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H.B. 324
136th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. A. Mathews and Craig

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SUMMARY

- Charges the Director of Health with determining if a 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 requiring hospitalization, 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.
- Prohibits a retailer, including a pharmacy, from *selling an over-the-counter drug* if it causes severe adverse effects in greater than 5% of the drug's users.
- Also prohibits a retailer, pharmacy, or wholesale drug distributor from *selling by mail any drug* causing severe adverse effects in greater than 5% of the drug's users.
- Establishes conditions on a prescriber when issuing a prescription for such a drug, 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 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.

DETAILED ANALYSIS

Drugs causing severe adverse effects

H.B. 324 addresses drugs causing severe adverse effects in greater than 5% of users, including by charging the Director of Health with determining if drugs cause these effects at the bill's threshold, establishing conditions on their prescribing, and prohibiting certain sales of the drugs.[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 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 drug may have.

Drug list

The bill requires the Director of Health to prepare and update as needed a list containing each 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]

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[1] R.C. 3715.39.

[2] R.C. 3715.39(A)(3).

[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 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, which includes a physician, advanced practice registered nurse, and physician assistant, may issue for a patient a prescription for a 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]

Prohibited sales

Over-the-counter drugs

The bill prohibits a retailer or pharmacy (referred to in the bill as a *terminal distributor of dangerous drugs*) from selling, or offering to sell, a drug available without a prescription, if the drug causes one or more severe adverse effects in greater than 5% of the drug's users.[9]

Sales by mail

The bill also prohibits a retailer, pharmacy, or wholesale distributor of dangerous drugs from selling by mail, or offering to sell by mail, any drug that causes one or more severe adverse effects in greater than 5% of the drug's users.[10]

Given the FDA's authority to regulate drug sales and recalls, the foregoing prohibitions also might prompt preemption questions.

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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)(3). See also R.C. 4729.01, not in the bill.

[9] R.C. 3715.39(B)(1). See also R.C. 3715.05 and 4729.01, neither in the bill.

[10] R.C. 3715.39(B)(2). See also R.C. 3715.05 and 4729.01, neither in the bill.

HISTORY

Action	Date
Introduced	06-03-25

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