Legislative Analysis

DRUG PRICING TRANSPARENCY

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House Bill 4347 (H-1) as amended and passed by the House
Sponsor: Rep. Angela Witwer

Analysis available at
http://www.legislature.mi.gov

House Bill 4350 (H-5) as passed by the House
Sponsor: Rep. Stephanie Young

House Bill 4353 as passed by the House
Sponsor: Rep. Bronna Kahle

Committee: Health Policy
Complete to 8-23-21

SUMMARY:

House Bill 4347: Drug Manufacturer Data Reporting Act

House Bill 4347 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. Violation could be prosecuted by the applicable county prosecutor or the attorney general.

House Bill 4350: Generic Equivalent Rebate

House Bill 4350 would amend the Health Care False Claim Act to change two exceptions from being considered a violation of the act's prohibition against kickbacks and bribes.

Section 4 of the act provides that a person who solicits, offers, pays, or receives a kickback or bribe in connection with furnishing goods or services for which payment is or may be made in whole or in part by a health care corporation or health care insurer, or who receives a rebate of a fee or charge for referring an individual to another person for health care benefits, is guilty of a felony punishable by imprisonment for up to four years or a fine of up to $50,000, or both.

Section 4a of the act provides that the prohibition in section 4 does not apply to a rebate or discount from a drug manufacturer or from a company that licenses or distributes the drugs of a drug manufacturer to a consumer for the consumer's use of a drug manufactured or licensed or distributed by the drug manufacturer or company. The prohibition also does not apply to a monetary payment from a drug manufacturer to a consumer, the consumer's health professional, or a vendor that has a contract with the drug manufacturer, for a health care service that the prescribing information of a qualified drug requires or recommends for initiating drug therapy.

The bill would amend both of these exceptions, with one set of rules in place through 2022 and the other beginning in 2023.

Under the bill, through December 31, 2022, the prohibition in section 4 would not apply to a rebate or discount from a drug manufacturer or a company that licenses or distributes the drugs of a drug manufacturer to or for the benefit of a consumer for the consumer's use of a drug manufactured, licensed, or distributed by the drug manufacturer or company.

Then, beginning January 1, 2023, the prohibition would not apply to a rebate, discount, product voucher, or other reduction in a consumer's out-of-pocket expenses, including a copayment or deductible, from a drug manufacturer or a company that licenses or distributes the drugs of a

drug manufacturer to or for the benefit of the consumer for the administration or the consumer's use of a drug manufactured, licensed, or distributed by the drug manufacturer or company, but only if the reduction was not for a drug that had a generically equivalent drug product or biosimilar drug product, for which a contract, certificate, or policy issued by a health care insurer or health care corporation covering the consumer provides coverage on a lower cost-sharing tier, unless any of the following apply:

- The consumer obtains access to the drug through prior authorization, a step-therapy protocol, or a health care insurer's or health care corporation's exception process.
- The consumer's prescriber has instructed a pharmacist to dispense the drug as allowed for a generically equivalent drug product or interchangeable biological drug product.
- The drug is required under an FDA Risk Evaluation and Mitigation Strategy to monitor or facilitate the use of a drug according to its prescribing information.

The bill also would amend the requirement that the other exception in section 4a be for payment for services called for by a "qualified" drug (which is currently defined as a drug indicated to treat multiple sclerosis): it would apply to a qualified drug through December 31, 2022, and for a drug beginning January 1, 2023.

MCL 752.1002 and 752.1004a

House Bill 4353: Accumulators

House Bill 4353 would amend the Insurance Code to provide that a health insurance policy delivered, issued for delivery, or renewed in Michigan after December 31, 2022, that provides coverage for ***prescription drugs*** must apply any amount paid by the insured (or on behalf of the insured by another person that is not an unauthorized payer) when calculating the insured person's overall contribution to any out-of-pocket maximum or cost-sharing requirement. If any provision of the bill conflicted with a federal law, the federal law would prevail.

> ***Prescription drug*** would conform with its typical meaning under the Public Health Code (a drug dispensed pursuant to a prescription; one bearing the federal legend "CAUTION: federal law prohibits dispensing without prescription" or "Rx only"; or one designated by the Board of Pharmacy as a drug that can only be dispensed pursuant to a prescription), but it would not include a drug with a generic equivalent unless the insured obtained access to the drug through any of the following:
>
> - Prior authorization.
> - A step therapy protocol.
> - The insurer's exemption process.

However, if that payment was a kickback or bribe in violation of section 4 of the Health Care False Claims Act, a person could be guilty of a felony punishable by imprisonment of up to four years or a fine of up to $50,000, or both.

