persons listed in section 4729.541 of the Revised Code**.**

(D) A distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons listed in section 4729.541 of the Revised Code and shall ensure the purchaser meets the exemption criteria.

(1) To confirm a purchasing prescriber meets the exemption criteria pursuant to section 4729.541 of the Revised Code, the drug distributor shall comply with all the following:

(a) Provide the prescriber the requirements in Ohio law of when a prescriber is required to hold a license as a terminal distributor of dangerous drugs;

(b) Verify the prescriber is appropriately licensed in this state to prescribe dangerous drugs or drug therapy related devices in the course of the individual's professional practice;

(c) Require the prescriber who claims an exemption to the terminal distributor of dangerous drug licensing requirement to attest in writing, which may include an electronic signature, that the prescriber meets the licensing exemptions in section 4729.541 of the Revised Code on an annual basis; and

(d) Ensure that all attestations are maintained by the drug distributor for a period of ~~**three**~~ **five** years after the sale or distribution of the dangerous drug.

(2) To confirm any other person purchasing dangerous drugs meets the exemption criteria pursuant to section 4729.541 of the Revised Code, the drug distributor shall comply with all the following:

(a) Provide the person the requirements in Ohio law of when a person is required to hold a license as a terminal distributor of dangerous drugs;

(b) Require the person who claims an exemption to the terminal distributor of dangerous drug licensing requirement to attest in writing, which may include an electronic signature, that the person meets the licensing exemptions in section 4729.541 of the Revised Code on an annual basis; and

(c) Ensure that all attestations are maintained by the drug distributor for a period of **~~three~~** **five** years after the sale or distribution of the dangerous drug.

(E) Except as provided in paragraph (F) of this rule, before a drug distributor located in this state may purchase or receive dangerous drugs, the distributor shall conduct a documented query of a roster maintained by the board to determine if the seller is licensed as a distributor of dangerous drugs. If a licensed drug distributor conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the distributor shall be deemed not to have violated this rule.

(F) A **third-party** **~~third party~~** logistics provider is exempt from the requirements of paragraph (B) of this rule if the licensee has access to documentation indicating the entity responsible for directing the sale or disposition of the drugs has complied with the requirements of this rule.

Rule 4729:6-3-05 | Suspicious Order Monitoring and Due Diligence. (AMEND)

(A) As used in this rule:

(1) "Customer" means a person located in this state that orders or seeks to order a reported drug from an Ohio licensed drug distributor and includes the following:

(a) A licensed terminal distributor of dangerous drugs; or

(b) A prescriber who possesses, or possesses for sale or sells, at retail, a dangerous drug.

(2) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(3) "Reported drug" means any dangerous drug whose sale is required to be reported to the drug database pursuant to ~~**agency 4729**~~ **division 4729:8** of the Administrative Code. **A reported drug shall not include any list I or list II chemicals listed in 21 CFR Section 1310.02 (10/31/2023).**

(B) This rule only applies to the following drug distributors licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs;

(2) Virtual wholesalers;

(3) Manufacturers of dangerous drugs; and

(4) Outsourcing facilities.

(C) Drug distributors listed in paragraph (B) of this rule shall design and operate a system to identify and report suspicious orders by customers for reported drugs. Suspicious orders shall include, but are not limited to, the following:

(1) Orders of unusual size;

(2) Orders deviating substantially from a normal pattern; and

(3) Orders of unusual frequency.

(D) Prior to any shipment of an order that a distributor has identified as suspicious, two persons designated by the distributor's responsible person must independently analyze the order. In order to proceed with the shipment and complete the sale, each of the two ~~**persons**~~ **people designated** must determine that the order is not likely to be diverted from legitimate channels.

(E) All suspicious orders, regardless of actual sale, shall be submitted electronically in a manner and format determined by the board. The electronic submission of suspicious orders shall include all information as required by the board and shall be submitted within five days of the order being identified as suspicious by the drug distributor.

(F) All drug distributors listed in paragraph (B) of this rule shall submit a zero report, in a manner determined by the board, if no suspicious orders have been identified by the distributor in a

calendar month. The zero report shall be submitted within fifteen days of the end of the calendar month.

