Rule for Stakeholder Feedback – Pharmacist Administration of Injectable Dangerous Drugs

Comments Due 4/11/2025

Section 4729.45 of the Ohio Revised Code governs a pharmacist's ability to administer injectable drugs pursuant to a protocol. To ensure the rule mirrors the statute, the Board is proposing the following amendments to rule 4729:1-3-03:

- Authorizes pharmacists to administer HIV treatment drugs in long-acting or extended-release form **(NOTE: Added by law effective 4/9/25)**.
- Adds certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner to those prescribers who can authorize a pharmacist's drug administration protocol.

IMPORTANT REMINDER: Recent changes to Ohio law permit the Board to add additional drugs that a pharmacist may administer via injection. Currently, the list includes the following:

1. An addiction treatment drug administered in a long-acting or extended-release form. (NOTE: This includes opioid antagonists and partial agonists approved by the FDA for the treatment of addiction, which includes relapse prevention).
2. An antipsychotic drug administered in a long-acting or extended-release form.
3. A human immunodeficiency virus treatment drug administered in a long-acting or extended-release form. **(NOTE: Added by law effective 4/9/25)**
4. Hydroxyprogesterone caproate.
5. Medroxyprogesterone acetate.
6. Cobalamin, to include cyanocobalamin, hydroxocobalamin, or any other vitamin B12 injection approved by the United States food and drug administration.

If a commenter would like to see an expansion of this list, please provide the following with your comments:

- Type of drug (must be a specific drug or drug class that must be administered via injection).
- A detailed justification of how authorizing additional drugs would improve patient health and access.

Comments on the proposed rules will be accepted until the close of business on **Friday, April 11, 2025**. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov.

4729:1-3-03 **Administration of dangerous drugs by injection.**

(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer, by injection, any of the ~~following~~ dangerous drugs listed in paragraph (B) of this rule, 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) 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; and

(2) Is being administered in accordance with approved labeling by the United States food and drug administration.

~~(1) 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) 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) Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.~~

(B) The following dangerous drugs may be administered by a pharmacist in accordance with this rule:

(1) An addiction treatment drug administered in a long-acting or extended-release form;

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

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

(4) Hydroxyprogesterone caproate for pregnant women;

(5) Medroxyprogesterone acetate for non-pregnant women;

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

(7) Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.

~~(B)~~(C) 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~~M) 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 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~~G) and (~~G~~H) of this rule.

~~(C)~~(D) 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~~K) of this rule.

(5) In the case of an ~~opioid antagonist~~addiction treatment drug, obtain, in accordance with paragraph (~~D~~E) 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)~~(E) A pharmacist may obtain the test results described in paragraph (~~C~~D)(5) of this rule:

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

(2) By ordering blood and urine tests for the individual to whom the ~~opioid antagonist~~addiction treatment drug is to be administered.

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

~~(F)~~(G) A protocol ~~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~~B) 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~~F) 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~~K) 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)~~(H) 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 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, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner 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 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)~~(I) 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)~~(J) 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)~~(K) 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)~~(L) Administration records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

~~(L)~~(M) 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~~B) 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~~addiction treatment drug, 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~~D)(5) of this rule and the evaluation of such tests.

(3) A pharmacist is not required to meet the training requirements of paragraph (~~L~~M)(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~~M)(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~~B) of this rule.

~~(M)~~(N) 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)~~(O) 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~~B) of this rule.

~~(O)~~(P) 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~~M) of this rule; and

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