Legislative Analysis

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DRUG MANUFACTURER DATA REPORTING ACT

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House Bill 4409 as reported from committee
Sponsor: Rep. Samantha Steckloff
Committee: Health Policy
Complete to 6-28-23

SUMMARY:

House Bill 4409 would create a new act, the Drug Manufacturer Data Reporting Act, which would require drug manufacturers to disclose certain information on costs and pricing to the Department of Insurance and Financial Services (DIFS) on an annual basis. The reports and information would be exempt from disclosure under the Freedom of Information Act (FOIA). DIFS could promulgate rules to implement the act.

Annual wholesale acquisition cost report

A drug manufacturer would have to submit a report to the DIFS director within 30 days after increasing the wholesale acquisition cost of a ***qualified prescription drug*** by 15% or more in a given year or by 40% or more over a three-year period. This report would have to include the name of the drug; whether it is a brand name or generic drug or a biological or biosimilar drug product; the effective date and percentage of change in the wholesale acquisition cost; the aggregate company-level research and development costs for the previous year; the cost of researching and developing the drug with money available through a state or federal program; the name of each of the manufacturer's prescription drugs approved by the U.S. Food and Drug Administration (FDA) in the previous five years; and the name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous five years.

> ***Qualified prescription drug***, in this context, would mean a prescription drug with a wholesale acquisition cost of $500 or more for a 30-day supply.

As with the annual cost report, the quality of this information would have to be consistent with that included by the manufacturer on the U.S. Securities and Exchange Commission's Form 10-K.

Notification of a drug exceeding Medicare Part D cost threshold

A drug manufacturer would have to notify the DIFS director when introducing a new prescription drug to the market at a wholesale acquisition cost exceeding the threshold set for a specialty drug under the Medicare Part D Program. The manufacturer would have to provide this notice within three days after the release. The notice could be made pending approval by the FDA if commercial availability were expected within three days of that approval.

The notice would have to include whether the FDA granted the drug a breakthrough therapy designation or a priority review, the date of and price paid for the acquisition of the drug (if not developed by the drug manufacturer), and the costs for researching and developing the drug with money made available through a state or federal program.

Reporting by DIFS

DIFS, in turn, would have to prepare an annual report based on the information received under the new act and file it with the House and Senate health policy committees, fiscal agencies, and policy offices. DIFS would also have to post the report on a publicly accessible portion of its website. The report would have to contain aggregate data and could not include information that the DIFS director determined would cause financial, competitive, or proprietary harm to a drug manufacturer.

Penalty

A drug manufacturer that violated the act could be ordered to pay a civil fine of up to $100,000 per month for each month that a report was not filed. A violation could be prosecuted by the applicable county prosecutor or the attorney general.

The new act would take effect January 1, 2024.

BACKGROUND:

House Bill 4409 is virtually identical to HB 4347 of the 2021-22 legislative session, as passed by the House. That bill was a reintroduction of HB 5937 of the 2019-20 legislative session, which was considered by the House Health Policy committee and referred to the House Ways and Means committee. HBs 4347 and 5937 were each part of a larger package of bills. They were linked by tie-bar to two other bills pertaining to the treatment of rebates and certain payments in relation to current prohibitions against kickbacks and bribes (HBs 4350 and 4353 of 2021-22 and HBs 5943 and 5944 of 2019-20).

FISCAL IMPACT:

House Bill 4409 would have an indeterminate fiscal impact on the Department of Insurance and Financial Services. The bill would expand the department's responsibilities with respect to reviewing drug manufacturer filings and require the department to prepare an annual report based on information received under the bill. It is presently indeterminate whether additional resources would be necessary to support these activities within DIFS.

The bill also would have an indeterminate fiscal impact on the state and on local units of government. A drug manufacturer that violates reporting requirements under the bill may be ordered to pay a civil fine of up to $100,000 per month for each month that a report is not filed. Revenue collected from the payment of civil fines is used to support public and county law libraries, but, under section 8827(4) of the Revised Judicature Act, $10 of the civil fine would have to be deposited into the state's Justice System Fund, so revenue to the state would also be increased. Justice System Fund revenue supports various justice-related endeavors in the judicial branch; the Departments of State Police, Corrections, Health and Human Services, and Treasury; and the Legislative Retirement System. The fiscal impact on local court systems would depend on how provisions of the bill affected caseloads and related administrative costs. Because there is no practical way to determine the number of violations that will occur under provisions of the bill, an estimate of the amount of additional revenue the state would collect, revenue for libraries, or costs to local courts cannot be made.

The bill would authorize the Department of the Attorney General (AG) or local prosecutors to prosecute violations of the bill's requirements. The bill therefore would potentially increase

caseloads and personnel work hours for the AG and local prosecutors if they choose to prosecute. Depending on the extent to which violations occur and the work hours required, the AG or local prosecutors could require additional attorneys or support personnel to assist with cases if existing personnel are not able to adequately cover them. The annual FTE cost of an attorney for the AG is approximately $200,000.

POSITIONS:

Representatives of the following entities testified in support of the bill:

- Department of Insurance and Financial Services (5-11-23)
- Michigan Association of Health Plans (4-20-23)

The following entities indicated support for the bill:

- AARP (5-11-23)
- America's Health Insurance Plans (4-20-23)
- Blue Cross Blue Shield of Michigan (4-20-23)
- Economic Alliance of Michigan (5-11-23)
- Health Alliance Plan (4-20-23)
- McLaren Health Plan (4-20-23)
- Meridian Health Plan (4-20-23)
- Michigan Health and Hospital Association (4-20-23)
- Michigan Nurses Association (4-20-23)
- Michigan Retailers Association (5-11-23)
- Upper Peninsula Health Plan (4-20-23)

A representative of the Pharmaceutical Research and Manufacturers of America testified in opposition to the bill. (4-20-23)

The following entities indicated opposition to the bill:

- Gilead Sciences (4-20-23)
- MichBio (4-19-23)
- Michigan Chamber of Commerce (5-11-23)
- Michigan Manufacturers Association (4-20-23)

Legislative Analyst: Susan Stutzky
Fiscal Analysts: Marcus Coffin
Robin Risko
Michael Cnossen

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