(G)

(1) Except as provided in paragraph (G)(2) of this rule, a drug distributor listed in paragraph (B) of this rule shall exercise due diligence to identify customers ordering or seeking to order reported drugs to establish the normal and expected transactions conducted by those persons and to identify and prevent the sale of reported drugs that are likely to be diverted from legitimate channels. Such measures shall include, but are not limited to, the following which shall ~~to~~ be conducted prior to an initial sale and on an annual basis:

(a) Questionnaires and affirmative steps by the drug distributor to confirm the accuracy and validity of the information provided.

(b) For a customer who is a prescriber, confirmation of prescriber type (physician, dentist, veterinarian, etc.), specialty practice area (oncology, geriatrics, pain management, etc.) and if the prescriber personally furnishes reported drugs and the quantity personally furnished.

(c) Review of drug utilization reports.

(d) Obtaining and conducting a review of the following information:

(i) The methods of payment accepted (cash, insurance, medicaid, medicare) and in what ratios;

(ii) The ratio of controlled vs. non-controlled drug orders and overall sales;

(iii) Orders for reported drugs from other drug distributors made available by the United States drug enforcement ~~administrations~~ **administration's** automation of reports and consolidated orders system; and

(iv) The proportion of out-of-state patients served compared to in-state patients.

(2) A drug distributor receiving a request for an initial sale for a reported drug may conduct the sale without complying with paragraph (G)(1) of this rule if all the following applies:

(a) The sale is to an institutional facility as defined in ~~agency 4729~~ **Chapter 4729:5-9** of the Revised Code that is a new customer of the distributor;

(b) The drug distributor documents that the order is to meet an emergent need; and

(c) The drug distributor completes the requirements set forth in paragraph (G)(1) of the rule no later than sixty days from the date of sale.

(H) Any customer that may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels, including those to whom a drug distributor refuses to sell, shall be electronically reported by the drug distributor in a manner and format determined by the board. The electronic submission of such customers shall include all information as required by the board and shall be submitted within five days of refusal, cessation~~,~~ or identification by the drug distributor.

~~**(I) Within ninety days of the effective date of this rule, a drug distributor shall provide, in a manner and format determined by the board, information on all customers in this state the distributor has refused to sell to or has stopped selling to within the past three years because the distributor has identified the customer as engaging in possible activities that may cause reported drugs to be diverted from legitimate channels. The submission of information shall contain the customer's name, address, drug enforcement administration registration (if applicable), terminal distributor of dangerous drugs license number (if applicable), and a detailed explanation of why the distributor identified the customer as a possible diversion risk.**~~

(**I** ~~J~~) All drug distributors described in paragraph (~~A~~ **B**) of this rule shall maintain and implement policies and procedures that include all the following:

(1) The design and operation of a suspicious order monitoring and reporting system.

(2) A system to collect the necessary information on customers in accordance with paragraph (G) of this rule.

(3) Mandatory training, to be conducted annually, for staff responsible for the processing of all orders for reported drugs that includes all the following:

(a) The drug distributor's suspicious order monitoring system;

(b) The process to collect all relevant information on customers in accordance with paragraph (G) of this rule;

(c) The process for submission of suspicious orders and customers who may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels to the board; and

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

(**J** ~~K~~) All policies and procedures maintained in accordance with paragraph ~~(J)~~ **(I)** of this rule shall be reviewed and updated on an annual basis.

Rule 4729:6-3-06 | Controlled Substances Inventory Requirements. (AMEND)

(A) All category III drug distributor licenses shall complete a controlled substances inventory in accordance with section 1304.11 of the Code of Federal Regulations (9/9/2014).

(B) The drug distributor's responsible person shall be responsible for completing and maintaining this inventory record.

(C) All inventory records shall be maintained for a period of ~~**three**~~ **five** years from the completion date of the inventory and made readily retrievable.

(D) When a drug or compound is added to the schedule of controlled substances by state or federal law, rule~~,~~ or regulation, a drug distributor shall complete an inventory pursuant to paragraph (A) of this rule of all stocks of such substance no later than ten days after the drug is added to the schedule.

Rule 4729:6-3-07 | Sales of dangerous drugs on-line. (AMEND)

(A) All persons selling or offering to sell dangerous drugs at ~~**retail or**~~ wholesale **via the internet** into, out of, or within Ohio must be appropriately licensed by the state board of pharmacy.

(B) All drug distributors licensed with the state board of pharmacy and who sell or offer to sell dangerous drugs on the internet to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws, rules**,** and regulations governing the legal distribution of dangerous drugs.

(C) Websites owned and/or maintained by Ohio licensed dangerous drug distributors who sell or offer to sell dangerous drugs on the internet must provide the following information to the public:

(1) Name under which the dangerous drug distributor is licensed to do business as in Ohio.

