

DRUG PRICING TRANSPARENCY

Phone: (517) 373-8080
<http://www.house.mi.gov/hfa>

House Bill 5937 as introduced
Sponsor: Rep. Hank Vaupel

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

House Bill 5938 as introduced
Sponsor: Rep. Frank Liberati

House Bill 5944 as introduced
Sponsor: Rep. Ben Frederick

Committee: Health Policy
Complete to 7-22-20

SUMMARY:

House Bill 5937: Drug Manufacturer Data Reporting Act

House Bill 5937 would create a new act, called the Drug Manufacturer Data Reporting Act, which would require drug manufacturers to disclose certain information as to costs and pricing to the Department of Insurance and Financial Services (DIFS) on an annual basis. The reports and information received under the act would be exempt from disclosure under the Freedom of Information Act (FOIA). DIFS could promulgate rules to implement the act.

Annual cost report

Beginning January 1, 2022, and annually thereafter, or more frequently if required by the director of DIFS, a drug manufacturer would have to file a report with DIFS containing:

- All of the following for the preceding calendar year:
 - The aggregate wholesale acquisition cost charged by the manufacturer for each therapeutic category of prescription drugs, net of all rebates and other fees and payments, direct or indirect, from all sources.
 - The aggregate amount of rebates paid by the manufacturer to PBMs, including any utilization discounts.
 - The aggregate amount of all fees from all sources, direct or indirect, that the manufacturer paid to PBMs.
 - Whether the manufacturer had a contract or other arrangement with a PBM to exclusively provide a prescription drug and the consideration or economic benefit provided under the contract or arrangement.
 - Information on financial incentives and structures used by the manufacturer.
- All of the following for each of the drug manufacturer's prescription drugs:
 - The total amount of research and development costs to bring the drug into the market.

- The total costs paid by the manufacturer and any predecessor manufacturer for manufacturing and distributing the drug for the period of time that the drug has been on the market.
- The total amount of marketing and advertising costs for the drug for the period of time that it has been on the market.
- Any other information required by the DIFS director.

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.

Annual wholesale acquisition cost report

Beginning January 1, 2022, and annually thereafter, a drug manufacturer would have to submit a report to the DIFS director containing information on the wholesale acquisition cost of each prescription drug sold in Michigan by that manufacturer.

Additionally, the 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 10% or more in a given year or 20% 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; 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 U.S. in the previous five years.

Qualified prescription drug, in this context, would mean a prescription drug with a wholesale acquisition cost of \$100 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 that exceeded the threshold set for a specialty drug under the Medicare Part D Program. The manufacturer would have to provide this notice within three days following 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 proposed act and would have to file it with the House and Senate Health Policy committees, fiscal agencies, and policy offices. 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 5938: Pharmacy Benefit Manager Licensure and Regulation Act

House Bill 5938 would create a new act, called the Pharmacy Benefit Manager Licensure and Regulation Act, to govern *pharmacy benefit managers* (PBMs).

Pharmacy benefit managers, generally, would be persons that contract with a pharmacy on behalf of an employer, multiple employer welfare arrangement, public employee benefit plan, state agency, insurer, managed care organization, or other third-party payer to provide pharmacy health benefits services or administration that includes, but is not limited to, all of the following:

- Contracting directly or indirectly with pharmacies to provide drugs to enrollees or other covered persons.
- Administering a drug benefit.
- Processing or paying pharmacy claims.
- Creating or updating drug formularies.
- Making or assisting in making prior authorization determinations on drugs.
- Administering rebates on drugs
- Establishing a pharmacy network.

A PBM would not include the Department of Health and Human Services (DHHS) or an insurer.

Licensure

Under the bill, a PBM that provided services to Michigan residents would have to apply for, obtain, and maintain a license to operate as a PBM from the director of DIFS. A license under the proposed act would be renewable biennially and would be nontransferable.

An applicant for a license would have to submit to the DIFS director an application form that included the contact information for the PBM, as well as for specified associated persons, and an application fee.

The DIFS director could suspend, deny, or restrict the license for a violation of the proposed act or on other grounds or violations of state or federal laws. If the license were

suspended or restricted, the director could permit the operation of the PBM for up to 60 days with conditions and restrictions determined by the director (and could revoke the license thereafter). The suspended or restricted PBM would be subject to a fine of up to \$5,000 per month until the violation had been remedied.