Proposed MCL 500.3406v

Tie-bars

House Bill 4347 is tie-barred to HB 4353, and HB 4353 is tie-barred to HB 4350. A bill cannot take effect unless every bill to which it is tie-barred is also enacted.

BACKGROUND:

House Bills 4347, 4350, and 4353 are, respectively, reintroductions of HBs 5937, 5943, and 5944 of the 2019-20 legislative session.[1] Those bills were considered by the House Health Policy committee and referred to the House Ways and Means committee.

FISCAL IMPACT:

House Bill 4347 would have an indeterminate fiscal impact on DIFS. 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 not more than $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 be required 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 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.

House Bill 4350 would not have an appreciable fiscal impact on the state or on any unit of local government.

House Bill 4353 would have an indeterminate fiscal impact on the state and on local units of government. Under section 3406v(1) of the bill, if a payment was a kickback or bribe in violation of the Health Care False Claims Act, the person making the payment could be guilty of a felony punishable by imprisonment of up to four years or a fine of up to $50,000, or both. New felony convictions would result in increased costs related to state prisons and state probation supervision. In fiscal year 2020, the average cost of prison incarceration in a state facility was roughly $42,200 per prisoner, a figure that includes various fixed administrative and operational costs. State costs for parole and felony probation supervision averaged about

[1] http://www.legislature.mi.gov/documents/2019-2020/billanalysis/House/pdf/2019-HLA-5937-4396DAFF.pdf

$4,300 per supervised offender in the same year. Those costs are financed with state General Fund/General Purpose revenue. The fiscal impact on local court systems would depend on how provisions of the bill affected court caseloads and related administrative costs. Any increase in penal fine revenue would increase funding for public and county law libraries, which are the constitutionally designated recipients of those revenues. Because there is no practical way to determine the number of violations that will occur under provisions of the bill, an estimate of costs to the state or to local units, or revenue for libraries cannot be made.

POSITIONS:

HB 4347

Representatives of the following entities testified in support of HB 4347 (3-4-21):

- Blue Cross Blue Shield of Michigan
- Michigan Association of Health Plans

The following entities indicated support for HB 4347:

- National Multiple Sclerosis Society (3-4-21)
- Grand Rapids Chamber of Commerce (3-4-21)
- Economic Alliance for Michigan (3-11-21)

Representatives of the following entities testified in opposition to HB 4347 (3-4-21):

- Biotechnology Innovation Organization
- Pharmaceutical Research and Manufacturers of America (PhRMA)

The Michigan Manufacturers Association indicated opposition to HB 4347. (3-11-21)

HB 4350

The following entities indicated support for HB 4350 (3-10-21):

- Economic Alliance for Michigan
- Michigan Manufacturers Association

Representatives of the following entities testified in opposition to HB 4350 (3-10-21):

- Blue Cross Blue Shield of Michigan
- Michigan All Copays Coalition
- Michigan Association of Health Plans

The following entities indicated opposition to HB 4350:

- Boehringer Ingelheim (3-10-21)
- Detroit Regional Chamber (3-16-21)

HB 4353

Representatives of the following entities testified in support of HB 4353:

- Hemophilia Foundation of Michigan (3-4-21)
- National Psoriasis Foundation (3-10-21)
- Arthritis Foundation (3-10-21)

The following entities indicated support for HB 4353:

- Allergy and Asthma Network (3-10-21)
- American Diabetes Association (3-10-21)
- Association for Clinical Oncology (3-4-21)
- Cystic Fibrosis Foundation (3-10-21)
- Epilepsy Foundation of Michigan (3-10-21)
- HIV + Hepatitis Policy Institute (3-10-21)
- Lupus and Allied Diseases Association (3-10-21)
- Michigan All Copays Count Coalition (3-3-21)
- Michigan Chapter of the American College of Cardiology (3-10-21)
- Michigan Society of Hematology and Oncology (3-10-21)
- National Multiple Sclerosis Society (3-10-21)
- Otsuka Pharmaceutical (3-10-21)
- Pharmaceutical Research and Manufacturers of America (PhRMA) (3-10-21)
- Rock CF Foundation (3-10-21)

Representatives of the following entities testified in opposition to HB 4353 (3-10-21):

- Blue Cross Blue Shield of Michigan
- Michigan Association of Health Plans

The following entities indicated opposition to HB 4353:

- America's Health Insurance Plans (3-10-21)
- CVS/Aetna (3-10-21)
- Economic Alliance for Michigan (3-10-21)
- Michigan Chamber of Commerce (3-10-21)
- Michigan Manufacturers Association (3-11-21)
- Small Business Association of Michigan (3-10-21)

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.