(2) Full address of licensed location.

(3) Telephone number where the drug distributor may be contacted during regular business hours.

(4) A list of the states in which the dangerous drug distributor may legally sell dangerous drugs.

(5) The name, address**,** and how the state licensing agency and the drug enforcement administration may be contacted in each state in which the person is authorized to do business. This may include a link to the agency's and the drug enforcement ~~**administrations**~~ **administration's** website.

(D) Any Ohio licensed drug distributor requesting personal information from the public by way of the internet (**e.g.,** questionnaire forms or e-mail) must provide for security and confidentiality of the information. This portion of the website must also provide information regarding how the personal information will be used, pursuant to all federal and state laws, rules, and regulations, and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

Rule 4729:6-3-08 | Distributor of dangerous drugs samples and complimentary supplies. (AMEND)

(A) As used in this rule:

(1) "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Except as provided in paragraph (E) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code in accordance with paragraph (B) of this rule.

(2) "Complimentary supply" also known as "starter packs," "initial dose packs," "starter stocks," "replacement programs," or any other similar supply means a drug or pharmaceutical preparation that is distributed without charge by licensed drug distributors to pharmacies licensed as terminal distributors of dangerous drugs or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug.

(B) No drug distributor or distributor's representative, including sales representatives, may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber and the entity:

(1) Is licensed as a distributor of dangerous drugs **or is exempted from licensure in accordance with 4729.541 of the Revised Code**; and

(2) Maintains a record of such distribution for five years from the date of sale or distribution. Such records shall be made readily retrievable.

(C) Complimentary supplies are subject to the same requirements as stock shipments of dangerous drugs pursuant to agency 4729 of the Administrative Code and Chapters 4729., 3719., and 3715. of the Revised Code.

(D) A drug distributor shall comply with rule 4729:6-3-04 of the Administrative Code prior to the sale or distribution of complimentary supplies and samples.

(E) Nothing in this rule prohibits a pharmacist working, regardless of compensation, in a charitable pharmacy from dispensing a sample drug to a person in accordance with section 3719.811 of the Revised Code and agency 4729 of the Administrative Code.

(F) Paragraph (A)(1) of this rule does not permit a pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code from ordering, dispensing, or personally furnishing a sample within a pharmacy licensed as a terminal distributor of dangerous drugs.

Rule 4729:6-5-01 | Wholesale Distributors - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for distribution and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph (B)(2)-(a) of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(a) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(3) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to regularly document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than ~~**three**~~ **five** years from the last documented temperature and humidity reading.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and expired dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are expired, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify,**~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug

meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling~~,~~ as a result of storage or shipping.

(G) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures with all the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~**of**~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education, experience~~,~~ and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws, rules~~,~~ and regulations. This shall include, but is not limited to, all applicable laws, regulations~~,~~ and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(K) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws, rules~~,~~ or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work**,** or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a wholesale distributor of dangerous drugs for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in **21 CFR 1301.72 (10/3/2023)** ~~**section 1301.72 of the code of federal regulations (2/28/2018)**~~. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Rule 4729:6-5-02 | Wholesale distributors - recordkeeping. (AMEND)

(A) Wholesale distributors of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the receipt, sale, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Wholesale distributors located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the wholesale distributor.

(4) A wholesale distributor maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Wholesale distributors shall submit wholesale sale information to the drug database in accordance with section 4729.78 of the Revised Code.

Rule 4729:6-6-01 | Virtual wholesalers - general operations. (AMEND)

The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs with a virtual wholesaler classification:

(A) Virtual wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt, sale**,** and distribution or other transfer of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~**principle**~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, quantity of the drugs received, distributed, sold, disposed**,** or returned.

(c) The dates of receipt, sale**,** and distribution of the drugs.

(d) The name and ~~**principle**~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Virtual wholesalers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the wholesale distributor.

(4) A virtual wholesaler maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) Virtual wholesalers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. At a minimum, virtual wholesalers shall include in their written policies and procedures with all the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall address recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~**of**~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that virtual wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(C) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(D) Virtual wholesalers shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(E) Virtual wholesalers shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(F) Virtual wholesalers shall be subject to the provisions of any applicable federal, state, or local laws, rules**,** or regulations that relate to dangerous drug salvaging or reprocessing.