For the purpose of these licensing rules, a PBM would have the same rights to notice and hearings as are provided to insurers under the Insurance Code.

A contract between a PBM and an insurer that existed on the date the PBM was licensed would have to comply with the requirements of the proposed act as a condition of licensure for the PBM.

To renew a PBM license, an applicant would have to submit a renewal application, renewal fee, and PBM network adequacy report, described below.

PBM duties

Under the bill, a PBM would have to exercise good faith and fair dealing when performing contractual duties, and a contract provision purporting to waive or limit those duties would be void. A PBM would have to notify a carrier of any activity, policy, or practice that directly or indirectly presented a conflict of interest with those duties.

PBM Network

A PBM would have to provide a reasonably adequate and accessible PBM network for the provision of drugs for a health plan that must provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence. A PBM could not include a mail-order pharmacy in calculating PBM network adequacy.

If unable to comply with the adequacy requirements, a PBM could apply for a two-year renewable waiver from the DIFS director. To apply, a PBM would have to submit an application that demonstrates why the PBM is unable to meet adequacy requirements and describes the steps the PBM has taken and will take to address network adequacy. If approved, a waiver would expire after two years, but would be renewable depending on the steps the PBM had taken over the waiver period to address network adequacy.

Conflict of interest reporting

A PBM that had an ownership interest in a pharmacy would have to disclose to a contracting carrier any difference between the amount paid to the pharmacy and the amount charged to the carrier.

Generally, a PBM could not penalize, require, or provide financial incentives to an enrollee as an incentive to use a pharmacy in which a PBM had an interest (or which had an interest in the PBM). However, this requirement would not apply in the following instances:

- If the PBM offered an enrollee the same financial incentives for a pharmacy in which the PBM had no interest.
- If the network pharmacy agreed to the same terms related to cost that are in the agreement with the pharmacy in which the PBM had the interest.

- If the pharmacy's status within the pharmacy network was identified as a preferred pharmacy if the payment to that pharmacy was not higher than to a nonpreferred pharmacy.

Typically, a PBM or carrier could not impose limits, including quantity or refill frequency limits, on an enrollee's access to medication that differed based solely on whether the carrier or PBM had an ownership interest in the pharmacy or the pharmacy had an ownership interest in the PBM. However, this would not prohibit a PBM from imposing those limits based on whether the enrollee used a mail-order pharmacy or retail pharmacy if the enrollee had the option to use one of those pharmacies (and those pharmacies had the same limits imposed).

A PBM or carrier could not prohibit a **340B Program entity** or 340B-contracted pharmacy with a license in good standing from participating in the PBM's or carrier's provider network. A PBM or carrier could not reimburse one of those entities differently than other similarly situated pharmacies.

340B Program entity would mean an entity authorized under section 340B of the Public Health Service Act, which requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for uninsured and low-income patients. These organizations include qualifying hospitals, federal grantees from the Health Resources and Services Administration, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.¹

No limit on disclosing risks and alternatives

The bill would not allow a contract between a PBM and a pharmacist or pharmacy that provided drug coverage for health plans to restrict or penalize a pharmacy or pharmacist from disclosing, as the party deemed appropriate:

- The nature of the treatment or the risks or the alternatives to the treatment.
- The availability of alternate therapies, consultations, or tests.
- The decision of utilization reviewers or similar persons to authorize or deny services.
- The process used to authorize or deny health care services or benefits.
- Information on financial incentives and structures used by an insurer.

Additionally, a PBM could not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a drug or from selling a more affordable alternative to the enrollee or insured if the alternative is available.

