Legislative Analysis

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ANNUAL REPORT ON PRESCRIPTION DRUG COSTS

House Bill 5223 (proposed substitute H-2)
Sponsor: Rep. Hank Vaupel
Committee: Health Policy
Complete to 12-4-18

SUMMARY:

House Bill 5223 would amend the Public Health Code to require manufacturers of prescription drugs for sale in Michigan that met certain requirements to file an annual report with the Department of Health and Human Services (DHHS).

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 the drug were distributed for sale in Michigan and met one of the following requirements:

- The prescription drug is remanufactured, resulting in a decrease in the prescription drug's shelf life.
- The prescription drug has an annual wholesale acquisition price of at least $500 or a wholesale acquisition cost of at least $500 per course of treatment.
- The prescription drug has a list price for a 30-day supply that has increased by 25% or more during the five years immediately preceding the calendar year covered by the report or by 5% or more during the preceding calendar year.

A manufacturer who failed to file the report would be subject to an administrative fine of $100,000 per month for every month the report was not filed.

The report would have to 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.
- The aggregate rebates paid by the manufacturer to pharmacy benefit managers that were related to the use of the prescription drug by health insurers.

Additionally, the report would have to contain information about each increase in the list price for a 30-day supply of the prescription drug and the drug's price for foreign consumers for the calendar year covered by the reports.

The bill would require DHHS to 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 would have to 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, could promulgate any rules to implement these report and audit requirements.

House Bills 5223 and 6435 are tie-barred together, meaning that neither could take effect unless both were enacted.

Proposed MCL 333.17748e

FISCAL IMPACT:

House Bill 5223 has cost implications for the Department of Health and Human Services (DHHS) of approximately $500,000. The bill requires DHHS to establish a process for detailed pharmaceutical reporting and verification from manufacturers and auditors, maintain a list of auditors and forms, provide a publicly accessible database which would require information technology costs for web page, data entry and reporting, and maintain a retention system for reports. It is not known at this time how many manufacturers would be required to report under the bill, or how many prescription drugs would be required to be reported on.

Revenue could result from the administrative fine of $100,000 established under the bill, payable per month 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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