Common Sense Initiative

Mike DeWine, *Governor*
Jim Tressel, *Lt. Governor*
Joseph Baker, *Director*

Business Impact Analysis

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

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

FYR TDDDs

Rule Number(s): 4729:5-3-02, 4729:5-3-12, 4729:5-3-13, 4729:5-3-14, 4729:5-3-15, 4729:5-3-16, 4729:5-4-02, 4729:5-5-03, 4729:5-5-05, 4729:5-5-07, 4729:5-5-08, 4729:5-5-09, 4729:5-5-10, 4729:5-5-11 (new), 4729:5-5-11 (rescind), 4729:5-5-12 (rescind), 4729:5-5-13, 4729:5-5-16, 4729:5-5-17, 4729:5-5-22, 4729:5-5-23, 4729:5-5-24

Date of Submission for CSI Review: 1/12/2026

Public Comment Period End Date: 2/10/2026

Rule Type/Number of Rules:

New/_1_ rules **No Change/__3__ rules (FYR? _Y_)**

Amended/_16_ rules (FYR? _Y_) **Rescinded/__2__ rules (FYR? _Y_)**

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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.

4729:5-3-02: Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs. Changes required reporting time from thirty to forty-five days to mirror recent changes to the federal rule.

4729:5-3-12: Provides the requirements for protocols for medication administration via a protocol or standing order. Adds standing order to the definition of protocol. Adds the administration of contrast and radiopharmaceuticals and glucose to newborns as protocols. Adds positive identification requirement to the protocol description. Updates cross references in the rule.

4729:5-3-13: Authorizes the temporary removal of dangerous drugs from a licensed location. Updates instances of "naloxone" to "overdose reversal drug" (ORD) as defined in rule 4729-8-02 of the Administrative Code and removes physical storage requirements for ORDs. Adds anesthesiologists to licensees who can temporarily remove the drugs. Reformatted some paragraphs to improve readability.

4729:5-3-14: Provides general security requirements for terminal distributors of dangerous drugs. Adds requirement that a pharmacy dispensing dangerous drugs cannot operate out of a residence or personal dwelling.

4729:5-3-15: Permits a prescriber of a hospital to utilize the hospital's DEA registration for the purpose of issuing controlled substance prescriptions. Requires the reporting of DEA registration information to the Board. Rewords rule reference to hospitals or other institutions. Makes small grammatical changes.

4729:5-3-16: The rule provides the specific instances where drugs may be returned to a terminal distributor of dangerous drugs. Adds drugs dispensed in error to the exceptions for returning drugs. Updates agency, chapter, and rule references.

4729:5-4-02: Requires terminal distributors of dangerous drugs to report errors in dispensing as well as employees who have resigned or been terminated by the pharmacy for recklessness, unprofessional conduct, errors in dispensing, and issues related to substance use disorder or a mental health condition. Adds the receipt of prescriptions that a pharmacist refuses to dispense and the receipt of an illegitimate product to the report list, with specific reporting requirements and reporting timelines. Updates "employer" to "pharmacy" in the reporting requirements.

4729:5-5-03: Provides the requirements for filing and storage of prescriptions in an outpatient pharmacy. No changes were made to this rule.

4729:5-5-05: Sets forth the standard format for outpatient prescriptions. Removed "written" from outpatient prescription. Updates agency, rule, and CFR references. Makes small grammatical changes.

4729:5-5-07: Provides the requirements for patient profiles maintained by outpatient pharmacies. Makes a small grammatical change.

4729:5-5-08: Requires pharmacists dispensing prescriptions to conduct a prospective drug utilization review. Makes a small grammatical change.

4729:5-5-09: Provides the requirements for the counseling of patients by pharmacists and pharmacy interns. Makes small grammatical changes.

4729:5-5-10: Provides the requirements for the dispensing of a prescription in an outpatient pharmacy. Updates incorporation by rule reference and adds a provision allowing for the partial filling of schedule II controlled substances in accordance with federal regulations.

4729:5-5-11: Sets forth the requirements for when a pharmacist or pharmacy intern may transfer a prescription to another pharmacy. This rule is being rescinded and replaced with a new rule that reflects the requirements set forth in federal regulations by the Drug Enforcement Administraiton. Requires the transfer happen in no later than three business days.

4729:5-5-12: Authorizes outpatient pharmacies to partially dispense schedule II controlled substances. This rule is being rescinded and its content added to OAC 4729:5-5-10.

4729:5-5-13: Requires outpatient prescriptions to be serially numbered. No changes were made to this rule.

4729:5-5-16: Provides the requirements allowing a pharmacist to make modifications to a prescription. Allows a pharmacist to modify a drug's prescription to include a drug delivery device in accordance with Ohio law. Updates rule references.

4729:5-5-17: Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. Requires compliance with federal repackaging standards established by the FDA. No changes were made to this rule.

4729:5-5-22: Establishes the standards and procedures for return to stock in a pharmacy. Adds relabeling as an exception for removing a label on a container. Allows a pharmacy to return drugs to stock if the drugs were dispensed to a TDDD under common ownership with the pharmacy. Updates agency and rule references. Makes small grammatical changes.

4729:5-5-23: Provides security, control, and storage requirements for dangerous drugs maintained by an outpatient pharmacy. Adds examples for biannual and daily observations. Allows a TDDD to keep unopened bottled water in refrigerators that store dangerous drugs to maintain consistent temperatures. Makes small grammatical changes.

4729:5-5-24: Provides the requirements for the drug inventory records at an outpatient pharmacy. Adds requirement of a transaction statement in accordance with Section 582 of the FD&C Act. Makes small grammatical changes.

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 9.79, 3715.69, 3719.28, and 4729.26 of the 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.

Yes, DEA regulations authorize the use of an institutional DEA registration by prescribers working at the facility only upon authorization at the state level. Rule 4729:5-3-15 provides such authorization to this practice. Additionally, rules 4729:5-3-02 and 4729:5-4-02 require adherence to federal laws regarding theft/loss of controlled substance medications.

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 the operation of pharmacies 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 governing controlled substances.

These rules are necessary to promote patient safety by adopting uniform standards for the use of dangerous drugs.

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.

This rule package was reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists and pharmacy technicians from several practice settings, is responsible for reviewing and approving rules prior to their legislatively mandated five-year review date. Prior to filing with CSI, the rules were 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?

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. The Committee recommended and the Board approved the forty-five-day change for reporting theft or significant loss of dangerous drugs; the requirement that a pharmacy dispensing dangerous drugs may not operate out of a residence or personal dwelling; and allowing unopened bottled water in refrigerators that store dangerous drugs to maintain consistent temperatures.

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 these rules.

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 security and the distribution of dangerous drugs, the 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 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 and quarterly 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

- Pharmacies licensed as terminal distributors of dangerous drugs
- Pharmacists
- Pharmacy interns
- Pharmacy technicians

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 terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine, and/or revocation of a license.

4729:5-3-02: A licensee must report theft or significant loss of a dangerous drug immediately by phone and complete a form within forty-five days. The theft or significant loss form can take about 30 minutes to complete but it may take additional time to gather the information necessary to complete the form.

4729:5-3-12: This rule will result in increased administrative costs to a licensee seeking to administer drugs via protocol. Such costs include the time it takes to establish and approve a protocol as well as the requirement to review each protocol every two years.

4729:5-3-13: A licensee that seeks to store drugs off-site for more than 24 hours may incur additional costs to ensure drugs are maintained at the proper temperature and are stored securely.

4729:5-3-14: This rule may require expanded security measures in the event that physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the licensee. This language mirrors current DEA regulations and already a requirement in existing rule.

4729:5-3-15: Requires the reporting of DEA registration information to the Board. The Board has developed an electronic method for reporting this information as the requirement exists in current rule. The rule would impose an administrative cost on a hospital or institutional facility to report to the Board if there were modifications to the staff utilizing the facility's DEA registration to prescribe controlled substances.

