

HOUSE COMMITTEE ON APPROPRIATIONS

FISCAL NOTE

HOUSE BILL NO. 2084

PRINTER'S NO. 2818 PRIME SPONSOR: Briggs

COST / (SAVINGS)

FUND	FY 2023/24	FY 2024/25
General Fund	No Fiscal Impact	\$110,000

SUMMARY:

Amends the Wholesale Prescription Drug Distributors License Act to include a definition for virtual manufacturer and to establish a license for virtual manufacturers in the Commonwealth.

ANALYSIS:

House Bill 2084 amends Act 145 of 1992, known as the Wholesale Prescription Drug Distributors License Act, to allow virtual manufacturers to be licensed as wholesale distributors of prescription drugs by the Commonwealth. A virtual manufacturer is an entity with a place of business located in the Commonwealth in the business of manufacturing and distributing a drug or medical device that:

- 1. Holds the drug or device approval and label code or is otherwise identified on the product label from the United States Food and Drug Administration; and
- 2. At no time takes physical possession of any drug or device in the Commonwealth.

The bill adds to Section 5(A) (License Application) to require license applications to include documentation showing compliance with federal, state, and local business registration requirements. It also requires a surety bond of a minimum of \$25,000 and a maximum of \$100,000, depending on the amount of gross receipts.

The bill exempts virtual manufacturers from certain requirements for wholesale distributors of prescription drugs if no drugs or devices are physically stored or handled at the principal place of business listed on the application. However, the bill requires virtual manufacturers to ensure minimum requirements are met at any location or contract facility where any drug or medical devices are physically stored or handled on behalf of the virtual manufacturer.

This legislation shall take effect in 180 days upon enactment.

FISCAL IMPACT:

Enactment of House Bill 2084 will require increased licensing and, therefore, result in administrative costs for the Department of Health. The department anticipates the need to hire one additional staff member, as well as increased Information Technology (IT) and legal support to carry out this work. As such, the department estimates that it will incur \$110,000 in additional costs in 2024/25 to accommodate the changes in the legislation. Increased IT and legal costs are indeterminate at this time. Due to the effective date of the legislation, there will be no impact in the fiscal year 2023/24.

PREPARED BY:Aniam Iqbal, Budget Analyst
House Appropriations Committee (D)**DATE:**April 29, 2024

Estimates are calculated using the best information available. Actual costs and revenue impact incurred may vary from estimates.