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OHIO LEGISLATIVE SERVICE COMMISSION

Office of Research
and Drafting

Legislative Budget
Office

S.B. 198
136th General Assembly

Fiscal Note & Local Impact Statement

[Click here for S.B. 198's Bill Analysis](#)

Version: As Introduced

Primary Sponsor: Sen. Koehler

Local Impact Statement Procedure Required: No

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Highlights

- The bill would increase the Department of Insurance's administrative costs due to additional regulatory and enforcement functions under the bill. Any increase in such costs would be paid from the Department of Insurance Operating Fund (Fund 5540). However, the bill allows the Superintendent of Insurance to impose civil penalties, which would be deposited in Fund 5540. Thus, any penalties collected by the Superintendent would offset the Department's administrative costs.
- The bill may increase the State Board of Pharmacy's administrative costs if the Superintendent delegates authority to implement the bill's provisions or refers any complaint of the bill's violations to the Board. The Board's operating expenses are paid from DPF Fund 4K90 ALI 887609, Operating Expenses.
- The bill could potentially lead to future savings for publicly funded health care entities or the state's Medicaid Program, although the extent to which these savings would be realized is unclear. As a further consequence, the bill could possibly lead to decreased prescription drug rebates being received by Ohio's Medicaid Program.

Detailed Analysis

340B drugs

The bill prohibits a manufacturer of dangerous drugs, repackager of dangerous drugs, or third-party logistics provider, or an agent or affiliate of any of those entities from: (1) denying, prohibiting, restricting, discriminating against, or otherwise limiting the acquisition of a 340B drug by a delivery of a 340B drug to a 340B grantee, unless the purchase or delivery is prohibited by the U.S. Department of Health and Human Services (U.S. HHS) and (2) requiring a 340B grantee to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug

by or delivery of a 340B drug to a 340B grantee, unless the claims or utilization data sharing is required by U.S. HHS. The term “340B drug” is defined by the bill and references the ongoing 340B Drug Pricing Program.

Fiscal effect

It is possible that a 340B covered entity under the bill that is a public entity, such as the Ohio Department of Health’s Ryan White HIV Drug Assistance Program, could experience a decrease in administrative costs if they are currently required to submit any claims or utilization data as a condition for acquiring a 340B drug. If these entities are currently experiencing any limitations in acquiring a 340B drug, and thus not able to purchase such a drug at the reduced price, there could be some savings associated with the bill’s provisions if the reduced price is obtained in the future.

Similarly, if there are any Medicaid providers in the state who are currently not able to purchase drugs at the reduced 340B rate, the bill’s provisions could help the state’s Medicaid Program realize prescription drug savings in the future, if providers are able to obtain the reduced price for eligible drugs. To the extent this caused drugs to be distributed by 340B entities as opposed to by other Medicaid prescription drug providers, the bill’s provisions could possibly decrease the amount of prescription drug rebate revenue received by Ohio’s Medicaid Program.

Superintendent of Insurance

The bill specifies that whoever violates the bill’s provisions is considered engaging in an unfair and deceptive insurance act under existing law and is subject to proceedings under current law. Under current unfair and deceptive insurance practices, the Superintendent may assess civil penalties. In addition to the administrative remedies under current law, the bill allows the Superintendent to impose a civil penalty of \$50,000 for each such violation, but not to exceed \$10 million annually, if by written order the Superintendent finds that any person is about to engage, is engaging, or has engaged in a violation of the bill’s provisions. The bill specifies that each package of 340B drugs determined by the Superintendent to be subject to a prohibited act under the bill constitutes a separate violation.

The bill allows the Superintendent to refer any complaint of such violations to the State Board of Pharmacy for the Board’s considerations for any sanctions under existing law. The bill allows the Superintendent to adopt rules or delegate authority to the State Board of Pharmacy to implement the bill’s provisions.

The bill must not be construed to conflict with or be less restrictive than applicable federal law or regulations or applicable state laws or regulations.

Fiscal effect

The bill requirements would increase the Department of Insurance’s administrative costs to enforce and regulate acquisition of 340B drugs by covered entities. Any increase in such costs would be paid from the Department of Insurance Operating Fund (Fund 5540). However, any such cost increase may be offset by civil penalties collected under the bill, which are also deposited in Fund 5540. The bill may also increase the State Board of Pharmacy’s administrative costs if the Superintendent of Insurance delegates authority to implement the bill’s provisions or refers any complaint of the bill’s violations to the Board. The Board’s operating expenses are paid from Dedicated Purpose Fund (Fund 4K90) appropriation line item 887609, Operating Expenses.