4729:5-3-16: The adverse costs associated with this rule would be the cost of drugs that cannot be returned that have left the possession of the terminal distributor of dangerous drugs. Additionally, a pharmacy may experience increased administrative costs to ensure compliance with the requirements of the rule.

4729:5-4-02: Requires terminal distributors of dangerous drugs to report errors in dispensing as well as employees who have resigned or been terminated by the pharmacy for recklessness, unprofessional conduct, and errors in dispensing. The Board estimates that the notification requirements will take anywhere between 15-30 minutes to complete. Additionally, failure to comply with the requirements of this rule may result in disciplinary action by the Board including reprimand, denial of a license, suspension of a license, monetary fine ($1000), and/or revocation of a license.

4729:5-5-03: Provides the requirements for filing and storage of prescriptions in an outpatient pharmacy. This rule does allow for the scanning and disposal of prescription documents after 180 days. A pharmacy that wishes to keep paper records electronically will have to invest in scanning equipment and a system that meets the requirements set forth in the rule.

4729:5-5-05: The cost of compliance for this rule is the time of the pharmacist to ensure the prescription is formatted correctly.

4729:5-5-07: Provides the requirements for patient profiles maintained by outpatient pharmacies. These are the current requirements in the existing rule. The cost of this rule would be to ensure all electronic systems can collect the required patient profile information.

4729:5-5-08: This rule includes a requirement to check OARRS for most new controlled substance prescriptions. The average time to check a patient's OARRS report is between 3-5 minutes using the web-based portal. However, the Board covers the cost of integrated access to OARRS that reduces the time to view a patient's OARRS report to 15-30 seconds.

4729:5-5-09: Provides the requirements for the counseling of patients by pharmacists and pharmacy interns. The adverse impact of this rule is the time a pharmacist or intern would take to counsel a patient or caregiver only if requested by the patient or caregiver.

4729:5-5-10: This rule requires adherence to standards based on how a prescription is transmitted to a pharmacy. Adverse costs include administrative costs of pharmacists to determine whether a prescription is valid in accordance with the rule, required documentation necessary to perform partial fills of controlled substances, and any necessary system upgrades to meet the standards in the rule.

4729:5-5-11: Sets forth the requirements for when a pharmacist or pharmacy intern may transfer a prescription to another pharmacy. The current rule is being rescinded. Adverse costs include the time it takes pharmacy personnel to comply with the necessary

documentation requirements when receiving or transferring a prescription, including the patient consent requirement.

4729:5-5-12: Authorizes outpatient pharmacies to partially dispense schedule II controlled substances. This rule is being rescinded and should have no adverse impact. The ability to conduct partial dispensing of Schedule II controlled substances is now in OAC 4729:5-5-10.

4729:5-5-13: Requires outpatient prescriptions to be serially numbered. These are the exact requirements listed in the current rule For a new outpatient pharmacy, the cost of implementing this rule would be the development of a recordkeeping system that would permit the serial numbering of prescriptions.

4729:5-5-16: Provides the requirements allowing a pharmacist to make modifications to a prescription. Allows a pharmacist to modify a drug's prescription to include a drug delivery device in accordance with Ohio law. Updates rule references. This cost of the this rule is the documentation and consultation requirements for a pharmacist. However, the rule does allow a pharmacist to add a device that is missing, which could reduce the overall burden on the pharmacy but not having to track down the issuing prescriber to obtain a device perscription.

4729:5-5-17: Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. There may be increased administrative costs to ensure compliance with recordkeeping and labeling requirements for pharmacies that relabel/repackage drugs, including the additional requirements of the NDC or UPC codes. This is a no change rule.

4729:5-5-22: The regulation may require upgrades to pharmacy computer systems to ensure the proper expiration date is included on the prescription label. Furthermore, entities that add new labeling (which is optional) will be required to have pharmacists conduct additional checks of medications that are returned to stock. Depending on volume, this may require additional pharmacist hours to meet this requirement.

4729:5-5-23: This rule requires the implementation of both a physical barrier and alarm system to deter and detect the diversion of dangerous drugs from a pharmacy. This may result in costs for pharmacies that only have an alarm system or a physical barrier. Additionally, pharmacies will be required to record daily temperature logs and implement a system to detect temperature excursions. This will add to overall compliance costs. A search conducted by the Board found automated temperature monitoring products available for around $100.

4729:5-5-24: Outpatient pharmacies may experience increased compliance costs to maintain records in accordance with this rule. However, it should be noted that the only additional requirement of the rule, the transaction statement, is required to be provided to pharmacies by trading partners pursuant to federal law. Therefore, the impact of this amendment should be minimal.

16. **Are there any proposed changes to the rules that will <u>reduce</u> 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).***

4729:5-3-02: Extends the requirements of reporting a theft or significant loss from thirty to forty-five days. This may give pharmacies more time to report to the Board.

4729:5-3-13: Adds anesthesiologists to the types of licenses who can temporarily remove the drugs. This may allow a wider number of employees at the TDDD to remove the drugs and reduce compliance time.

4729:5-3-16: Allows drugs dispensed in error to be returned to the terminal distributor to be dispensed or personally furnished. This requirement may save pharmacies in drug stocking costs.

4729:5-5-16: Permits a pharmacist to add a device to a prescription. This may save staff time, as the pharmacy will not need to obtain another prescription for the device.

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 regulations for the safe operation of an outpatient pharmacy.

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 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 distribution of dangerous drugs or practice of pharmacy 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. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Additionally, to assist our licensees, including those representing small businesses, the Board developed inspection guides. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board. The guides may be accessed by visiting: www.pharmacy.ohio.gov/inspection. The Board also has a number of resources on its licensing and continuing education websites to educate our licensees.

Rule 4729:5-3-02 | Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (AMEND)

(A) A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;

(2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (~~**9/9/2014**~~ **June 22, 2023**);

(3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

(B) The theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within ~~**thirty**~~ **forty-five** days.

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported to the state board of pharmacy, in a manner determined by the board, by the licensee within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within ~~**thirty**~~ **forty-five** days.

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(D) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

(E) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (~~**9/9/2014**~~ **September 30, 2019**) of the theft or loss of any DEA form 222.

Rule 4729:5-3-12 | Protocols and pre-printed orders for medication administration. (AMEND)

(A) A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs pursuant to a protocol. As used in this rule, "protocol" **or "standing order"** means a definitive set of written treatment guidelines with orders for drugs and their specified dosages for administration to individuals under the following circumstances:

(1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the ~~revised code~~ **Revised Code** to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks;

(2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases;

(3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns;

(4) The administration of erythromycin for prevention of ophthalmia neonatorum; ~~and~~

(5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in ~~agency 4729~~ **Chapter 4729:5-9** of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention**;**

(6) The administration of contrast and radiopharmaceuticals by radiographers and nuclear medicine technologists in accordance with Chapter 4773. of the Revised Code; and

(7) The administration of glucose to newborns for the management of hypoglycemia.

(B) A protocol described in paragraph (A) of this rule shall:

(1) Include a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification of the prescriber as defined in ~~agency 4729~~

rule 4729:5-1-02 of the Administrative Code; and date of signature **or other form of positive identification used**;

(2) Be administered by an individual authorized by law to administer the drugs;

(3) Be made readily retrievable;

(4) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care; and

(5) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.

(C) A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration pursuant to a pre-printed order. As used in this rule, "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. The prescriber must complete an assessment and make a diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. The pre-printed order may only be initiated upon the order of a prescriber authorized by law to prescribe the drugs listed in the pre-printed orders. The drugs shall be administered by an individual authorized by law to administer the drugs.

(D) A pre-printed order described in paragraph (C) of this rule shall:

(1) Include the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as calculations and patient physiologic data; signature of the prescriber or some other form of positive identification of the prescriber as defined in ~~agency 4729~~ **rule 4729:5-1-02** of the Administrative Code; and date of signature;

(2) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;

(3) Can be performed without requiring the exercise of medical judgment;

(4) Will lead to results that are reasonably predictable and safe;

(5) Can be performed safely by the individual authorized to administer the drugs and without the need for repeated medical assessments;

(6) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of initiation. A pre-printed order which becomes a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph;

(7) Be made readily retrievable;

(8) If performed improperly, would not present a danger of immediate and serious harm to the patient; and

(9) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care.

