

Ohio Legislative Service Commission

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H.B. 80 135th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsor: Rep. Lipps

Audra Tidball, Attorney

SUMMARY

- Authorizes pharmacists, in accordance with a statewide written protocol, to conduct screenings, order lab and diagnostic tests, evaluate the results of screenings and tests, and treat: the flu, COVID-19, and strep throat.
- Authorizes pharmacists, in accordance with a physician-developed protocol, to administer by injection (1) HIV treatment drugs in long-acting or extended release forms and (2) other drugs specified by the State Board of Pharmacy in rules.

DETAILED ANALYSIS

Practice of pharmacy

The bill modifies the services that pharmacists are permitted to provide as part of their licensed practice. Specifically, as referenced in the statutory definition of "practice of pharmacy," the bill:

- Authorizes pharmacists, in accordance with a statewide written protocol, to conduct screenings, order lab and diagnostic tests, evaluate the results of screenings and tests, and treat limited health conditions, including by initiating drug therapy;²
- Expands the authority of pharmacists to administer injections of drugs by expressly including HIV treatment drugs administered in long-acting or extended release forms

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¹ R.C. 4729.01(B).

² R.C. 4729.21.

and also by authorizing the State Board of Pharmacy, through rules, to permit other drugs to be injected.³

Each provision is discussed in greater detail below.

Statewide protocol for pharmacists to screen, test, and treat

The bill authorizes a pharmacist, in accordance with a statewide written protocol to be developed by the Pharmacy Board in rules, to conduct screenings and order lab and diagnostic tests, and to evaluate the results of those screenings and tests, in order to treat the flu, COVID-19, and strep throat.⁴

Screening and testing

Under the bill, a pharmacist may use any established screening procedure that can safely be performed by the pharmacist. A pharmacist may use any test to guide diagnosis or clinical decision-making that qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments (CLIA) and related federal regulations. CLIA regulates U.S. facilities that perform lab testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease. Waived tests must be simple and have a low risk for erroneous results.

Under the bill, a pharmacist may delegate technical and administrative tasks associated with screening and testing to a pharmacy intern, registered pharmacy technician, or certified pharmacy technician, so long as the intern or technician is working under the direct supervision of the pharmacist.⁷

Treatment by initiating drug therapy

The bill authorizes a pharmacist, as part of treating one of the health conditions identified above, to initiate drug therapy.⁸

Existing authority

The bill specifies that its provisions are an alternative to existing pharmacist authority to (1) manage a patient's drug therapy under a consult agreement with a prescriber and (2) order

⁴ R.C. 4729.21(A).

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³ R.C. 4729.45.

⁵ R.C. 4729.21(B)(1) and (2).

⁶ <u>Waived Tests</u>, available by searching "CLIA waived tests" on the U.S. Centers for Disease Control and Prevention's website: cdc.gov.

⁷ R.C. 4729.21(B)(3).

⁸ R.C. 4729.21(C).

and administer diagnostic tests for COVID-19 and tests for COVID-19 antibodies. The bill does not modify that existing authority.⁹

Rules

The bill requires the Pharmacy Board to adopt rules as necessary to implement its provisions, including establishing the statewide written protocol. The rules must be adopted in accordance with the Administrative Procedure Act.¹⁰

Injections by pharmacists

The bill authorizes a pharmacist to administer by injection the following drugs, if prescribed by a physician who has an ongoing physician-patient relationship with the patient:¹¹

- An HIV treatment drug administered in a long-acting or extended release form;
- Any other drug that is specified in rules adopted by the Pharmacy Board.

Similar authority exists in current law for a pharmacist to administer by injection addiction treatment drugs and antipsychotic drugs, both of which must be in long-acting or extended release forms. Other drugs that a pharmacist may administer by injection include cobalamin (vitamin B12) and medroxyprogesterone acetate (a contraceptive and hormone therapy drug marketed under the brand name Depo-Provera). Hydroxyprogesterone caproate (known by its brand name Makena) is currently listed as a pharmacist-injectable drug, but the federal government recently withdrew its approval of the drug for reducing the risk of preterm birth and it is no longer available. 12

The bill applies requirements in existing law for pharmacist injections to the new authority being granted to pharmacists to administer additional injections. These requirements address pharmacist training, practicing in accordance with a physician-established protocol, obtaining patient permission, and physician notification.¹³

If the Pharmacy Board adopts rules to specify other drugs that a pharmacist may administer by injection, the rules must be adopted in accordance with the Administrative Procedure Act, and the Pharmacy Board must consult with the State Medical Board.¹⁴

¹¹ R.C. 4729.45(B)(1).

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⁹ R.C. 4729.21(E), citing R.C. 4729.39 and 4729.42, not in the bill.

¹⁰ R.C. 4729.21(D).

¹² <u>FDA News Release</u>, available by searching "Makena approval withdrawal" on the U.S. Food and Drug Administration's website: fda.gov.

¹³ R.C. 4729.45(C) through (G).

¹⁴ R.C. 4729.45(H)(2) and (3).

HISTORY

Date
02-27-23