(G) Virtual wholesalers shall submit wholesale sale information to the drug database in accordance with section 4729.78 of the Revised Code.

(H) The following minimum standards shall apply to the storage and transportation methods utilized by virtual wholesalers for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in section 1301.72 of the code of federal regulations (2/28/2018). In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(I) A virtual wholesaler seeking to engage in any other activities relating to the distribution of dangerous drugs shall obtain additional licensure for the operations conducted pursuant to those rules.

(J) The requirement to obtain licensure as a **virtual** wholesaler pursuant to section 4729.52 of the Revised Code does not apply to any of the following:

(1) A board of health, as defined in section 3701.048 of the Revised Code, that is licensed as a terminal distributor of dangerous drugs for the purpose of distributing dangerous drugs to another terminal distributor during a declared public health emergency or emergency preparedness incident; or

(2) A board of health, as defined in section 3701.048 of the Revised Code, that is a certified covered entity as defined in Section 340B(a)(4) of the Public Health Service Act (1/24/2020) to perform the functions of a virtual wholesaler with a contracted pharmacy licensed as a terminal distributor of dangerous drugs that has a "ship to, bill to" arrangement in accordance with all applicable requirements of the federal health resources and services administration (HRSA). A certified covered entity shall be responsible for all of the following:

(a) Maintaining records of drug distribution in accordance with paragraph (A) of this rule; and

(b) Ensuring the contracted pharmacy is appropriately licensed as a terminal distributor of dangerous drugs in accordance with Chapter 4729. of the Revised Code.

Rule 4729:6-7-01 | Brokers - general operations. (AMEND)

The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs with a broker classification:

(A) Brokers shall establish and maintain records of all transactions regarding the transfer, sale, or other disposition of dangerous drugs.

(1) The records shall include, but shall not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Brokers in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board ~~by~~ in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the broker.

(4) A broker maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) Brokers shall only engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are unopened (i.e., no partial stock bottles) and packaged in the manufacturer's original container.

(C) Brokers shall operate in compliance with all applicable federal, state, and local laws, rules, and regulations.

(D) Brokers shall permit properly identified and authorized state board of pharmacy **employees** ~~agents~~, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(E) A broker seeking to engage in activities relating to the distribution of dangerous drugs other than those of a broker shall obtain additional licensure for the operations conducted pursuant to those rules.

(F) Brokers shall verify that the seller and buyer are appropriately licensed or exempt from licensure in accordance with rule 4729:6-3-04 of the Administrative Code.

(G) Brokers shall not engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are controlled substances.

(H) Brokers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations. This shall include, but is not limited to, all applicable laws, regulations, and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(I) An entity engaged in the brokering of dangerous drugs for the sole purpose of reverse distribution (e.g., disposal) shall not be required to obtain a license as a wholesale distributor of dangerous drugs with a broker classification.

Rule 4729:6-8-01 | Manufacturers - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as a manufacturer of dangerous drugs:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for manufacturing, distribution, and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph (B)(2)(a) of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(a) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(3) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used for manufacturing and drug storage shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and adulterated**,** dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify**~~, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety,

identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling**,** as a result of storage or shipping.

(G) Manufacturers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Manufacturers shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~**of**~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that manufacturers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs ~~**shall**~~ be segregated from other drugs and destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the manufacture and distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Manufacturers of dangerous drugs shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Manufacturers of dangerous drugs shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(K) Manufacturers of dangerous drugs shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the board, of any new facilities, work**,** or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a manufacturer of distributor of dangerous drugs for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in section 1301.72 of the code of federal regulations (2/28/2018). In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(N) A manufacturer shall comply with current good manufacturing practices pursuant to **21 CFR Part 211 (1/1/2024)** ~~**Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015)**~~.

Rule 4729:6-8-02 | Manufacturers - recordkeeping. (AMEND)

(A) Manufacturers of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the manufacture, receipt, sale**,** and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~**principle**~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code and quantity of the drugs received, distributed, sold, disposed**,** or returned.

(c) The dates of receipt, sale**,** and distribution of the drugs.

(d) The name and ~~**principle**~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Manufacturers in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the manufacturer.

(4) A manufacturer maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Manufacturers shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.

Rule 4729:6-9-01 | Repackagers - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as a repackager of dangerous drugs:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for repackaging, distribution**,** and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph (B)(2)(a) of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

(a) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(3) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used for repackaging and storing drugs shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and adulterated**,** dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify**~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions

under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling**,** as a result of storage or shipping.

