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Administration of Injections by Pharmacists

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Effective October 2, 2017, section 4729.45 of the Ohio Revised Code and rule 4729-5-40 of the Ohio Administrative Code authorizes a pharmacist to administer, by injection, any of the following dangerous drugs as long as the 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 opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. ***NOTE:*** *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 (including the administration of cyanocobalamin, hydroxocobalamin or any other FDA-approved B_{12} injection).

For questions regarding the new rule, please review the rule (included at the end of this document) and the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Frequently Asked Questions

Q1) How does a pharmacist become authorized to administer injections?

A pharmacist must comply with all of the following:

1. Successfully complete a course in the administration of drugs that satisfies the requirements pursuant to paragraph (K) of rule 4729-5-40.

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 physician-established protocol that meets the requirements of paragraphs (F) and (G) of rule 4729-5-40.

Q2) Are pharmacy interns allowed to administer injections?

No. The law limits administration to pharmacists.

Q3) Do I need to have a consult agreement with a physician in order to administer injections?

No. A consult agreement is not required. Please see the Q1 of this document for the requirements.

Q4) What cobalamin formulations are approved for administration?

The Board adopted the following resolution on August 7, 2017:

The State of Ohio Board of Pharmacy hereby recognizes the following, as it applies to the administration of cobalamin pursuant to section 4729.46 of the Ohio Revised Code and rule 4729-5-40 of the Ohio Administrative Code:

Cobalamin includes the administration of cyanocobalamin, hydroxocobalamin or any other FDA-approved B_{12} injection.

Q5) Where do I find training courses that meet the requirements set forth in the rule?

The Board does not have a list of courses available. Pharmacists are encouraged to contact their professional association(s) or employer for more information.

Q6) What is being tested to determine whether it is appropriate to administer an opioid antagonist in accordance with paragraph (E) of the rule?

Naltrexone is contraindicated for any individual who has a positive drug screen for opioids. A pharmacist should consult the authorizing protocol or contact the prescribing physician for additional guidance.

Q7) Does the physician-established protocol need to be authorized by the physician who issued the prescription?

No.

Q8) What formulation of dyphenhydramine may be administered to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist?

The specific formulation should be indicated in the physician-established protocol.

Q9) If I am an immunization-certified pharmacist, am I exempt from some of the training requirements?

Yes. Please refer to paragraphs (K)(3) and (K)(4) of the rule.

Q10) How do I become a Board-approved in-state provider of continuing pharmacy education?

More information about this process can be accessed here:
http://www.pharmacy.ohio.gov/Licensing/CE.aspx

Q11) Do I have to be the dispensing pharmacist in order to administer an injection?

No. The drug could be provided by a patient or another pharmacy (in accordance with rule 4729-5-10). However, the pharmacist that administers the drug is required to notify the prescribing physician in accordance with the provisions of the rule.

Q12) Is the pharmacy permitted to maintain a multi-dose vial of a patient-specific drug for patient administration?

Yes. However, the pharmacy is responsible for the proper storage of the drug in accordance with the manufacturer's labeling. Please note: The drug is the property of the patient.

Q13) Does the drug have to be prescribed by a physician?

Yes. The drug must be prescribed by a physician. While the rule does allow mid-level practitioners (PA/APRN) to manage patient-care, the law and the rule require a physician-issued prescription.

Q14) What basic life-support training courses certified by the American Red Cross or American Heart Association satisfy the requirements of the law?

The Board has determined that a pharmacist may satisfy this training requirement by completing a certified course that either provides CPR & AED training for lay persons or a more advanced basic life-support training course for healthcare providers.

For the American Red Cross: This includes either CPR/AED (note First Aid is not required) or the more advanced Basic Life Support for Healthcare Providers (BLS).

For the American Heart Association: This includes either Heartsaver® CPR AED or the more advanced Basic Life Support (BLS) for Healthcare Providers.

Please note: A course that offers a blended learning model (offering in-person training and self-directed learning) meets the requirements of the law.

Q15) Has the Board approved additional basic life-support training courses?

Yes. The Board adopted the following resolution on April 3, 2017:

The Board hereby recognizes that CPR/AED or Basic Life Support certification provided by American Safety and Health Institute (ASHI) meets the basic-life support training requirements pursuant to sections 4729.41 and 4729.45 of the Revised Code.

Q16) Do I need a to comply with the requirements of this rule if I am administering injections pursuant to a consult agreement?

No. The provisions of this rule do not apply for pharmacists that are administering these drugs under a consult agreement. Please refer to the following guidance document for more information regarding consult agreements: www.pharmacy.ohio.gov/consult

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 relationship with the physician, an advanced practice registered nurse practicing 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 opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form.

(a) 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.

(B) To be authorized to administer drugs pursuant to this rule, a pharmacist shall comply with 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, 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) and (G) of this rule.

(C) Each time a pharmacist administers a drug pursuant to this rule, 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) 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 (I) 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;

(iv) Electronic prescribing system;

(v) Electronic pharmacy record system;

(vi) Documented verbal communication;

(vii) 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 physician or the physician's agent; or

(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 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 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; and

(h) The type of tests that may be conducted 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 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 shall engage in the administration of dangerous drugs in accordance with paragraph (I) 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 physician 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 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 of the state board of pharmacy.

(4) 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 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's prescription department.

(J) Records shall be maintained for three years for all dangerous drugs administered in accordance with this rule and shall include 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 person who provides permission to administer the dangerous drug pursuant to paragraph (C) of this rule.

(K) 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 or a board approved in-state provider of continuing pharmacy education.

(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) Appropriate routes of administration;

(iv) Appropriate injection sites and ensuring patient privacy;

(v) Appropriate dosages and administration schedules;

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

(vii) Appropriate patient populations;

(viii) Precautions and contraindications;

(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;

(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 (K)(2)(b) of this rule if:

(a) The pharmacist has met the training requirements in paragraphs (A)(3)(c), (A)(3)(e) and (A)(3)(f) of rule 4729-5-36 of the Administrative Code;

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

(a) The pharmacist has met the training requirements in paragraph (A)(3)(d) of rule 4729-5-36 of the Administrative Code; and

(b) The instruction on administration techniques provided in accordance with rule 4729-5-36 of the Administrative Code includes the same techniques necessary to administer each category of dangerous drug covered by the training.

(5) Each 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.

(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 specified in this rule prior to the administration of a 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 at the location where the pharmacist administers medications in accordance with this rule.

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Five Year Review (FYR) Dates: 10/02/2022

CERTIFIED ELECTRONICALLY

Certification

09/11/2017

Date

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