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OHIO LEGISLATIVE SERVICE COMMISSION

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H.B. 588
135th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Holmes and John

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SUMMARY

- Prohibits a manufacturer of dangerous drugs, repackager of dangerous drugs, third-party logistics provider, or wholesale distributor of dangerous drugs from denying, prohibiting, restricting, discriminating against, or limiting the acquisition of drugs under the 340B Drug Pricing Program by a covered entity participating in that program.
- Prohibits a manufacturer of dangerous drugs, repackager of dangerous drugs, third-party logistics provider, or wholesale distributor of dangerous drugs from requiring a 340B covered entity to submit claims or utilization data as a condition for acquiring certain drugs.
- Makes a violation of these provisions a violation of Ohio's Consumer Sales Practices Act and authorizes the Attorney General to take actions to enforce compliance with the bill's provisions.
- Specifies that the bill's provisions are not to be construed as to conflict with or be less restrictive than applicable federal or state laws and regulations.

DETAILED ANALYSIS

Acquisition of drugs by 340B covered entities

Generally, the bill prohibits a manufacturer of dangerous drugs, repackager of dangerous drugs, third-party logistics provider, or wholesale distributor of dangerous drugs from taking certain actions related to the acquisition of certain drugs by a 340B covered entity. A 340B covered entity is an entity that under federal law is authorized to participate in the 340B Drug Pricing Program and includes certain categories of hospitals and certain nonhospital providers

that are eligible based on receiving federal funding and that generally provide care to the medically underserved.¹

Under the bill, a manufacturer of dangerous drugs, repackager of dangerous drugs, third-party logistics provider, or wholesale distributor of dangerous drugs may not deny, prohibit, restrict, discriminate against, or otherwise limit the acquisition or delivery of a drug included in the 340B Drug Pricing Program (referred to in the bill as a “340B drug”) by or to a 340B covered entity, unless the purchase or delivery of the drug is prohibited by the U.S. Department of Health and Human Services (HHS). Similarly, the bill prohibits an entity described above from requiring a 340B covered entity to submit any claims or utilization data as a condition for the acquisition or delivery of a 340B drug by a 340B covered entity, unless the claim or utilization data sharing is required by HHS.²

Enforcement

The bill includes a violation of the above-mentioned provisions as an unfair or deceptive act or practice in connection with a consumer transaction under Ohio’s Consumer Sales Practices Act (CSPA).³ The CSPA generally permits the Attorney General to impose a civil penalty of up to \$5,000 or \$25,000, depending on the offense. It also grants a private right of action for the consumer against the alleged violator.⁴ Instead, the bill specifies that if a manufacturer of dangerous drugs, repackager of dangerous drugs, third-party logistics provider, or wholesale distributor of dangerous drugs violates the bill’s provisions, the Attorney General may initiate criminal proceedings in accordance with existing law or may assess a civil penalty of \$50,000 for each violation.⁵

The bill specifies that each package of drugs determined to be a violation of the bill’s prohibitions constitutes a separate violation. In addition to the enforcement mechanisms described above, the bill permits the Attorney General to refer complaints to the State Board of Pharmacy for the Board to consider imposing additional sanctions as permitted by existing law. The Attorney General may adopt rules or delegate rulemaking authority to the State Board of Pharmacy to implement the bill’s requirements.⁶

The bill specifies that its provisions are not to be construed to conflict with or be less restrictive than applicable federal law or regulations, or existing state law or regulations.⁷

¹ R.C. 4729.521(A)(1).

² R.C. 4729.521(B)(1) and (2).

³ R.C. 1345.02, not in the bill.

⁴ R.C. 1345.07(A) and (C) and 1345.09, not in the bill.

⁵ R.C. 4729.521(C).

⁶ R.C. 4729.521(C) and (D).

⁷ R.C. 4729.521(E).

HISTORY

Action	Date
Introduced	05-15-24