(G) Repackagers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Repackagers shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(2) A procedure to ensure that repackagers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the repackaging and distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Repackagers of dangerous drugs shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Repackagers of dangerous drugs shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures.

(K) Repackagers of drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the board, of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a repackager of distributor of dangerous drugs for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in **21 CFR 1301.72 (10/3/2023)** ~~**section 1301.72 of the code of federal regulations (2/28/2018)**~~. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Rule 4729:6-9-02 | Repackagers - recordkeeping. (AMEND)

(A) Repackagers of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the repackaging, receipt, sale, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Repackagers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the repackager.

(4) A repackager maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Repackagers shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.

Rule 4729:6-10-01 | Outsourcing Facilities - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as outsourcing facilities:

(A) All facilities shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) ~~**Shall be**~~ **Be** registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for compounding, distribution**,** and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph (B)(2) (a) of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(3) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All outsourcing facilities shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions.

(F) All returned, damaged, and adulterated**,** dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~**whose**~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, **identity,** ~~**identify,**~~ strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the

conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling**,** as a result of storage or shipping.

(G) Outsourcing facilities shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Outsourcing facilities shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the outsourcing facility to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(2) A procedure to ensure that outsourcing facilities prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~**three**~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the compounding, manufacturing**,** and distribution of dangerous drugs shall be required to have appropriate education, experience**,** and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Outsourcing facilities shall operate in compliance with applicable federal, state, and local laws, rules**,** and regulations. This shall include, but is not limited to, all applicable laws, regulations**,** and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Outsourcing facilities shall permit properly identified and authorized state board of pharmacy **employees** ~~**agents**~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures.

(K) Outsourcing facilities shall be subject to the provisions of any applicable federal, state, or local laws, rules or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work**,** or storage areas to be constructed or utilized for dangerous drugs in this state.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by an outsourcing facility for the storage, transportation**,** and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in **21 CFR 1301.72 (10/3/2023)** ~~**section 1301.72 of the code of federal regulations (2/28/2018)**~~. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or **in-transit** losses.

(3) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents. ~~**(N) An outsourcing facility shall comply with all labeling requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015).**~~

(N) An outsourcing facility shall comply with current good manufacturing practices pursuant **to 21 CFR Part 211 (1/1/2024)** ~~**Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015)**~~.

(O) If an entity licensed as an outsourcing facility sells or dispenses patient specific drugs, it must also maintain licensure as a terminal distributor of dangerous drugs. All laws and rules applicable to licensure as a terminal distributor of dangerous drugs shall apply to the dispensing of patient specific drugs.

Rule 4729:6-10-02 | Outsourcing facilities - recordkeeping. (AMEND)

(A) Outsourcing facilities shall establish and maintain inventories and records of all transactions regarding the compounding, manufacturing, sale, receipt, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, formulation (i.e., active ingredients), dosage form, and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Outsourcing facilities located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the outsourcing facility.

(4) An outsourcing facility maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(C) Outsourcing facilities shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.

(D) Outsourcing facilities shall comply with all recordkeeping requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015).

Rule 4729:6-11-01 | Third-Party Logistics Providers - General Operations. (AMEND)

The following requirements shall apply to all persons licensed as third-party logistics providers:

(A) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(B) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for distribution and sale.

(1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph **(B)(2)-(a)** of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

(3) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used by third-party logistics providers shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lit.

(3) Entry into areas where dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than ~~three~~ **five** years from the last documented temperature and humidity reading.

(E) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be visually examined for identity and to prevent the shipping of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(F) All returned, damaged, and adulterated~~,~~ dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.

(2) Any dangerous drugs ~~whose~~ **where the** immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, ~~identify~~ **identity**, strength, quality, or purity, then the drug shall be destroyed~~,~~ or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug distributor shall consider, among other things, the conditions

under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(G) Third-party logistics providers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. Third-party logistics providers shall include in their written policies and procedures all of the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing ~~of~~ existing merchandise with an improved product or new package design.

(2) A procedure to ensure that third-party logistics providers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of adulterated dangerous drugs. This documentation shall be maintained for ~~three~~ **five** years after disposition of the adulterated drugs.

(H) Personnel employed in the distribution of dangerous drugs shall be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.