(E) Nothing in this rule shall be construed to otherwise prohibit the dispensing or administration of dangerous drugs pursuant to a protocol that is specifically authorized in the Revised Code or agency 4729 of the Administrative Code.

(F) For purposes of this rule, a terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration to animals pursuant to a protocol in accordance with the provisions of paragraphs (A) and (B) of this rule or a pre-printed order in accordance with the provisions of paragraphs (C) and (D) of this rule.

Rule 4729:5-3-13 | Temporary removal of dangerous drugs from a licensed location. (AMEND)

No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs at retail or maintain possession, custody, or control of dangerous drugs for any purpose at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, except as follows:

(A) A licensed health professional authorized to prescribe drugs may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(B) A person authorized to personally furnish or dispense ~~**naloxone**~~ **an overdose reversal drug** in accordance with ~~**a physician**~~ **an** approved protocol. The ~~**naloxone**~~ **overdose reversal drug(s)** shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The authorized person shall maintain direct supervision and control over the ~~**naloxone**~~ **overdose reversal drug(s)** removed from the terminal distributor. If direct supervision is not provided, the ~~**naloxone**~~ **overdose reversal drug(s)** shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(C) A licensed health care professional, in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed

health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(D) An emergency medical service (EMS) organization providing emergency medical services and in accordance with Chapter 4729:5-14 of the Administrative Code.

(E) A veterinarian licensed pursuant to Chapter 4741. of the Revised Code may maintain a supply of dangerous drugs obtained from a licensed terminal distributor of dangerous drugs at another location in order to treat current or prospective patients.

(1) A veterinarian shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(2) Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal, and inventory requirements of division 4729:5 of the Administrative Code. Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-20 of the Administrative Code.

(3) The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph.

(4) A veterinarian maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs.

(5) The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site for more than twenty-four hours: name, strength, dosage form, and quantity of the

controlled substance dangerous drugs, the positive identification of the veterinarian who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location.

(6) All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return.

(7) Failure by a veterinarian to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(F) A person licensed or certified under Chapter 4765. of the Revised Code may maintain a supply of medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)** obtained from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients in the event of an emergency. The medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)** shall be maintained for an amount of time as determined by written authorization from the licensee's medical director. Medical oxygen and ~~**naloxone**~~ **overdose reversal drug(s)** shall only be administered in accordance with the licensee's protocol or valid prescriber order. The individuals authorized by ~~**to**~~ this paragraph shall maintain personal supervision and control over the medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)** removed from the terminal distributor. If personal supervision is not provided, the medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)** shall be ~~**physically secured in a manner to prevent unauthorized access and shall be**~~ stored at temperatures and conditions which will ensure the integrity of the medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)**prior to its use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(G) A certified officer, as defined in section 4729.533 of the Revised Code, may maintain a supply of dangerous drugs, as authorized in rule 4729:5-15-05 of the Administrative Code, obtained from a licensed terminal distributor of dangerous drugs with a chemical capture classification at another location in order to engage in chemical capture.

(1) A certified officer shall maintain direct supervision and control over the dangerous drugs, equipment, and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs, equipment, and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(2) Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal, and inventory requirements of division 4729:5 of the Administrative Code.

(3) Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-15 of the Administrative Code. The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph.

(4) A certified officer maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs.

(5) The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the certified officer who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location.

(6) All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return.

(7) Failure by a certified officer to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(H) An opioid treatment program operating a mobile opioid treatment program in accordance with rule 4729:5-21-05 of the Administrative Code.

(I) An anesthesiologist licensed in accordance with Chapter 4731. of the Revised Code or a dental anesthesiologist that possesses a general anesthesia permit issued under Chapter 4715. of the Revised Code or has obtained provisional general anesthesia privileges in accordance with Chapter 4715. of the Administrative Code, may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within five days (one hundred and twenty hours). The anesthesiologist or

dental anesthesiologist shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(**J**) As used in this rule, "direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.

Rule 4729:5-3-14 | General security requirements. (AMEND)

(A) All terminal distributors of dangerous drugs shall provide effective controls and procedures to:

(1) Deter and detect the theft and diversion of dangerous drugs; and

(2) Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code.

(B) Substantial compliance with the standards set forth in this division of the Administrative Code may be deemed sufficient by the state board of pharmacy after evaluation of the overall security system and needs of the licensee or applicant. In evaluating the overall security system of a licensee or applicant, the state board of pharmacy may consider any of the following factors, as deemed relevant, for compliance with security requirements:

(1) The type of activity conducted;

(2) Type and form of dangerous drugs handled;

(3) Quantity of dangerous drugs handled;

(4) Location of the premises and the relationship such location bears on security needs;

(5) Type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) Type of vaults, safes, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) Type of closures on vaults, safes, and secure enclosures;

(8) Adequacy of key control systems and/or combination lock control systems;

(9) Adequacy of electronic detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;

(10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) Adequacy of supervision over authorized employees having access to areas containing dangerous drugs;

(12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel; and

(13) Adequacy of the licensee's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.

(C) When physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the licensee during normal business operation, the physical security controls shall be expanded and extended accordingly.

(D) Any applicant seeking to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in this division of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the state board of pharmacy.

(E) No pharmacy engaged in the dispensing of dangerous drugs shall operate out of a residence or personal dwelling.

Rule 4729:5-3-15 | Use of hospital and other institution D.E.A. registrations. (AMEND)

~~**(A) As used in this rule, "hospital or other institution" has the same meaning as in Part 1301 of the Code of Federal Regulations.**~~

(~~**B**~~ **A**) A prescriber who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, personally furnish, or prescribe controlled substances under the "Drug Enforcement Administration" (D.E.A.) registration of the hospital **or other institution in accordance with 21 CFR Part 1301.22 (March 24, 1997)**.

(~~**C**~~ **B**) A person pursuing an approved training program within the jurisdiction of the hospital or other institution and authorized to write prescriptions pursuant to paragraph (B) of rule 4729:5-1-02 of the Administrative Code may administer, personally furnish, or prescribe controlled substances under the registration of the hospital or other institution. Persons pursuing such approved training programs may function in sites outside the physical confines of the hospital or other institution only if such sites are part of the training program and the persons are under the employment and jurisdiction of the hospital or other institution administering the approved program. While functioning in the outside sites, such persons may continue to use the internal code assigned by the hospital or other institution administering the approved program, upon mutual agreement of the hospital or other institution and the outside site.

(~~**D**~~ **C**) The administering, personally furnishing, or prescribing must be done in the usual course of the person's professional practice and only within the scope of the person's employment in the hospital or other institution.

(~~**E**~~ **D**) Each person so authorized must be assigned a specific internal code number by the hospital or other institution which will be used as a suffix to the hospital D.E.A. registration number. Such internal code number shall consist of numbers, letters, or a combination thereof~~,~~ **;** shall be preceded by a hyphen~~,~~ **;** and no more than ten characters in length, excluding the hyphen. A current list of the internal codes and the corresponding individual prescribers must be kept by the hospital or other institution and made available at all times to other registrants~~,~~ **;** state board of pharmacy designated agents~~,~~ **;** investigators of the state medical board~~,~~ **;** and federal, state, county, or municipal law enforcement agencies for verification.

A current list of internal codes and the corresponding individual prescribers shall be filed with the state board of pharmacy, in a manner and format determined by the board. Additions, deletions**,** or

changes to the list must be submitted to the state board of pharmacy within ten business days of any such addition, deletion, or change.

(~~F~~ **E**) A pharmacist practicing under a consult agreement, as authorized in section 4729.39 of the Revised Code, shall not prescribe controlled substances under the registration of the hospital or other institution.

