



Pharmacist Administration of Drugs by Injection – Public Comments Requested

Pursuant to section 4729.45 of the Ohio Revised Code (effective 4.6.2017), the State of Ohio Board of Pharmacy is required to adopt rules regarding the administration of certain injectable drugs by pharmacists pursuant to both a physician protocol and a prescription.

For more information on this new law, please visit:

<https://www.legislature.ohio.gov/legislation/legislation-summary?id=GA131-SB-332>

At this time, public comment is being sought on draft rule 4729-5-40 (*see next page*) prior to the rule being filed with the Common Sense Initiative.

Comments on the proposed rule will be accepted until close of business on **March 24, 2017**.

Please send all comments to the following email address:

Cameron.mcnamee@pharmacy.ohio.gov



4729-5-40 Pharmacist 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 as long as 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 physician-patient relationship with the physician:

- (1) An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form;
- (2) An antipsychotic drug administered in a long-acting or extended-release form;
- (3) Hydroxyprogesterone caproate;
- (4) Medroxyprogesterone acetate; or
- (5) Cobalamin.

(B) To be authorized to administer drugs pursuant to this section, a pharmacist must do all of the following:

- (1) Successfully complete a course in the administration of drugs that satisfies the requirements pursuant to paragraph (K) 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 or American heart association. 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 section, the pharmacist shall comply with all of 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 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 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 permission from the person authorized to make such decisions on the individual's behalf.

(4) The pharmacist shall obtain written permission of the patient, parent, or legal guardian of the patient. Permission shall also include notification of the patient's right to request a private room in accordance with paragraph (J) of this rule.

(5) In the case of an 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 who prescribed the drug within seven days that the drug has been administered to the individual.

(a) Notification of the physician may be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(i) Electronic mail;

(ii) Interoperable electronic medical records system;

(iii) Facsimile;

(ix) Electronic prescribing system;

(x) Electronic pharmacy record system;

(xi) Documented verbal communication;

(xii) 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 in either of the following ways:

(1) From the physician;

(2) 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 opioid antagonist. A pharmacist's authority to evaluate test results under this division 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 must include the following:

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

- (a) Name and strength;
- (b) Precautions and contraindications;
- (c) Intended audience or patient population;
- (d) Appropriate dosage;
- (e) Appropriate administration schedules;
- (f) Appropriate routes of administration;
- (g) Appropriate injection sites;

(2) The length of time the pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. 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 or pharmacy intern under the direct supervision of a pharmacist may 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 must be signed and dated by the physician prior to implementation and maintained by the administering pharmacist. The pharmacy's responsible person must renew the protocol biennially with the physician.

(2) The protocol must be established by a physician 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) 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.

(I) Dangerous drugs administered in accordance with this rule shall be administered in a location that ensures the privacy and dignity of the patient. When necessary to protect

patient privacy or if requested by the patient, this shall include a private room located outside of the prescription department.

(J) Records shall be maintained for three years on all dangerous drugs administered pursuant to section 4729.45 and must include at least the following information:

- (1) Full name and address of the patient;
- (2) Patient's date of birth or age;
- (3) Patient's gender;
- (4) Patient's applicable allergy information;
- (5) Date of administration;
- (6) Name, strength, and dose of the drug administered;
- (7) Lot number and expiration date of the drug;
- (8) Route of administration;
- (9) Location of the injection site;
- (10) Positive identification of the administering pharmacist;
- (11) Identification of the patient, parent, or legal guardian of the patient who provides permission to administer a dangerous drug pursuant to paragraph (B) of this rule.

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

- (1) The course shall be conducted by an Accreditation Council for Pharmacy Education (ACPE) accredited provider.
- (2) The course shall be taught in-person 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.
- (3) The course must be a minimum of eight hours (0.8 C.E.U.s) in length and include, at a minimum, the following:
 - (a) A review of the dangerous drugs included in the categories listed in paragraph (A) of this rule that includes:
 - (i) A review of the conditions treated or prevented;
 - (ii) Mechanisms of action;
 - (iii) Appropriate routes of administration;
 - (v) Appropriate injection sites and ensuring patient privacy;

- (vi) Appropriate dosages and administration schedules;
 - (vii) Appropriate monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;
 - (viii) Appropriate patient populations;
 - (ix) Precautions and contraindications;
 - (x) Proper storage requirements.
- (b) A review of sterile technique in injectable dosage preparation and administration.
- (c) A minimum of one hour of documented and supervised physical participation in administration techniques.
- (d) A review of the proper disposal procedures for contaminated needles and dangerous drugs.
- (e) A review of the proper procedures for accidental needle sticks.
- (f) A review of the tests necessary to comply with paragraph (C)(3) of this rule and evaluating such tests.
- (4) The course must provide a method to evaluate the successful mastery of the content.
- (5) The course must provide a method to demonstrate the pharmacist has successfully completed the course.
- (L) Courses may be reviewed by the state board of pharmacy. The Board reserves the right to disapprove a course that fails to meet the requirements set forth in this rule.
- (M) 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 in this rule prior to the administration of any dangerous drug listed in paragraph (A) of this rule.
- (N) A pharmacist shall maintain proof of successful completion of a training course pursuant to this rule on file in the pharmacy.