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Office of Research and Drafting

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H.B. 324*
136th General Assembly

Bill Analysis

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Version: As Reported by House Health

Primary Sponsors: Reps. A. Mathews and Craig

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SUMMARY

- Charges the Director of Health with determining if a prescription drug causes severe adverse effects in greater than 5% of the drug's users and requires the Director to do so in consultation with the Superintendent of Insurance and Executive Directors of the State Board of Pharmacy and State Medical Board.
- Defines a severe adverse effect to mean any of the following: death, infection or hemorrhaging requiring hospitalization, organ failure, or sepsis.
- Requires the Director to base the severe adverse effects determination on the greater of insurance claims, patient reports to health care professionals, and any applicable data available from the federal Food and Drug Administration.
- Establishes conditions when prescribing a prescription drug causing severe adverse effects at the bill's threshold, including that the prescriber first conduct an in-person examination of the patient, inform the patient of the severe adverse effects, and schedule the patient for a follow-up appointment.
- Requires the Director of Health to prepare and update as needed a list of prescription drugs determined by the Director to cause severe adverse effects at the bill's threshold and to make the list, and any updates, available on the Department of Health's website.
- Names the act the Patient Protection Act.

* This analysis was prepared before the report of the House Health Committee appeared in the House Journal. Note that the legislative history may be incomplete.

DETAILED ANALYSIS

Prescription drugs causing severe adverse effects

H.B. 324 addresses prescription drugs causing severe adverse effects in greater than 5% of users, including by (1) charging the Director of Health with determining if drugs cause these effects at the bill's threshold and (2) establishing conditions on their prescribing.[1] For purposes of the bill, a severe adverse effect means any of the following:

- Death;
- Infection requiring hospitalization;
- Hemorrhaging requiring hospitalization;
- Organ failure;
- Sepsis.[2]

Director of Health determination

Under the bill, the Director of Health is responsible for determining if a prescription drug causes one or more severe adverse effects in greater than 5% of the drug's users.[3] In making the determination, the Director must consult with the Superintendent of Insurance and Executive Directors of the State Board of Pharmacy and State Medical Board, and must base the determination on the greater of the following:

- Insurance claims;
- Patient reports of severe adverse effects to health care professionals;
- Any applicable data available from the federal Food and Drug Administration (FDA).[4]

The bill does not address how the Director obtains insurance claim information or patient reports or determines, for purposes of calculating the bill's threshold percentage, how many total users an individual prescription drug may have.

Drug list

The bill requires the Director of Health to prepare and update as needed a list containing each prescription drug the Director determines causes one or more severe adverse effects in greater than 5% of the drug's users. The Director must make the list, and each of its updates, available to the public on the Department of Health's website.[5]

[1] R.C. 3715.39.

[2] R.C. 3715.39(A)(2).

[3] R.C. 3715.39(C)(1).

[4] R.C. 3715.39(C)(1)(a) to (b).

[5] R.C. 3715.39(C)(2).

Federal law

The federal Food, Drug, and Cosmetic Act grants the FDA authority to regulate the approval, labeling, sale, and recall of drugs,[6] which often involves the FDA evaluating the safety and effectiveness of drugs. Legislation that charges the Director of Health with the responsibility for separately determining if a prescription drug causes severe adverse effects in a certain percentage of users might prompt questions about federal preemption. In general, when federal and state law conflict, federal law will displace, or preempt, state law.[7] However, only a reviewing court can determine if federal law displaces a state law. For more information about preemption, please see National Association of Attorneys General - Preemption, which may be accessed by conducting a keyword "preemption" search on the Association's website: naag.org.

Conditions on prescribing

Before a prescriber may prescribe a patient a prescription drug causing one or more severe adverse effects in greater than 5% of the drug's users, the prescriber must do all of the following:

- Conduct an in-person examination of the patient;
- Inform the patient that the drug causes one or more severe adverse effects in greater than 5% of the drug's users;
- Schedule the patient for a follow-up appointment.[8]

For purposes of the bill, a prescriber includes a physician, advanced practice registered nurse, and physician assistant, but not a veterinarian.[9]

HISTORY

Action	Date
Introduced	06-03-25
Reported, H. Health	--

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[6] 21 United States Code 301 *et seq*.

[7] U.S. Constitution, Article VI, Section 2 (Supremacy Clause).

[8] R.C. 3715.39(B).

[9] R.C. 4729.01, not in the bill, and R.C. 3715.39(A)(1).