Rule 4729:5-3-16 | Returned drugs. (AMEND)

(A) No drug that has been dispensed pursuant to a prescription or personally furnished by a prescriber and has left the physical premises of the terminal distributor of dangerous drugs shall be returned to the terminal distributor or dispensed or personally furnished again, except as follows:

(1) Drugs dispensed for inpatients, as defined in ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code, or personally furnished to inpatients provided that:

(a) The drugs are packaged in unopened, single-dose or tamper-evident containers; and

(b) The drugs have not been in the possession of the ultimate user.

(2) Drugs dispensed for inpatients, as defined in ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code, in accordance with rule 4729:5-9-02.11 of the Administrative Code.

(3) Drugs dispensed for outpatients in accordance with rules 4729:5-5-22**,** ~~**and**~~ 4729:5-5-18**, and 4729:5-3-24** of the Administrative Code.

(4) Drugs dispensed for patients, which have not been dispensed or personally furnished directly to the ultimate user, that require further manipulation prior to administration.

(5) Drugs donated to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code.

(6) Drugs returned for destruction or disposal in accordance with division 4729:10 of the Administrative Code and rule 4729:5-5-14 of the Administrative Code.

(7) Hazardous drugs for destruction or disposal in accordance with all applicable federal, state, and local laws, rules, and regulations.

(8) Drugs dispensed in error (e.g., drug dispensed to wrong patient, incorrect drug dispensed, etc.) for destruction or disposal in accordance with all applicable federal, state, and local laws, rules, and regulations.

(B) As used in this rule, "hazardous drug" means any drug listed on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code.

(C) Except as provided in section 4729.43 of the Revised Code, nothing in this rule prohibits a terminal distributor of dangerous drugs from administering a dangerous drug that was dispensed or personally furnished directly to a patient or patient's caregiver.

Rule 4729:5-4-02 | Duty to Report. (AMEND)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Dispensing error" or "error in dispensing" has the same meaning as rule 4729:5-3-22 of the Administrative Code.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(4) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B) A pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report, from direct observation or objective evidence, the following to the board in accordance with paragraph (C) of this rule:

(1) Any error in dispensing when the error is the result of reckless behavior.

(2) Any error in dispensing where the error results in any of the following per the "National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index (Revised 2/20/2001)":

(a) Category G: an error occurred that resulted in permanent patient harm.

(b) Category H: an error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).

(c) Category I: an error occurred that resulted in patient death.

(3) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on an error or errors in dispensing.

(4) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on engaging in unprofessional conduct, dishonesty, or reckless behavior.

(5) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(6) The receipt of a prescription or medication order where a pharmacist refuses to dispense the prescription or medication order on the basis that it is or is suspected to be fraudulent.

(7) The receipt of an illegitimate product as defined in 21 U.S.C. 360eee (November 27, 2013) and the United States food and drug administration guidance: "definitions of suspect product and illegitimate product for verification obligations under the drug supply chain security act guidance for industry" (March 2023).

(C) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's website: www.pharmacy.ohio.gov), or telephone and shall include the following information:

(1) For violations listed in paragraphs (B)(1) through (B)(5) of this rule:

(a) The name of the ~~**employer**~~ **pharmacy** and the **pharmacy's** ~~**employer's**~~ terminal distributor license number;

(b) If applicable, the full name and license or registration number of the licensee or registrant for which a report is being made;

(c) If applicable, an explanation of the error in dispensing that occurred, including details regarding any patient harm;

(d) If applicable, an explanation of the circumstances that resulted in the individual's termination or resignation from employment; and

(e) The date(s) of and place(s) of occurrence(s), if known.

(2) For violations listed in paragraphs (B)(6) of this rule:

(a) The name of the pharmacy and the pharmacy's terminal distributor license number;

(b) A description of the prescription or order that is or is suspected to be fraudulent;

(c) Name and address of the issuing prescriber; and

(d) The date the prescription or order was received.

(3) For violations listed in paragraph (B)(7) of this rule, the pharmacy shall submit a copy of the required form FDA 3911 (May 2023).

(D) All reports submitted in accordance with this rule shall protect the confidentiality of patients. The Board may request additional information, including patient information, as part of an investigation conducted in accordance with Chapter 4729. of the Revised Code.

(E) All required reporting shall be submitted to the board no later than:

(1) For an error in dispensing pursuant to paragraphs (B)(1) to (B)(3) of this rule, ten days from the date the quality assurance program review in accordance with rule 4729:5-3-22 of the Administrative Code was completed; and

(2) For the termination or resignation of an employee pursuant to paragraphs (B)(4) and (B)(5) of this rule, ten days from the date the individual is terminated or resigns from employment.

(3) For the receipt of a fraudulent or suspected fraudulent prescription or medication order, ten days from the date the pharmacist refused to dispense the prescription or medication order.

(4) For the receipt of an illegitimate product, twenty-four hours from the date the product is determined, in coordination with the manufacturer, to be illegitimate.

(F) Notwithstanding any provision of agency 4729 of the Administrative Code, a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee shall not be required to make a report to the board pursuant to the applicable duty to report rules in divisions 4729:1, 4729:2, and 4729:3 of the Administrative Code if the licensee or registrant is employed by or under contract with a pharmacy licensed as a terminal distributor of dangerous drugs and the terminal distributor submits a report in accordance with this rule.

(G) In accordance with section 4729.23 of the Revised Code, information submitted to the board in accordance with this rule shall be deemed confidential, is not a public record, and is not subject to discovery in any civil action.

Rule 4729:5-5-03 | Filing and storage of prescriptions. (NO CHANGE)

All original outpatient prescriptions shall be filed in the following manner:

(A) Prescriptions for schedule II controlled substances shall be maintained in a separate prescription file for schedule II prescriptions.

(B) Prescriptions for schedule III, IV, and V controlled substances shall be maintained in a separate prescription file for schedule III, IV, and V prescriptions.

(C) Prescriptions for non-controlled substances shall be maintained in a separate prescription file for non-controlled prescriptions.

(D) Prescriptions containing multiple drug orders shall be filed in the most restrictive file.

(E) All non-controlled hard copy prescriptions, including facsimiles, maintained pursuant to this rule may be electronically maintained, provided that the system creates and maintains electronic records in accordance with the following:

(1) All hard copy prescriptions for non-controlled dangerous drugs may be electronically filed and then destroyed after one hundred and eighty days from the date of creation or receipt. Disposal of the hard copy shall use a secure method of destruction to ensure privacy and confidentiality of the contents.

(2) All hard copy prescriptions electronically filed in accordance with this rule shall be scanned front and back in full color (i.e., retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user. Prior to scanning, the written or faxed prescription shall be clearly notated to indicate it has been received by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription.

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

(4) The electronic form shows the exact and legible image of the original hard copy prescription.

(5) All hard copy prescriptions filed electronically in accordance with this rule shall be deemed the original prescription.

(F) All electronically transmitted prescriptions, including faxed prescriptions received in an electronic format, shall be electronically stored and maintained in accordance with this rule.

(G) All electronic systems used to maintain prescription images or data shall:

(1) Contain security features to prevent unauthorized access to the records; and

(2) Contain daily back-up functionality to protect against loss of records.

(H) All prescription records stored in accordance with this rule shall be uniformly maintained for a period of three years.

(I) An outpatient pharmacy shall ensure that original prescriptions are properly filed in compliance with this rule and rule 4729:5-5-13 of the Administrative Code.

Rule 4729:5-5-05 | Prescription format requirements. (AMEND)

(A) Except as provided in paragraph (E) of this rule, no pharmacist shall dispense dangerous drugs pursuant to a ~~**written**~~ outpatient prescription unless the following conditions are met:

(1) The prescription is issued in compliance with rule 4729:5-5-15 of the Administrative Code.

(2) If handwritten, typewritten, or computer-generated hard copy, there are no more than three non-controlled substance prescription orders per prescription form.

(3) If preprinted with multiple drug names or strength combinations:

(a) There are no controlled substances among the choices; **and**

(b) There is only one prescription order selected per form.

(B) Except as provided in paragraph (E) of this rule, no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:

(1) The prescription has been issued in compliance with rule 4729:5-5-15 of the Administrative Code.

