

Ohio Legislative Service Commission

Office of Research and Drafting Legislative Budget Office

H.B. 73 135th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Gross and Loychik

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SUMMARY

- Authorizes a prescriber to prescribe an off-label drug and generally requires a pharmacist to dispense the drug, including when a patient has not been tested or screened for or exposed to a particular disease, illness, or infection.
- Prohibits a licensing board from pursuing a disciplinary action against a prescriber who
 prescribes the off-label drug or a pharmacist who dispenses it.
- Prohibits disciplinary action against a licensed health care professional for expressing a medical opinion that does not align with those of the licensing board, a local board of health, or the Ohio Department of Health.
- Prohibits a political subdivision, public official, or state agency from enforcing any rule or order issued by a federal agency that prohibits the use of an off-label drug.
- Prohibits a hospital from denying nutrition or fluids to a patient who has refused a hospital's treatment intervention or standard protocol.
- Generally prohibits the hospital from denying the patient's standard daily medications.
- Names the act the Dave and Angie Patient and Health Provider Protection Act.

DETAILED ANALYSIS

Off-label drugs – prescribing and dispensing

H.B. 73 authorizes a prescriber to issue for a patient a prescription for any drug, including an off-label drug – if the prescriber has obtained the patient's informed consent.¹

¹ R.C. 3792.06(B).

Under the bill, a prescriber includes a physician, advanced practice registered nurse, physician assistant, optometrist, or dentist.² The bill defines an off-label drug as a drug that is (1) approved by the federal Food and Drug Administration to treat or prevent a disease, illness, or infection, but prescribed for or used to treat or prevent another disease, illness, or infection and (2) legal for use in Ohio.³

The bill also requires a pharmacist to dispense the off-label drug, except when the pharmacist declines to do so on the basis of the pharmacist's moral, ethical, or religious beliefs or convictions.⁴

Authority to prescribe off-label

In general, once the federal Food and Drug Administration (FDA) approves a drug for a specific indication, it may be prescribed by a health care provider for any indication, absent state law to the contrary, if the provider judges it medically appropriate. This is often referred to as "off-label" use.⁵ The bill codifies that authority.

Test results and positive screenings

The bill specifies that the prescriber and pharmacist are not required to obtain a test result before issuing the off-label drug's prescription or dispensing the drug for the patient's use at home or for other outpatient treatment.⁶ Moreover, the patient is not required by the bill to have had a positive screen for a particular disease, illness, or infection before the prescriber issues the prescription or the pharmacist dispenses the off-label drug.⁷

Exposures

The bill also specifies that the patient is not required to have been exposed to a disease, illness, or infection before a prescriber may issue a prescription for the patient's prophylactic use of the off-label drug or a pharmacist dispenses the drug for such use.⁸

Disciplinary actions

H.B. 73 prohibits the following licensing boards from considering any action taken by a prescriber or pharmacist under the bill to be unlawful, unethical, unauthorized, or unprofessional conduct: the State Medical Board, Ohio Board of Nursing, State Dental Board,

² R.C. 4729.01(I), not in the bill.

³ R.C. 3792.06(A)(3).

⁴ R.C. 3792.06(C) and R.C. 4743.10, not in the bill.

⁵ U.S. Food and Drug Administration, <u>Understanding Unapproved Use of Approved Drugs "Off Label"</u> (February 5, 2018), which is also available by conducting a keyword "off label" search on the FDA's website: <u>fda.gov</u>.

⁶ R.C. 3792.06(B)(1) and (C)(1).

⁷ R.C. 3792.06(B)(2) and (C)(2).

⁸ R.C. 3792.06(B)(3) and (C)(3).

State Vision Professionals Board, and State Board of Pharmacy.⁹ It further prohibits such a board from pursuing an administrative or disciplinary action against the prescriber or pharmacist, except in cases of recklessness or gross negligence.¹⁰

Medical opinions

The bill prohibits a board that licenses or regulates a health care professional from pursuing an administrative or disciplinary action against a prescriber, pharmacist, or other licensed health professional for publicly or privately expressing a medical opinion that does not align with the opinions of the board, a local board of health, or the Ohio Department of Health.¹¹

Hospitals and other health care facilities

Under the bill, a hospital or other health care facility is prohibited from denying nutrition or fluids to a patient who has refused a hospital's or facility's treatment intervention or standard protocol.¹²

The bill also prohibits a hospital or other health care facility from denying a patient, while under the hospital's or facility's care, the standard daily medications as prescribed by the patient's prescriber, unless that medication conflicts with a medication or treatment administered by the hospital's or facility's employee or agent with the patient's informed consent.¹³

Enforcement of federal rules or orders

The bill prohibits a political subdivision, public official, or state agency from enforcing any rule or order issued by a federal agency that prohibits the use of an off-label drug.¹⁴

HISTORY

Action	Date
Introduced	02-27-23

ANHB0073IN-135/ts

⁹ R.C. 3792.06(D). ¹⁰ R.C. 3792.06(D).

¹¹ R.C. 3792.06(D).

¹² R.C. 3792.06(F).

¹³ R.C. 3792.06(F).

¹⁴ R.C. 3792.06(E).