Legislative Analysis

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ANNUAL REPORT AND ADVISORY COMMISSION ON PRESCRIPTION DRUG COSTS

House Bill 5223 as introduced
Sponsor: Rep. Hank Vaupel
Committee: Health Policy
Complete to 3-13-18

SUMMARY:

House Bill 5223 would amend the Public Health Code to require manufacturers of prescription drugs for sale in Michigan that have a certain wholesale acquisition cost to file an annual report with the Department of Health and Human Services (DHHS). The bill would also create a Prescription Drug Cost Advisory Commission in DHHS. The commission would create a master report that includes the data obtained from the individual reports, including drug prices, costs, and cost trends, and ways to mitigate price increases and reduce costs.

Individual reports

Beginning May 1, 2019 and on or before May 1 of each subsequent year, manufacturers would file an ***annual report*** with DHHS on costs associated with a prescription drug for the preceding calendar year if they meet both of the following requirements on January 1, 2019:

- The prescription drug has an annual wholesale acquisition cost of at least $10,000 or a wholesale acquisition cost of at least $10,000 per course of treatment.
- The manufacturer distributes the prescription drug in Michigan.

A manufacturer who failed to file the report would be subject to an administrative fine of $100,000.

The report must contain an ***itemized account*** of the following for the calendar year covered by the report:

- Total costs paid by the manufacturer and any predecessor manufacturer for manufacturing and distributing the prescription drug.
- Costs paid by the manufacturer or any predecessor manufacturer for researching and developing the prescription drug, including all of the following:
    - Costs for researching and developing the prescription drug with money available to the manufacturer through a federal, state, or other governmental program or through a subsidy, grant, or other form of monetary support.
    - After-tax research and development costs for the prescription drug.
    - Costs of clinical trials for the prescription drug.
- Research and development costs paid by a third party for the prescription drug.
- Costs paid by the manufacturer or any predecessor manufacturer for acquiring the prescription drug, including costs paid for purchasing a patent or licensing the prescription drug or costs paid to acquire a property right to the prescription drug.

- Costs paid by the manufacturer for marketing and advertising the prescription drug to consumers of the prescription drug, including any costs associated with offering and redeeming coupons or other discounts.

Additionally, the report must contain information about all of the following for the calendar year covered by the reports: each increase in the average wholesale price and wholesale acquisition cost for the prescription drug, total profit expected from the drug's sales, and the drug's price for foreign consumers.

DHHS must post a ***searchable database*** with data from these reports on its internet website, along with any information DHHS determines is necessary to assist the public in understanding the data.

Independent audit of the report

Before filing the report, a manufacturer must obtain an independent audit from list of DHHS-approved auditors. The third party who conducted the audit must file a ***summary of the audit*** with DHHS on or by May of the following year, with the manufacturer paying all costs associated with the audit and filing.

DHHS, along with the Department of Licensing and Regulatory Affairs (LARA) and the Michigan Board of Pharmacy, may promulgate any rules to implement these report and audit requirements.

Commission responsibilities

The Commission would create a ***master report*** that includes all of the following based on the individual manufacturers' reports:

- Details on prescription drug prices, costs, and cost trends.
- Policy recommendations on ways to mitigate increases in the prices of prescription drugs as a means to reduce the costs of health care in Michigan while maintaining access to quality health care.
- Any additional information considered necessary by DHHS.

The Commission would also recommend to DHHS the countries that should be included in the individual reports for the purpose of listing the prices charged to consumers in those countries for prescription drugs.

Potential violation of Michigan statute

If, based on the individual reports, DHHS or the Commission determined that a manufacturer had potentially violated the Michigan Antitrust Reform Act or Michigan Consumer Protection Act or any other Michigan law, they would notify the Attorney General's office. The individual reports would be exempt from the Freedom of Information Act (FOIA) or from publication under the bill's provisions if the Attorney General determines that publication would be inappropriate or would undermine an investigation or litigation.

Other information about the Commission

The Commission would consist of one representative from each of the following stakeholders: the pharmaceutical industry, the largest insurer in Michigan, a health maintenance organization (HMO), and pharmaceutical benefits managers. It would also include one or more individuals representing prescription drug consumers and one or more representing prescribers.

Initial members would be appointed within 15 days of the bill's effective date. Terms would be four years long, but one initial member would serve for 1 year, three for 2 years, and three for 3 years. The DHHS director would appoint individuals to fill vacancies, and may remove members for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

The members would elect a chairperson and other officers at the first meeting as they consider necessary, and would meet at least quarterly. Members would serve without compensation but could be reimbursed for necessary expenses incurred in the performance of their duties. The Commission would be subject to the Open Meetings Act, and its writings would be subject to FOIA.

The bill would take effect 90 days after enactment.

Proposed MCL 333.17748e and 333.17748f

FISCAL IMPACT:

House Bill 5223 has cost implications for the Department of Health and Human Services (DHHS) of approximately $500,000 or more. The bill requires DHHS to establish a process for detailed pharmaceutical reporting from manufacturers and public access to data, including a list of auditors, forms, publicly accessible database requiring information technology for web page and data entry, retention system for reports, organize and staff the new Prescription Drug Cost Advisory Commission, and report on the program. It is not known at this time how many manufacturers would be required to report under the bill.

Revenue could result from the administrative fine of $100,000 established under the bill, payable by a manufacturer who fails to file the report required. Administrative fines are deposited to the state general fund unless they are directed by statute to a particular fund.

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