(2) The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, computer-generated hard copy, or preprinted.

(3) The quantity has been written both numerically and alphabetically.

(4) If preprinted, there is only one drug and strength combination printed on the form.

(C) A prescription for a controlled substance issued by a medical intern, resident, or fellow as described in rule 4729:5-1-02 of the Administrative Code may not be dispensed unless the prescription is issued in accordance with this rule and complies with the requirements for drug enforcement administration (D.E.A.) registration numbers for hospital and other institution employed prescribers pursuant to ~~**agency 4729**~~ **4729:5-3-15** of the Administrative Code.

(D) A prescription for a controlled substance issued by a staff prescriber of a hospital or other institution may not be dispensed unless the prescription is issued in accordance with this rule and complies with either:

(1) The requirements for D.E.A. registration numbers for hospital or other institution employed prescribers pursuant to ~~**agency 4729**~~ **4729:5-3-15** of the Administrative Code; or

(2) Includes the prescriber's D.E.A. registration number.

(E) For purposes of preprinted outpatient prescription forms for hospice care programs, the following conditions apply:

(1) Preprinted prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to the form.

(2) Preprinted forms shall not contain prescription orders for schedule II controlled substances. Schedule II controlled substances may be manually added to the preprinted forms and signed by the prescriber.

(3) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either:

(a) Manually indicating the total drug orders authorized on the form; or

(b) Manually initialing each drug order.

(4) All written drug orders must be signed by the prescriber.

(5) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy.

(6) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II controlled substances.

(7) All schedule II controlled substance prescriptions shall comply with 21 C.F.R. 1306.11 (~~**3/31/2010**~~ **March 31, 2010**).

Rule 4729:5-5-07 | Patient profiles. (AMEND)

All outpatient pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from the pharmacy.

(A) All patient profile systems shall maintain, at a minimum, the following data:

(1) The patient's data record, which shall contain all the following information:

(a) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals.

(b) Residential address, including the physical street address and telephone number of the patient or owner.

(c) Patient's date of birth.

(d) Patient's gender.

(e) A list of current patient-specific data consisting of at least the following, if made known to the pharmacist or agent of the pharmacist:

(i) Drug related allergies;

(ii) Previous drug reactions;

(iii) History of or active chronic conditions or disease states; and

(iv) Other drugs, including nonprescription drugs, devices, and nutritional supplements used on a routine basis.

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

(2) The patient's drug therapy record, which shall contain the following information for all prescriptions dispensed by the pharmacy within the last twelve months:

(a) The original prescription number.

(b) Date of issuance of the original prescription by the prescriber.

(c) Full name and address of the prescriber, including the physical address of the prescriber's practice location.

(d) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription.

(e) Directions for use.

(f) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed.

(g) The strength, dosage form, and quantity of the drug or device dispensed.

(h) The prescriber's federal drug enforcement administration registration number, if applicable.

(i) The total number of refills authorized by the prescriber.

(j) The date of dispensing.

(k) The refill history of the prescription, including all the following:

(i) The prescription number;

(ii) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;

(iii) The date(s) of dispensing; and

(iv) The quantity dispensed.

(B) A pharmacist or an agent of the pharmacist shall make a reasonable effort to obtain a patient's medical history necessary to conduct a prospective drug utilization review. An agent of the pharmacist described in this paragraph shall be limited to the following persons: a pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(C) The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This record may be a hard copy or maintained as a part of computerized system.

Rule 4729:5-5-08 | Prospective Drug utilization review. (AMEND)

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying the following:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment; and

(9) Food-nutritional supplements-drug interactions.

(B) Upon identifying any issue listed in paragraph (A) of this rule, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include, but shall not be limited to, the following:

(1) Requesting and reviewing an OARRS report or another state's prescription drug monitoring report;

(2) Consulting with the prescriber; or

(3) Counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (i.e., scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information; and

(3) United States pharmacopeia drug information.

(D) Prior to dispensing an outpatient prescription for a controlled substance dangerous drug or a drug containing gabapentin, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug or a drug containing gabapentin to the patient's therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs or a drug containing gabapentin from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a controlled substance dangerous drug, or an unfamiliar patient requesting a reportable drug by specific name, street name, color, or identifying marks.

(E) In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to reviewing a report.

(F) A pharmacist may use a delegate licensed or registered in accordance with Chapter 4729. of the Revised Code to request an OARRS report.

(G) Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Rule 4729:5-5-09 | Patient counseling. (AMEND)

(A) A pharmacist or the pharmacist's designee shall verbally offer to provide the service of counseling pursuant to paragraph (B) of this rule to a patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist or pharmacy intern under the personal supervision of a pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the dispensed drug or incorporated as part of documentation, in a conspicuous manner, that is included with the dispensed drug. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

(B) In the event a patient or caregiver accepts an offer to counsel or requests counseling, a pharmacist~~,~~ or a pharmacy intern under the personal supervision of a pharmacist~~,~~ shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:

(1) The name and description of the drug;

(2) The dosage form, dose, strength, frequency, route of administration, and duration of drug therapy;

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

(4) Special directions and precautions for preparation, administration, handling, storage, disposal, and use by the patient;

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

(6) Techniques for self-monitoring drug therapy;

(7) Proper storage and disposal;

(8) Prescription refill information;

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

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

(C) Other forms of information may be used when appropriate to supplement the counseling by the pharmacist or intern. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictograph labels, and video programs.

(D) Notwithstanding any other rule of agency 4729 of the Administrative Code, "personal supervision," as used in paragraph (B) of this rule, means that a pharmacist is on the premises at all times and is aware of all counseling activities performed by the pharmacy intern. A pharmacist who has accepted responsibility for the supervision and training of a pharmacy intern is responsible for all acts performed by the pharmacy intern working under the pharmacist's supervision.

Rule 4729:5-5-10 | Manner of processing a prescription. (AMEND)

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) A pharmacist dispensing an outpatient prescription shall comply with the requirements of this chapter, including, but not limited to, the following:

(1) Ensure that patient information is profiled pursuant to rule 4729:5-5-07 of the Administrative Code;

(2) Perform prospective drug utilization review pursuant to rule 4729:5-5-08 of the Administrative Code; and

(3) Ensure that the drug is labeled pursuant to rule 4729:5-5-06 of the Administrative Code.

(C) Prescriptions:

(1) The front of hard copy prescriptions for controlled substance dangerous drugs shall be clearly notated to indicate receipt by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription.

(2) When a pharmacist dispenses a drug pursuant to an original prescription, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.

(3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.

(D) Oral prescriptions:

(1) A pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the source of the oral prescription.

(2) Upon receiving a prescription from a recording device or voice mail service, a pharmacist shall transcribe the information. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the prescription removed from the recording device or voice mail service.

(3) A licensed pharmacy intern may receive telephone prescriptions and remove prescriptions from a recording device or voice mail service if the pharmacist on duty who is personally supervising the activity of the intern determines that the intern is competent to perform this function.

(a) The intern shall immediately transcribe the prescription, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the oral order.

(b) The pharmacist on duty is responsible for the accuracy of the prescription.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription with the prescriber or the prescriber's agent.

(4) A certified pharmacy technician may receive telephone prescriptions and remove prescriptions from a recording device or voice mail service for non-controlled drugs in accordance with rule 4729:3-3-04 of the Administrative Code.

(E) Facsimile prescriptions:

A facsimile shall only be valid as a prescription if a pharmacy retains a printed copy of a facsimile prescription or an electronic copy of the facsimile prescription in accordance with rule 4729:5-5-03 of the Administrative Code. The facsimile prescription shall comply with the requirements of rule 4729:5-3-11 of the Administrative Code.

(F) Electronic prescriptions:

(1) A pharmacy receiving electronic prescriptions directly into its computer system shall ensure original prescription information received from the prescriber is maintained in accordance with rule 4729:5-5-03 of the Administrative Code.

