



Ohio Legislative Service Commission

Bill Analysis

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H.B. 421

131st General Assembly
(As Introduced)

Reps. LaTourette, Sprague, Koehler, Hambley, Sheehy

BILL SUMMARY

- Authorizes a pharmacist to administer, in accordance with a physician protocol, a specified drug by injection, if certain conditions are met.
- Requires the pharmacist to obtain permission from the intended recipient or the person authorized to make health care decisions on the recipient's behalf.
- Requires a pharmacist to notify the prescriber each time a drug is administered by injection and to observe the recipient for any adverse reactions.
- Requires the State Board of Pharmacy to adopt rules implementing the bill's provisions.
- Requires the State Medical Board to adopt rules establishing standards and procedures for a physician or physician assistant to follow when prescribing a drug that may be administered by injection by a pharmacist.

CONTENT AND OPERATION

Pharmacist authority to administer certain drugs by injection

The bill authorizes a pharmacist to administer by injection any of the following drugs, if the drug to be administered has been prescribed by a health professional authorized to prescribe it:¹

¹ R.C. 4729.45(A).

(1) An opioid antagonist (a prescription drug that blocks the effects of opioids) used to treat drug addiction and administered in a long-acting or extended-release form;²

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

(3) Hydroxyprogesterone caproate (a prescription hormone used to lower the risk of preterm birth);³

(4) Medroxyprogesterone acetate (a prescription contraceptive).⁴

The bill also permits a pharmacist to administer epinephrine or diphenhydramine, or both, to an individual in an emergency resulting from an adverse reaction to a drug administered by injection by the pharmacist.⁵ Epinephrine is used to treat life-threatening allergic reactions and works by relaxing the muscles in the airways and tightening the blood vessels.⁶ Diphenhydramine is an antihistamine used to treat allergy symptoms.⁷

Under current law, a pharmacist or pharmacy intern may administer certain immunizations, including those specified in State Board of Pharmacy rules or recommended by the federal Centers for Disease Control and Prevention Advisory Committee on Immunization Practices.⁸ When administering an immunization, existing

² National Institute on Drug Abuse, *Principles of Drug Abuse Treatment for Criminal Justice Populations*, available at <<http://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/what-role-medications-in-treating-substance-abusing>>. See also <<http://www.vivitrol.com/About/HowVIVWorksOPD>>.

³ National Institutes of Health, U.S. National Library of Medicine, DailyMed, *Makena-hydroxyprogesterone caproate injection*, available at <<http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a1998c1d-8337-4f00-8dcb-af3b54d39b77>>.

⁴ Mayo Clinic, Tests and Procedures, *Depo-Provera* (contraceptive injection), available at <<http://www.mayoclinic.org/tests-procedures/depo-provera/basics/definition/prc-20013801>>.

⁵ R.C. 4729.45(A).

⁶ National Institutes of Health, U.S. National Library of Medicine, *Epinephrine Injection*, available at <<https://www.nlm.nih.gov/medlineplus/druginfo/meds/a603002.html>>.

⁷ National Institutes of Health, U.S. National Library of Medicine, *Diphenhydramine*, available at <<https://www.nlm.nih.gov/medlineplus/druginfo/meds/a682539.html#why>>. See also <<http://www.drugs.com/diphenhydramine.html>>.

⁸ R.C. 4729.41, not in the bill.

law requires that a pharmacist or pharmacy intern do so in accordance with a protocol established by a physician and approved by the State Board of Pharmacy.

Qualifications

To be authorized to administer drugs by injection, a pharmacist must do all of the following:

(1) Successfully complete a course in the administration of drugs that has been approved by the State Board of Pharmacy;

(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;

(3) Practice in accordance with a protocol (see "**Protocol for pharmacist administration by injection**" below) that meets the bill's requirements.⁹

The bill prohibits a pharmacist from administering drugs by injection if the foregoing requirements have not been met. It also prohibits a pharmacist from delegating to any person the pharmacist's authority to administer drugs by injection.¹⁰

Protocol for pharmacist administration by injection

A protocol for administration by injection must be established by a physician, be reviewed and approved by the State Board of Pharmacy, and specify all of the following:

(1) A definitive set of treatment guidelines;

(2) The locations at which a pharmacist may engage in the administration of drugs;

(3) Procedures to be followed by a pharmacist when administering by injection, including processes for obtaining permission from the individual receiving the drug and notifying the prescriber, as well as the length of time and location at which the pharmacist must observe the individual receiving the drug (see "**Requirements when administering drugs by injection**" below);

⁹ R.C. 4729.45(B).

¹⁰ R.C. 4729.45(E).

(4) Procedures to be followed by a pharmacist when administering epinephrine or diphenhydramine, or both, to an individual having an adverse reaction to a drug administered by injection by the pharmacist.¹¹

Requirements when administering drugs by injection

Under the bill, a pharmacist must do all of the following each time the pharmacist administers a drug specified in the bill to an individual by injection:

- (1) Obtain permission to administer the drug from one of the following:
 - (a) The individual, if the individual is 18 years of age or older;
 - (b) The individual's parent or other person having care or charge of the individual, if the individual is under 18;
 - (c) The person authorized to make health care decisions on the individual's behalf, if the individual lacks the capacity to do so.
- (2) Notify the health professional who prescribed the drug;
- (3) Observe the individual who receives the drug to determine whether the individual has an adverse reaction to it.¹²

Prescribers

Under the bill, a pharmacist may administer by injection a specified drug that is prescribed by a health professional with authority to prescribe it. The following prescribers are generally authorized to prescribe any of the drugs specified by the bill: physicians (excluding podiatrists), physician assistants, and advanced practice registered nurses holding certificates to prescribe.¹³

State Board of Pharmacy rule-making authority

The State Board of Pharmacy must adopt rules governing pharmacist administration of drugs by injection, including rules addressing all of the following:

- (1) Approving courses in the administration of drugs;
- (2) Approving protocols for the administration of drugs;

¹¹ R.C. 4729.45(D).

¹² R.C. 4729.45(C).

¹³ R.C. 4723.481, 4730.41, 4730.411, and 4731.51.

(3) Specifying procedures that a pharmacist must follow when obtaining permission from an individual to administer a drug by injection;

(4) Establishing standards regarding the length of time and location at which a pharmacist must observe the individual who receives the drug to determine whether the individual has an adverse reaction to it.

The rules must be adopted in accordance with the Administrative Procedure Act (Chapter 119. of the Revised Code). The bill requires the Board to consult with the State Medical Board and the Ohio Board of Nursing before adopting rules regarding the approval of protocols.¹⁴ However, the bill does not permit a protocol to be established by an advanced practice registered nurse.

State Medical Board rule-making authority

Under the bill, the State Medical Board must adopt rules establishing the standards and procedures that a physician or physician assistant must follow when prescribing a drug that may be administered by injection by a pharmacist. The bill, however, does not require the Ohio Board of Nursing to adopt analogous rules for advanced practice registered nurses.

The State Medical Board must adopt the rules in accordance with the Administrative Procedure Act (Chapter 119. of the Revised Code) and in consultation with the State Board of Pharmacy. The Medical Board may determine whether the rules apply in situations in which the physician or physician assistant reasonably believes that the drug will be administered by an individual other than a pharmacist.¹⁵

Practice of pharmacy

The bill defines the "practice of pharmacy" to include engaging in the administration by injection of drugs in accordance with the bill's provisions.¹⁶

HISTORY

ACTION	DATE
Introduced	12-23-15

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¹⁴ R.C. 4729.45(F).

¹⁵ R.C. 4730.412 and 4731.057.

¹⁶ R.C. 4729.01(B).

