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

Rule Contact Name and Contact Information: Summer Reyburn, summer.reyburn@pharmacy.ohio.gov

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

Administration of Drugs by Injection and Dispensing Drugs to an Alternate Location

Rule Number(s): 4729:5-5-14; 4729:5-3-24; 4729:1-3-03

Date of Submission for CSI Review: 6/5/2025

Public Comment Period End Date: 6/30/2025

Rule Type/Number of Rules:

New/_1__ rules

No Change/____ rules (FYR? ___)

Amended/__1__ rules (FYR? _Y_)

Rescinded/_1__ rules (FYR? ___)

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

Common Sense Initiative

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

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.

4729:1-3-03: Revises the rule authorizing pharmacists to administer drugs via injection. Updated to reflect changes in Ohio law that allow APRNs to authorize protocols for drug administration and adds several new drugs that pharmacists may administer via prescription and pursuant to a protocol.

4729:5-3-24: Establishes standards for pharmacies to dispense dangerous drugs to locations other than a patient's residence (such as a clinic, hospital, or prescriber office). Rescinds current rule OAC 4729:5-5-14, which is the current version of this rule.

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

The proposed rules are authorized by sections 4729.26, 4729.45, and 3719.28 of the Ohio Revised Code.

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

These rules do not implement a federal requirement.

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 dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio Board of Pharmacy. Section 4729.45 of the Ohio Revised Code authorizes the Board to add additional drugs that may be administered by a pharmacist.

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 distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, prescribe, or administer controlled substances.

Section 4729.45 of the Ohio Revised Code authorizes the Board to add additional drugs that may be administered by a pharmacist.

Without these regulations, the Board of Pharmacy would not be able to ensure the safe distribution and administration 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 distributed for initial public comment by posting the rule package to the Board's proposed rules website.

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

The Board received comments in support of allowing the following drugs to be administered by pharmacists:

- HIV prevention medications;
- Antibiotics;
- Denosumab;
- Romosozumab;
- Methotrexate;
- Heparin, low molecular weight heparin, and factor Xa inhibitors.

Additionally, the Board did receive request for other drugs to be administered but determined those would not be appropriate for pharmacist administration.

The Board received comments on OAC 4729:5-3-24 asking for additional allowances to return dispensed drugs to stock. The Board incorporated that change into the proposed rule.

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

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

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

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the administration and 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 feedback from the Board's legal department for every citation submitted.

Additionally, the Board has developed inspection guides that licensees can use to conduct self-inspections. 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.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

- Terminal distributors of dangerous drugs;
- Pharmacists.

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 or pharmacist. Discipline might include reprimand, continuing education, suspension of a license, monetary fine, and/or revocation of a license.

Additionally, OAC 4729:1-3-03 requires a pharmacist to complete a training in drug administration. OPA offers a training for pharmacists that is $295 for members and $425 for non-members.

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).***

The Board made adjustments to OAC 4729:5-3-24 to add more allowances to return dispensed drugs to stock if under common ownership.

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

The Board believes that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. The rules ensure uniform regulations protect the health and safety of patients.

Regulatory Flexibility

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

This rule package does 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 regulations are 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 administration or distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

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

The Board has also developed inspection guides that licensees can use to conduct self-inspections. 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.

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

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

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

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

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

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

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

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

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

(6) Antibiotics;

(7) Denosumab;

(8) Romosozumab;

(9) Methotrexate;

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

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

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

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

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

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

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

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

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

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

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

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

(a) The initial dose of the drug;

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

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

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

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

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

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

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

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

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

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

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

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

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration;

(g) Injection sites; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The course must include the following components:

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

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

(ii) Mechanisms of action;

(iii) Routes of administration;

(iv) Injection sites and ensuring patient privacy;

(v) Dosages and administration schedules;

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

(vii) Patient populations;

(viii) Precautions and contraindications; and

(ix) Proper storage requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Donate to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code. For the purposes of meeting the requirements under division (H) of section 3715.873 of the Revised Code and rule 4729:5-10-06 of the Administrative Code, a terminal distributor of dangerous drugs that possesses an abandoned drug shall be deemed as the owner of the drug for the sole purpose of providing consent for the drug's donation to a drug repository program; **or**

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

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

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

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

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

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

(2) Danger or harm to the patient.

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

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

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

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