OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

Legislative Budget Office

H.B. 324
136th General Assembly

Fiscal Note & Local Impact Statement

Click here for H.B. 324's Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. A. Mathews and Craig

Local Impact Statement Procedure Required: No

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Highlights

- The Ohio Department of Health (ODH) will likely experience costs in the millions of dollars annually, including professional staffing and information technology and data management systems costs, to determine if a drug, including either a prescription or over-the-counter drug, causes severe adverse effects in greater than 5% of the drug's users. According to the federal Food and Drug Administration (FDA), the number of approved prescription drugs total over 23,000, while the number of over-the-counter drugs is estimated to be between 100,000 and 300,000.
- Public health plans may realize an increase in insurance claims related to the bill's requirement that prescribers of a drug that causes severe adverse effects conduct an in-person examination of the patient and schedule the patient for a follow-up appointment.
- Occupational licensing boards, such as the Pharmacy Board, Nursing Board, and State Medical Board, may realize an increase in costs related to any complaints regarding potential violations of the bill's provisions.

Detailed Analysis

The bill requires the Ohio Department of Health (ODH), in consultation with the Superintendent of Insurance and the executive directors of the State Board of Pharmacy (PRX) and the State Medical Board, to determine if a drug causes severe adverse effects (including death, infection or hemorrhaging requiring hospitalization, organ failure, or sepsis) in greater than 5% of the drug's users. Under the bill, ODH is required to base this 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 (FDA). The bill requires ODH to prepare

and update as needed a list of drugs determined to cause severe adverse effects at the bill's threshold and to make the list available on ODH's website. The bill does not address how ODH is to obtain insurance claim information or patient reports, or how ODH is to determine, for purposes of calculating the bill's threshold percentage, how many total users an individual drug may have. ODH will experience significant costs, likely in the millions of dollars, to determine if a drug, including either a prescription or over-the-counter drug, causes severe adverse effects in greater than 5% of the drug's users. The Department of Insurance, PRX, and the Medical Board may also share in these costs, as ODH will consult with these agencies to make the determinations. According to the FDA, the number of approved prescription drugs total over 23,000,[1] while the number of over-the-counter drugs is estimated to be between 100,000 and 300,000.[2] According to ODH, funding would be necessary to support professional staffing with expertise to conduct reviews of insurance claims, patient reports, and to determine whether a drug causes severe adverse effects. Funding would also be necessary to support secure information technology and data management systems to handle patient medical records and insurance claims. It is possible that ODH would need to enter into contracts between insurance and health care providers in order to obtain the necessary insurance claim and patient reporting data to conduct the work required under the bill. According to the Department of Insurance, the Department does not currently collect insurance claim data from health plan providers.

Additionally, the bill 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. Retailers, pharmacies, or wholesale drug distributers are prohibited under the bill from selling by mail any drug causing severe adverse effects in greater than 5% of the drug's users. The bill also requires prescribers, when issuing a prescription for such a drug, to 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. Public health plans may realize an increase in insurance claims related to the bill's requirement that prescribers conduct an in-person examination of a patient and schedule the patient for a follow-up appointment if prescribing a drug that causes severe adverse effects in greater than 5% of the drug's users. The number of additional claims is undetermined but will depend on the number of drugs that are determined by ODH to cause severe adverse effects at that threshold. Additionally, while the bill does not establish specific penalties for violating the bill's prohibitions, occupational licensing boards, including PRX, the Nursing Board, and the State Medical Board may realize an increase in costs to investigate any complaints regarding potential violations.

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[1] See the FDA at a Glance publication, which is available by conducting an "FDA at a Glance" keyword search on the FDA's website, fda.gov.

[2] See the FDA's Over-the-Counter (OTC) Drugs Branch webpage, which is available by conducting an "OTC drug review" keyword search on the FDA's website, fda.gov.