(2) A pharmacy computer system receiving electronic prescriptions shall:

(a) Comply with the applicable provisions of 21 C.F.R. 1311 (**August 28, 2025**); and

(b) Have the capability to receive an ICD-10-CM medical diagnosis code for all controlled substance prescriptions pursuant to rule 4729:5-5-15 of the Administrative Code.

(G) Except as provided for in section 4729.46 of the Revised Code, a pharmacist shall not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

(H) The quantity prescribed shall be considered the quantity dispensed, unless the quantity dispensed meets any of the following:

(1) If the dispensed prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or within a computerized recordkeeping system.

(2) If the quantity dispensed on a prescription is greater than the quantity prescribed, the pharmacist shall record on the original prescription or within a computerized recordkeeping system the name of the authorizing prescriber, the full name of the agent of the prescriber, if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(3) A prescription dispensed in accordance with section 4729.40 of the Revised Code. The pharmacist shall note the quantity dispensed on the original prescription or within a computerized recordkeeping system.

(I) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded in the record of dispensing by the pharmacist.

(J)

(1) A prescription issued by a prescriber who experiences a change of status, as defined in paragraph (J)(2) of this rule, that precludes a continued prescriber-patient relationship may be dispensed by a pharmacist in accordance with the following:

(a) In the exercise of the pharmacist's professional judgment:

(i) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient; or

(ii) Failure to dispense the drug to the patient could result in harm to the health of the patient.

(b) The prescription was issued prior to the prescriber's change of status, as defined in paragraph (J)(2) of this rule, and in accordance with all applicable provisions of state and federal laws, rules, and regulations.

(c) For a non-controlled substance prescription, a pharmacist may dispense up to a thirty-day supply as provided in the prescription or, if the standard unit of dispensing for the drug exceeds a thirty-day supply, the amount of the drug dispensed shall not exceed the standard unit of dispensing. The pharmacist shall exercise professional judgment in determining the amount of the drug to be dispensed.

(d) For a controlled substance prescription, a pharmacist may dispense up to a seventy-two-hour supply as provided in the prescription. The pharmacist shall exercise professional judgment in determining the amount of the drug to be dispensed.

(2) A change of status includes, but is not limited to, the following: death, incapacity, suspension, surrender or revocation of the prescriber's license or registration, or permanent relocation.

(3) A prescription for a dangerous drug dispensed in accordance with paragraph (J)(1) of this rule is considered void after the initial dispensing and may not be dispensed again. Following the initial dispensing of the drug, a pharmacist shall utilize a manual or electronic method for invalidating the prescription to prevent further dispensing.

(K) A valid prescription for a schedule II controlled substance may be partially dispensed by a pharmacist in compliance with 21 CFR 1306.13 (July 21, 2023).

Rule 4729:5-5-11 | Prescription transfers. (NEW) (RESCIND CURRENT)

(A) An outpatient pharmacy may transfer prescriptions in accordance with the following:

(1) Prescriptions may only be transferred between pharmacists, except as follows:

(a) Pharmacy interns may transfer non-controlled prescriptions in accordance with paragraph (H) of this rule; and

(b) Certified pharmacy technicians may transfer non-controlled prescriptions in accordance with rule 4729:3-3-04 of the Administrative Code.

(2) Transfers of controlled substance prescriptions shall be communicated directly between two pharmacists in accordance with all applicable federal regulations.

(B) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(C) Transfers are subject to the following requirements:

(1) The transferring pharmacist, pharmacy intern, or certified technician shall do the following:

(a) Write the word “VOID” on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(b) Record on the reverse of the invalidated prescription the name, address, name of the pharmacist, pharmacy intern, or certified technician receiving the prescription information, and, if applicable, the DEA registration number of the pharmacy to which it was transferred; for electronic prescriptions, such information must be added to the prescription record.

(c) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician transferring the information.

(d) Ensure copies of controlled substance prescriptions may only be transferred if the prescription record in the system is invalidated to prevent further dispensing at the original pharmacy.

(2) For paper prescriptions and prescriptions received orally and reduced to writing, the pharmacist, pharmacy intern, or certified pharmacy technician receiving the transferred prescription information must write the word “transfer” on the face of the transferred prescription and reduce to writing all

information required to be on a prescription pursuant to rule 4729:5-5-15 of the Administrative Code and include:

(a) Date of issuance of original prescription;

(b) Original number of refills authorized on original prescription.

(c) Date of original dispensing.

(d) Number of valid refills remaining and date(s) and locations of previous refill(s).

(e) Pharmacy's name, address, DEA registration number if transferring a controlled substance, and the serial prescription number from which the prescription information was transferred.

(f) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(g) Pharmacy's name, address, DEA registration number if transferring a controlled substance, and the serial prescription number from which the prescription was originally filled.

(3) For electronic prescriptions being transferred electronically, the transferring pharmacist, pharmacy intern, or certified pharmacy technician shall provide the receiving pharmacist, pharmacy intern, or certified pharmacy technician with the following information in addition to the original electronic prescription data as required by rule 4729:5-5-15 of the Administrative Code:

(a) The date of the original dispensing.

(b) The number of refills remaining and the date(s) and locations of previous refills.

(c) The transferring pharmacy's name, address, DEA registration number if transferring a controlled substance, and prescription number for each dispensing.

(d) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(e) The name, address, DEA registration number if transferring a controlled substance, and prescription number from the pharmacy that originally filled the prescription, if different.

(f) The contents of the prescription shall not be altered during transfer between pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(D) A prescription may be transferred by the use of a facsimile machine. A facsimile shall be considered a copy of the prescription if it meets the requirements of paragraph (C)(1) and (C)(2) of this rule, including invalidation of the original prescription. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(E) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient.

(1) If the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacy shall, upon the request of the patient or patient's caregiver, transfer the prescription information to a pharmacy designated by the patient.

(2) Unless otherwise prohibited by law, no pharmacy shall refuse to transfer information about a prescription to another pharmacy when requested by the patient, patient's caregiver, or pharmacy acting upon the request of the patient or patient’s caregiver. Prescription information shall be transferred in accordance with this rule as soon as possible, but no later than three business days, to ensure that the patient's drug therapy is not interrupted.

(3) A prescription may only be transferred upon the request or consent of the patient or patient's caregiver.

(F) The transfer for initial dispensing of an electronic prescription for a controlled substance in Schedule II-V is permissible between pharmacies, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(G) The transfer of an electronic prescription between pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one pharmacy to another pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription for a controlled substance to another form (*e.g.,* facsimile) for transmission.

(2) The contents of the prescription shall not be altered during transfer between pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) For controlled substances, the transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist, pharmacy intern, or certified pharmacy technician must add the following to the electronic prescription records maintained by the transferring pharmacy:

(a) Information that the prescription has been transferred.

(b) The name, address, the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription information, and, if transferring a controlled substance, the DEA registration number of the pharmacy to which the prescription was transferred.

(5) The receiving pharmacist, pharmacy intern, or certified pharmacy technician shall do the following:

(a) Add the word “transfer” to the electronic prescription record at the receiving pharmacy.

(b) Annotate the prescription record with the name, address, and, if receiving a controlled substance, the DEA registration number of the pharmacy from which the prescription was transferred.

(c) Record the full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(c) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription information.

(6) In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the information required, as outlined in this paragraph, from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(F) Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a licensed central fill pharmacy shall not be considered a prescription transfer and is not subject to the requirements of this rule.

(G) Records documenting the transfer prescriptions shall be maintained for three years from the date of transfer or receipt, in a readily retrievable manner, by both the pharmacy transferring the prescription and the pharmacy receiving the prescription.

(H) A licensed pharmacy intern may transfer and receive transfers for non-controlled prescriptions in accordance with the following:

(1) The pharmacist on duty who is supervising the activity of the intern determines if the intern is competent to engage in such activities.

(2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription transfer that is sent or received by the intern.

(3) The pharmacist on duty must be immediately available to answer questions or discuss the prescription transfer that is sent or received by the intern.

(4) The pharmacist or intern receiving a prescription transfer from an intern must document the full names of the intern and the intern's supervising pharmacist who transferred the prescription.