(I) Third-party logistics providers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations. This shall include, but is not limited to, all applicable laws, regulations, and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(J) Third-party logistics providers shall permit properly identified and authorized state board of pharmacy **employees** ~~agents~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(K) Third-party logistics providers shall be subject to the provisions of any applicable federal, state, or local laws, rules, or regulations that relate to dangerous drug salvaging or reprocessing.

(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs.

(M) The following minimum standards shall apply to the storage and transportation methods utilized by a third–party logistics provider for the storage, transportation, and delivery of dangerous drugs:

(1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.

(2) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Rule 4729:6-11-02 | Third-party logistics providers - recordkeeping. (AMEND)

(A) Third-party logistics providers shall establish and maintain inventories and records of all transactions regarding the receipt, sale, and distribution or other disposition of dangerous drugs.

(1) The records shall include, but not be limited to, the following information:

(a) The source of the drugs, including the name and ~~principle~~ **principal** address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned.

(c) The dates of receipt, sale, and distribution of the drugs.

(d) The name and ~~principle~~ **principal** address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.

(3) Third-party logistics providers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must obtain approval from the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or ~~contractor~~ **contractors** of the third-party logistics provider.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

Rule 4729:8-5-01 | Dispensary reporting into the prescription monitoring program. (NEW) (RESCIND 3796:6-3-10)

(A) **Pursuant to section 4729.771 of the Revised Code, a** dispensary**, licensed in accordance with Chapter 3796. of the Revised Code,** shall transmit electronically to the state board of pharmacy, in a format suitable to the board, the information set forth below within five minutes of the dispensing of any and all medical marijuana:

(1) State license number, which shall be populated by a number provided by the **Department of Commerce**;

(2) Dispensary name;

(3) Dispensary address;

(4) Dispensary telephone number;

(5) Patient full name;

(6) Patient registry identification number;

(7) Patient residential address;

(8) Patient telephone number;

(9) Patient date of birth;

(10) Patient gender;

(11) Recommending physicians full name (first name and last name);

(12) Drug enforcement administration physician identification number;

(13) Date recommendation was issued by the recommending physician;

(14) Indication whether the recommendation is new or a refill;

(15) Number of the refill being dispensed;

(16) Date order filled, which shall be the date medical marijuana is dispensed;

(17) Order number, which shall be the serial number assigned to each medical marijuana product dispensed to a patient;

(18) Quantity;

(19) Days supply;

(20) Product identifier, which shall be assigned by the **Department of Commerce**;

(21) Date order written, which shall be the date the written recommendation was issued;

(22) Payment code for either cash or third-party provider; and

(23) Drug name, which shall be the brand name of the medical marijuana.

(B) If a dispensary has no drug dispensing information required to be submitted to the board of pharmacy over any twenty-four-hour period, it must submit a "zero report."

(C) The dispensing report or the "zero report" shall be consecutive and inclusive from the last date and time that information was submitted and shall be reported no later than thirty-six hours after the last time reported on a previous report.

(D) Any dispensary whose normal business hours are not seven days per week shall electronically indicate its normal business hours to the board and a "zero report" will be automatically submitted on the dispensary's behalf on non-business days.

(E) If a dispensary ceases to possess medical marijuana for dispensing, the designated representative shall notify the board of pharmacy electronically or in writing. The board shall be notified if the dispensary resumes dispensing.

(F) All dispensing information required to be submitted to the board of pharmacy pursuant to paragraph (A) of this rule, must be transmitted in the format specified by the American society for automation in pharmacy ("ASAP"), for prescription monitoring systems.

(G) If a dispensary cannot electronically transmit the required information pursuant to paragraph (A) of this rule, they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The dispensary must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

(H) A dispensary shall transmit the information required pursuant to this section in such a manner as to ensure the confidentiality of the information in compliance with all federal and state laws, including the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

(I) All medical marijuana dispensing information submitted to the drug database pursuant to this rule must be reported in an accurate and timely manner.

(J) If the omission of dispensing information is discovered, the corrected information must be submitted to the board of pharmacy during the next reporting period after the discovery.

(K) If the omission of data or erroneous data is the result of a computer programming error, the dispensary must notify the board of pharmacy immediately by telephone and submit written documentation. The documentation shall fully describe the error and propose a date for submitting the corrected dispensing information. The board will review the written documentation to ensure compliance with paragraph (A) of this rule.

(L) Except as noted in paragraph (E) of this rule, all data must be submitted or corrected electronically unless prior permission for an alternate method is approved by the board of pharmacy.