Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

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Regulation/Package Title (a general description of the rules' substantive content):

FYR 2024 (Terminal Distributors)

Rule Number(s): 4729:5-1-02, 4729:5-3-01, 4729:5-3-03, 4729:5-3-05, 4729:5-3-06, 4729:5-3-07, 4729:5-3-08, 4729:5-3-10, 4729:5-7-01, 4729:5-7-02, 4729:5-7-03, 4729:5-7-04, 4729:5-7-05, 4729:5-12-01, 4729:5-12-02

Date of Submission for CSI Review: 2/13/2024

Public Comment Period End Date: 2/29/2024

Rule Type/Number of Rules:

New/___ rules

No Change/_4__ rules (FYR? _Y_)

Amended/_11_ rules (FYR? _Y_)

Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

Amend:

- 4279:5-1-02 – Defines who is a licensed health professional authorized to prescribe drugs. Makes a small grammatical correction.
- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs. Makes a minor grammatical change and updates all incorporation by references in the rule.
- 4729:5-3-03 – Allows board employees the authority to inspect terminal distributors of dangerous drugs, lays out what would constitute a violation, and what the licensee must do to correct violations. Makes minor grammatical changes to the rule.
- 4729:5-3-05 – Establishes requirements for terminal distributors of dangerous drugs when releasing confidential patient records. Makes a minor grammatical change.
- 4729:5-3-06 – Provides the requirements for the removal and storage of adulterated drugs by a terminal distributor of dangerous drugs. Adds an Oxford comma.
- 4729:5-3-08 – Requires all persons selling dangerous drugs via the internet at retail into or out of Ohio be licensed by the Board as well as maintain national accreditation. Removes specific reference to NABP programs and permits the Board to approve such accreditations.

- 4729:5-3-10 – Establishes the requirement that a terminal distributor of dangerous drugs shall not employ an individual with felony convictions if the position allows for access to controlled substances as required by federal regulations. Updates the incorporation by reference.
- 4729:5-7-02 – Provides the licensure requirements for a charitable pharmacy. Adds a comma.
- 4729:5-7-03 – Provides the requirements for the distribution of sample drugs by a charitable pharmacy. Permits a charitable pharmacy to accept drug samples if the pharmacy is operating a drug repository.
- 4729:5-12-01 – Defines terms related to medication therapy management. Adds a comma.
- 4729:5-12-02 – Establishes licensure and regulatory requirements of licensees providing medication therapy management. Makes a minor grammatical change.

No Change:

- 4729:5-3-07 – Establishes requirements that all category III terminal distributor licenses complete a controlled substances inventory.
- 4729:5-7-01 – Provides the definitions for the division governing charitable pharmacies.
- 4729:5-7-04 – Provides the eligibility requirements for sample drugs received by a charitable pharmacy.
- 4729:5-7-05 – Provides the requirements for dispensing of sample drugs by a charitable pharmacy.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   The proposed rules are authorized by sections 4729.26, 3719.28, and 3719.13 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   Rule 4729:5-3-01 requires adherence to federal rules regarding controlled substance drug destruction.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   This rule package exceeds federal requirements because the regulation of the practice of pharmacy and distribution of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

   Section 3719.13 of the Ohio Revised Code authorizes employees of the Board of Pharmacy to inspect prescriptions, orders, records, and stocks of dangerous drugs and controlled substances.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The rules in this package were distributed for public comment to all licensees and registrants of the Board.

   Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    The Board did not receive comments on the proposed rules during the initial public comment period.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Scientific data was not used to develop or review this rule.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    As the regulations are essential to protecting the public's safety by ensuring uniform standards for the inspection of sites with dangerous drugs, valid requirements for the release of confidential patient records, the regulation of terminal distributors of dangerous drugs, and oversight of licensees providing medication therapy management, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

14. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

    Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
        - Terminal distributors of dangerous drugs

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

In general, violation of these rules may result in administrative licensure discipline for a licensee. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

Amended

- 4729:5-1-02 – Defines who is a licensed health professional authorized to prescribe drugs. This is a definition rule and should have no impact on business.
- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs. Directors of nursing and nurses employed at long term care facilities must complete a proof of use sheet and be present for any transfer or destruction of controlled substances. Requirements of maintaining all destruction records for three years and complying with all federal destruction requirements, including utilization of a method that renders controlled substances "non-retrievable". It should be noted that maintaining records pertaining to controlled substances for three years is required by the Ohio Revised Code (3719.07). Licensees will experience administrative costs to ensure compliance with the recordkeeping requirements of the rule.
- 4729:5-3-03 – Allows board employees the authority to inspect terminal distributors of dangerous drugs, lays out what would constitute a violation, and what the licensee must do to correct violations. The time to complete a corrective response is based on the number of violations observed by inspection staff.
- 4729:5-3-05 – Establishes requirements for terminal distributors of dangerous drugs when releasing confidential patient records. This does require the maintenance of the consent forms and receipts for the release of patient records to be maintained by the terminal distributor. This may result in an administrative burden to the distributor based upon the number of requests for records received by the terminal distributor.
- 4729:5-3-06 – Provides the requirements for the removal and storage of adulterated drugs by a terminal distributor of dangerous drugs. This requires all terminal distributors to segregate adulterated and expired drugs. Expected costs include administrative time to review drugs for expiration and adulteration as well as the cost of disposal.
- 4729:5-3-08 – Requires all persons selling dangerous drugs via the internet at retail into or out of Ohio be licensed by the Board. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete. Additionally, this requires Accreditation from the National

Association of Boards of Pharmacy. The application fee for accreditation can cost anywhere between $5,000 and $8,000.

- 4729:5-7-02 - Provides the licensure requirements for a charitable pharmacy. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete.
- 4729:5-7-03 - Provides the requirements for the distribution of sample drugs by a charitable pharmacy. This rule includes compliance with record keeping which will result in administrative costs by the pharmacy.
- 4729:5-12-01: Defines terms related to medication therapy management. The regulation should have no adverse impact.
- 4729:5-12-02: Establishes licensure and regulatory requirements of licensees providing medication therapy management. The fee for a limited category II terminal distributor of dangerous drugs license with a medication therapy management classification is $160.00, while the application takes about 30-60 minutes to complete.

No Change

- 4729:5-3-07 – Requires all category III terminal distributors complete a controlled substances inventory on an annual basis. Depending on the stock of controlled substances, this may take several hours to complete.
- 4729:5-7-04 – Provides the eligibility requirements for sample drugs received by a charitable pharmacy. This rule will result in administrative costs to ensure the sample drugs meet the rule's requirements.
- 4729:5-7-05 – Provides the requirements for dispensing of sample drugs by a charitable pharmacy. There may be additional administrative costs associated with compliance.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

No, as a majority of the changes in these rules are grammatical in nature.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the operation of terminal distributor of dangerous drugs, including charitable pharmacies.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

    These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. **What resources are available to assist small businesses with compliance of the regulation?**

    Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

    Furthermore, the Board also developed external inspection guides available to all licensees to ensure compliance with our regulations.

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.