(5) The intern receiving a prescription transfer shall immediately transcribe the prescription and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the supervising pharmacist on duty shall be recorded to identify who is responsible for the receipt of the transfer.

(6) The pharmacist or intern transferring a prescription to an intern must document the full names of the receiving intern and the pharmacist on duty.

(7) The intern shall not transfer or receive a transfer for a controlled substance prescription.

(8) The intern and the pharmacist on duty shall comply with all the requirements of this rule.

Rule 4729:5-5-12 | Partial dispensing of schedule II of controlled substances. (RESCIND)

(A) A valid prescription for a schedule II controlled substance may be partially dispensed as follows:

(1) For a terminally ill patient or a patient residing in a long-term care facility, compliance with 21 C.F.R. 1306.13 (03/31/2010).

(2) For a patient who is not terminally ill or residing in a long-term care facility, the following must be observed:

(a) The partial dispensing shall be requested by the patient or the prescriber that issued the prescription;

(b) The total quantity dispensed in all partial dispensings shall not exceed the total quantity prescribed; and

(c) The remaining portions of a partially dispensed schedule II controlled substance prescription shall be filled not later than thirty days after the date on which the prescription is written.

(B) The partial dispensing of a schedule II controlled substance prescription can only occur at the pharmacy where the original prescription is on file.

(C) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription or within a computerized record keeping system pursuant to rule 4729:5-5-04 of the Administrative Code: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of the partial dispensing if different, and the manual initials or other form of positive identification of the dispensing pharmacist.

(D) If a computerized record keeping system is being used and the system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.

(1) A notation must also be made in the record keeping system that identifies the new prescription number as a partial dispensing and provides the serial number of the original prescription.

(2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription and all previous partial fills.

Rule 4729:5-5-13 | Serial numbering of prescriptions. (NO CHANGE)

All outpatient prescriptions must be serially numbered when entered into a computer system or when dispensed under a manual system.

(A) The serial number must appear on the original prescription.

(B) There must be a complete accounting of all numbers used in the serial numbering system.

(C) All prescriptions that cannot be refilled, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon an authorization for additional dispensing by a prescriber or prescriber's agent.

Rule 4729:5-5-16 | Pharmacist modifications to a prescription. (AMEND)

(A) For a schedule II controlled substance prescription:

(1) A pharmacist shall not make changes to the drug prescribed, except for substitution permitted by law, the prescriber's signature, or the patient's name.

(2) Any other modification, except for substitution permitted by law, may only be made after consultation with and agreement of the prescriber.

(B) For a schedule III-V controlled substance prescription:

(1) Except as provided for in paragraph (D) of this rule, a pharmacist shall not make changes to the drug prescribed, except for substitution permitted by law, the prescriber's signature, or the patient's name.

(2) Any other modification, except for substitution permitted by law, may only be made after consultation with and agreement of the prescriber or the prescriber's agent.

(C) For a non-controlled substance dangerous drug prescription:

(1) Except as provided for in paragraphs (D) and (E) of this rule, a pharmacist shall not make changes to the drug prescribed, except for substitution permitted by law, the prescriber's signature, or the patient's name.

(2) Any other modification, except for substitution permitted by law or in accordance with paragraph (E) of this rule, may only be made after consultation with and agreement of the prescriber or the prescriber's agent.

(D) Except for a schedule II controlled substance prescription, a pharmacist may correct a patient's name on a prescription after consultation with and agreement of the prescriber or the prescriber's agent.

(E) For a non-controlled substance prescription, a pharmacist may change the dosage form, drug strength, drug quantity, and directions for use without consultation with and agreement of the prescriber or agent of the prescriber in accordance with the following:

(1) The drug selected must be the same drug indicated on the prescription;

(2) The drug selected must have the same frequency and duration of therapy as the drug indicated on the prescription;

(3) The prescription is for a human patient;

(4) No modifications shall be made pursuant to this paragraph if "dispense as written" or another phrase or indicator having a similar meaning is indicated on the prescription;

(5) The pharmacist who selects the drug to be dispensed pursuant to this paragraph shall assume the same responsibility for selecting the dispensed drug as would be incurred in filling a prescription for a drug using the prescribed form; and

(6) The pharmacist shall not substitute between long-acting and short-acting forms of the drug.

(F) A pharmacist may dispense a quantity of a drug in a manner that varies from the prescription in accordance with ~~**paragraph (H) of**~~ rule 4729:5-5-10 of the Administrative Code ~~**or rule 4729:5-5-12 of the Administrative Code**~~ and all applicable federal and state laws, rules, and regulations.

(G) Pursuant to section 4729.391 of the Revised Code, a pharmacist may modify a drug's prescription to also include a drug delivery device, if the pharmacist determines that the device is necessary for the drug's administration.

(**H** ~~**G**~~) All consultations and corresponding changes performed in accordance with this rule shall be noted by the pharmacist on the prescription or in the patient's profile and shall be communicated to the patient or patient's caregiver.

Rule 4729:5-5-17 | Drugs repackaged or relabeled by a pharmacy. (NO CHANGE)

(A) As used in this rule, "repackaging" means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

(B) The following rule applies to dangerous drugs repackaged by an outpatient pharmacy. The rule does not apply to any of the following:

(1) Repackaging drug products for use in animals;

(2) Repackaging non-dangerous drug products;

(3) Radiopharmaceuticals as defined in Chapter 4729:5-6 of the Administrative Code;

(4) Repackaging conducted by outsourcing facilities or repackagers licensed in accordance with section 4729.52 of the Revised Code;

(5) Removing a drug product from the original container at the point of care (e.g., patient's bedside) for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient);

(6) Upon receipt of a valid patient-specific prescription or medication order, a licensed pharmacy removing from one container the quantity of non-sterile drug products (e.g., oral dosage forms) necessary to fill the prescription and placing it in a different container to dispense directly to the patient; and

(7) Investigational new drugs being studied under an investigational new drug application.

(C) Drugs repackaged by an outpatient pharmacy shall comply with the following:

(1) "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" guidance issued by the United States food and drug administration (January 2017) and any other subsequent repackaging guidance issued by the food and drug administration that is approved by the board;

(2) For sterile compounded drug preparations, United States pharmacopeia chapter <797> as referenced in rule 4729:7-1-01 of the Administrative Code.

(D) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

(1) Name of drug, strength, and dosage form;

(2) National drug code or universal product code, if applicable, which may be embedded in a bar code or quick response (QR) code on the label;

(3) The identification of the repackager by name or by the final seven digits of the terminal distributor of dangerous drugs license number;

(4) Pharmacy control number;

(5) The beyond-use date of the repackaged drug in accordance with the guidance listed in paragraph (C) of this rule.

(E) All drugs dispensed for outpatient use shall also be labeled in accordance with rule 4729:5-5-06 of the Administrative Code.

(F) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept in a readily retrievable manner for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include the following:

(1) Name of drug, strength, dosage form, and quantity;

(2) National drug code or universal product code, if applicable, which may be embedded in a bar code or quick response (QR) code on the label;

(3) Manufacturer's or distributor's control number;

(4) Manufacturer's or distributor's name, if a generic drug is used;

(5) Pharmacy control number;

(6) Manufacturer's or distributor's expiration date;

(7) The pharmacy's beyond-use date in accordance with the guidance listed in paragraph (C) of this rule;

(8) The positive identification of the individual responsible for the repackaging of the drug; and

(9) The positive identification of the pharmacist conducting the final verification of the repackaged drug to confirm the accuracy of the drug and conformity to the requirements of this rule prior to dispensing or distribution.

(G) A pharmacy that uses supplemental labels that contain a bar code or QR code for the purpose of identifying a repackaged drug shall capture the positive identification of the pharmacist responsible for the following:

(1) Association of the bar code to the drug product; and

(2) Association of the label to the drug product.

Rule 4729:5-5-22 | Return to stock in an outpatient pharmacy. (AMEND)

(A) As used in this rule:

(1) "Pharmacy delivery agent" means an employee of the pharmacy, United States postal service, or common or contract carrier who delivers dangerous drugs that have been dispensed.

