



Ohio Legislative Service Commission

Bill Analysis

Lisa Musielewicz

Sub. H.B. 421

131st General Assembly
(As Passed by the House)

Reps. LaTourette, Sprague, Koehler, Hambley, Sheehy, Barnes, Bishoff, Amstutz, Anielski, Antani, Antonio, Boose, Boyd, Brown, Burkley, Butler, Kunze, Manning, McClain, Patterson, Perales, Rezabek, Roegner, Rogers, Slaby, Sweeney

BILL SUMMARY

- Authorizes a pharmacist to administer by injection any of the following drugs if certain conditions are met: opioid antagonists, antipsychotics, specified drugs related to preterm birth risk and contraception, and vitamin B12.
- Requires a pharmacist to notify the prescribing physician 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 to be followed by a physician when prescribing a drug that a pharmacist may administer by injection.

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 physician and the individual to whom it was prescribed has an ongoing physician-patient relationship with the physician:¹

¹ R.C. 4729.45(A) and (B)(1).

(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

(5) Cobalamin (vitamin B12).

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

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(B)(2).

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>>.

Committee on Immunization Practices.⁸ When administering an immunization, existing 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 under the bill, a pharmacist must do all of the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements established in rules to be adopted 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 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

A protocol for administration by injection 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. In addition, a protocol must satisfy the requirements established in rules to be adopted by the State Board of Pharmacy and do all of the following:

(1) Specify a definitive set of treatment guidelines;

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

(3) Include provisions for implementing the requirements to be followed when administering by injection, including provisions specifying the length of time and location at which the pharmacist must observe the individual receiving the drug;

⁸ R.C. 4729.41, not in the bill.

⁹ R.C. 4729.45(C).

¹⁰ R.C. 4729.45(G).



(4) Specify 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 for consent, observation, and notification

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) In accordance with procedures established in rules to be adopted by the State Board of Pharmacy, obtain permission to administer the drug from one of the following:

- The individual, if the individual is 18 years of age or older;
- The individual's parent or other person having care or charge of the individual, if the individual is under 18;
- The person authorized to make health care decisions on the individual's behalf, if the individual lacks the capacity to do so.

(2) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to it;

(3) Notify the physician who prescribed the drug that it has been administered to the individual.¹²

Patient tests before administering opioid antagonists

When administering an opioid antagonist to an individual, the bill requires that the pharmacist obtain test results indicating that it is appropriate to administer the drug. The requirement applies when administering either of the following: (1) the initial dose or (2) any subsequent dose, if the administration occurs more than 30 days after the previous dose was administered.¹³

The bill authorizes a pharmacist to obtain the required test results from the prescribing physician or by ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered. In the event that a pharmacist orders blood and urine tests, the bill requires that the pharmacist evaluate test results. It also

¹¹ R.C. 4729.45(F).

¹² R.C. 4729.45(D).

¹³ R.C. 4729.45(D).



provides that the authority to evaluate test results does not authorize the pharmacist to make a diagnosis.¹⁴

Rules by the State Board of Pharmacy

With respect to pharmacist administration of drugs by injection, the bill requires the State Board of Pharmacy to adopt rules that include all of the following:

- (1) Requirements for courses in the administration of drugs;
- (2) Requirements for protocols for the administration of drugs;
- (3) Procedures to be followed in obtaining permission to administer a drug by injection.

The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.). The bill also requires that the Board consult with the State Medical Board before adopting rules regarding requirements for protocols.¹⁵

Rules by the State Medical Board

Under the bill, the State Medical Board must adopt rules establishing the standards and procedures that a physician must follow when prescribing a drug that may be administered by injection by a pharmacist. The rules must be adopted in accordance with the Administrative Procedure Act and in consultation with the State Board of Pharmacy.¹⁶

Practice of pharmacy

The bill modifies the existing law definition of "practice of pharmacy" to include engaging in the administration of drugs by injection in accordance with the bill's provisions.¹⁷

¹⁴ R.C. 4729.45(E).

¹⁵ R.C. 4729.45(H).

¹⁶ R.C. 4731.057.

¹⁷ R.C. 4729.01(B).



HISTORY

ACTION	DATE
Introduced	12-23-15
Reported, H. Health & Aging	05-12-16
Passed House (94-1)	05-18-16

H0421-PH-131.docx/ks