(2) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.

(B) An outpatient pharmacy may return dangerous drugs to stock shelves that have been dispensed, but have never left the pharmacy (i.e., never picked up by a patient or caregiver) or the control of a pharmacy delivery agent (i.e., never delivered to a patient or caregiver), if the pharmacy complies with all of the following:

(1) The pharmacy has the capability to place the expiration date, as required by this rule, on the prescription label.

(2) The expiration date on the label shall not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging.

(3) The dangerous drug products returned to stock shelves shall be maintained in the container in which they were filled and shall maintain their original prescription label containing the original expiration date assigned. The label on the container shall not be removed, altered, or replaced with another label or have any other label added, except as follows:

(a) Adding to or modifying the existing label, if the drug name, dose, and original expiration date are maintained.

(b) Adding a new label over the existing label on the container **or relabeling the container**. In this instance, the drug shall be verified by a pharmacist or an electronic verification system following the application of the new label. The new label shall include the expiration date assigned on the original label.

(c) A prescription label may be removed if the prescription container is the manufacturer's original sealed packaging and the removal of the label does not remove or otherwise cause to make unreadable the expiration date and lot number on the manufacturer's packaging.

(4) The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.

(5) When dispensing a dangerous drug that was previously returned to stock to another patient, a new container shall be used or, in the case of unit dose or unit of use products, all previous patient information shall be removed.

(6) Drugs returned to stock shelves shall be stored in accordance with rule 4729:5-5-02 of the Administrative Code. The pharmacy shall develop and implement a policy to ensure that drugs are maintained by pharmacy delivery agents within temperatures as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(7) In the case of recalls, any drugs returned to stock shelves containing the drug affected by the recall shall be removed from the shelves immediately, unless the lot number can be determined.

(8) A dangerous drug that leaves the prescription department of the pharmacy in the custody of a pharmacy delivery agent may only be returned to stock shelves if the drug meets either of the following prior to initially leaving the prescription department:

(a) Each dangerous drug prescription is dispensed in a tamper evident container or package prior to leaving the pharmacy; or

(b) The dangerous drug prescription is dispensed in the manufacturer's original tamper evident packaging.

(9) A dangerous drug that is dispensed and shows any signs of tampering or adulteration shall not be returned to stock shelves.

(C) A pharmacy may also return drugs to stock shelves if the drugs were dispensed to a terminal distributor of dangerous drugs that is under the same common ownership and control as the pharmacy in accordance with 4729:5-3-24 of the Administrative Code. All drugs returned to stock shelves in accordance with this paragraph shall comply with the requirements of this rule.

(**D** ~~C~~) A dangerous drug that exceeds its assigned expiration date, as described in paragraph (B) of this rule, shall be removed from the area for the storage of drugs used for dispensing and administration in accordance with rule 4729:5-3-06 of the Administrative Code.

(**E** ~~D~~) Non-controlled drugs dispensed by a government entity and delivered for outpatients to a psychiatric outpatient facility or to any service provider licensed as a terminal distributor of dangerous drugs may be returned to stock if all the following apply:

(1) The drugs are packaged in unopened, single-dose or tamper-evident containers; and

(2) The drugs have not been in the possession of the ultimate user.

(**F** ~~E~~) This rule does not apply to drugs dispensed for inpatients pursuant to ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code. Drugs dispensed for inpatients may be returned to stock in accordance with the applicable provisions of ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code.

(**G** ~~H~~) A pharmacy may transfer dangerous drugs that are returned to stock shelves that meet the requirements of this rule to another pharmacy if the transfer is conducted in accordance with paragraph (E) of rule 4729:5-3-09 of the Administrative Code.

Rule 4729:5-5-23 | Security, control, and storage of dangerous drugs in an outpatient pharmacy. (AMEND)

(A) The following applies to an outpatient pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Except as provided in paragraph (A)(6) of this rule, a pharmacist shall provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, **and** all records relating to the distribution of dangerous drugs, except where the board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code, at all times in order to deter and detect theft or diversion.

(2) The pharmacy shall be separated from the merchandising or public areas.

(3) The pharmacist or pharmacists on duty:

(a) Shall be physically present at the licensed location and responsible for the security of the pharmacy and supervision of pharmacy personnel.

(b) If the pharmacy is located within a store or business, shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacists on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule.

(4) No person, other than a licensed pharmacist, may enter the pharmacy unless the person is on business directly concerning the operation, maintenance, or repair of the pharmacy and a pharmacist employed by the pharmacy is physically present at the same time.

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

(6) Whenever a pharmacist cannot meet the supervision requirements in paragraph (A)(3)(a) of this rule, security of the pharmacy must be provided in accordance with the following:

(a) The pharmacy must be secured by either:

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

(ii) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis **(i.e., twice per year)**. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier in accordance with paragraph (A)(6)(a)(i) of this rule.

(b) Except as provided in paragraph (A)(6)(i) of this rule, the pharmacy must contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist.

(c) Only a licensed pharmacist may have access to keys or other methods of gaining access to the pharmacy.

(i) Keys to the pharmacy that are not in the possession of a licensed pharmacist that are maintained on-site shall be secured to prevent unauthorized access.

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

(d) All records relating to the distribution of dangerous drugs must be maintained in the pharmacy, except as follows:

(i) The board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code; or

(ii) Any designated area outside the pharmacy used to store records that complies with paragraph (A)(6)(i) of this rule.

(e) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the pharmacy.

(f) Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist.

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

(h) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.

(i) Any designated area outside the pharmacy at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, hypodermics, and records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to this chapter of the Administrative Code, and every other item or product that requires the supervision or sale by a pharmacist shall meet the following requirements:

(i) The designated area shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(ii) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.

(iii) Authorized personnel may have access if there is supervision by a pharmacist.

(iv) No controlled substances may be stored outside of the pharmacy, except as authorized under division 4729:10 of the Administrative Code.

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

(B) Refrigerators and freezers used for the storage of dangerous drugs shall comply with the following:

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

(a) Temperature logs with, at a minimum, daily observations **(i.e., shall be logged every day even if the facility is closed to the public)**; or

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

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs. **A terminal distributor may keep unopened bottled water in the refrigerator to help maintain consistent temperatures.**

(C) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

Rule 4729:5-5-24 | Drug inventory records and other record keeping provisions. (AMEND)

(A) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received~~,~~ **;** the name and address of the seller~~,~~ **;** the name and address of the recipient~~,~~ **; and** the date of receipt**; and a transaction statement if required in accordance with Section 582 of the Food, Drug, and Cosmetic (FD&C) Act (October 1, 2025)**.

(B) Temperature logs maintained in accordance with paragraph (B) of rule 4729:5-5-23 of the Administrative Code shall include either:

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

(2) For automated systems that provide temperature monitoring, either of the following:

(a) A report that provides, at a minimum, the date and time of observation and the temperature recorded; or

(b) A report that provides temperature excursions, if any, and the date, time, temperature recorded, and length of the noted excursion.

(C) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed~~,~~ **;** the date of disposal~~,~~ **;** the method of disposal~~,~~ **;** and the positive identification of the licensed or registered health care professional that performed the disposal.

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

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

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

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

sold~~;~~ **~~and~~** the date of transfer or sale**; and a transaction statement if required in accordance with Section 582 of the Food, Drug, and Cosmetic (FD&C) Act (October 1, 2025).**

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

(1) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

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

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

(G) All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years.

(H)

(1) Except as provided for in paragraph (H)(2) of this rule, all records maintained in accordance with this chapter shall be maintained on-site.

(2) An outpatient pharmacy located in this state intending to maintain records at a location other than the location licensed by the state board of pharmacy shall send a request in a manner determined by the board. The board will provide written or electronic notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(I) All records required in accordance with this chapter shall comply with the following:

(1) Be maintained under appropriate supervision and control to restrict unauthorized access, including security features to prevent unauthorized access to computerized records; and

(2) All computerized records shall contain daily back-up functionality to protect against record loss.

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