¹ <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>

Annual transparency report

Unless required more frequently by the DIFS director, beginning January 1, 2021, a PBM would have to file an annual transparency report with the director that contained the following information for the preceding calendar year:

- The aggregate wholesale acquisition costs from a manufacturer or wholesale drug distributor for each therapeutic category of drugs for all of the PBM's plan sponsors, net of all rebates and other fees and payments, direct or indirect, from all sources.
- The aggregate amount of all rebates that the PBM received from all manufacturers for all of the PBM's plan sponsors. The aggregate amount would have to include any utilization discounts the PBM received from a manufacturer or wholesale drug distributor.
- The aggregate amount of all fees that the PBM received.
- The aggregate amount of all rebates that the PBM received from all manufacturers that were not passed through to health plans or insurers.
- The aggregate amount of all fees that the PBM received from all manufacturers that were not passed through to health plans or insurers.
- The aggregate retained rebate percentage.

The DIFS director would have to conduct an annual review against all de-identified claims submitted to analyze whether pharmacy payment and patient cost-sharing variations have occurred, using specified data. (Certain data that would otherwise be used for these purposes would not be subject to FOIA or to subpoena or discovery or admissible in evidence in any private civil action, but the DIFS director could use the data in furtherance of any regulatory or action brought by the director.)

The reporting requirements outlined in this section would not apply if the PBM had contracted with DHHS under Medicaid.

DIFS annual report

DIFS would have to prepare an annual report based on the information received under the proposed act. The report would have to contain aggregate data and could not contain information that the director determined would cause financial, competitive, or proprietary harm to a PBM or carrier serviced by the PBM. The DIFS director would have to file the report with the House and Senate Health Policy committees, fiscal agencies, and policy offices.

Maximum allowable cost

For each drug for which a PBM established a maximum allowable cost, the PBM would have to do all of the following:

- Provide each pharmacy subject to a maximum allowable cost list with access to that list and the source used to determine the maximum allowable cost for each drug.
- Update its maximum allowable cost list at least once every seven days.
- Provide a process for each pharmacy subject to the maximum allowable cost list to receive prompt notification of an update to the maximum allowable cost list.

- Establish and maintain a reasonable administrative appeals process to allow a pharmacy subject to the maximum allowable cost list to challenge a listed maximum allowable cost.
- Respond in writing to any appealing pharmacy within 10 days of receiving the appeal (as long as the pharmacy appealed within 10 days of when the pharmacy's claim for reimbursement was adjudicated).

Before a PBM could place or continue a drug on a maximum allowable cost list, the drug would have to be available for purchase by each pharmacy in Michigan from national or regional wholesale drug distributors in Michigan, and the drug could not be obsolete.

Permissible use for data

The DHHS director could examine or audit a PBM's books and records providing claims processing services or *other drug and device services* for a health plan to determine if the PBM was in compliance with the act. All of the following would apply to this data or information:

- It would be proprietary and confidential.
- It would not be subject to FOIA.
- It could only be used for purposes of ensuring a PBM's compliance with the proposed act.

Other drug or device services would mean services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including any of the following:

- Negotiating rebates, discounts, or other financial incentives and arrangements with manufacturers.
- Disbursing or distributing rebates.
- Managing or participating in incentive programs or arrangements for pharmacist services.
- Negotiating or entering into contractual agreements with pharmacists or pharmacies.
- Developing drug formularies.
- Designing prescription drug benefit programs.
- Advertising or promoting services.

Rule promulgation

In order to implement the act, the DIFS director would have to promulgate rules, including fines, suspension of licensure, restriction of licensure, and revocation of licensure.

House Bill 5944

The bill would amend the Insurance Code to provide that a health insurance policy delivered, issued for delivery, or renewed in Michigan 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 any cost-sharing requirement. This provision would apply to a health insurance policy delivered, issued for delivery, or renewed in Michigan after December 31, 2021.

Unauthorized payer would mean a person that is prohibited from paying for prescription drug coverage by federal law, state law, or contractual requirements.

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 5938 is tie-barred to HB 5937, and House Bill 5937 is in turn tie-barred to HB 5944. A bill cannot take effect unless every bill to which it is tie-barred is also enacted.

FISCAL IMPACT:

House Bill 5937 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 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. We do not have a practical way to determine the number of violations that will occur under provisions of the bill, so cannot estimate revenue the state would collect, revenue for libraries, or costs to local courts.

A fiscal analysis for the Department of Insurance and Financial Services is in progress.

House Bill 5938 would permit the Department of Attorney General (AG), or local prosecutors, to prosecute violations of the bill's requirements. The bill would therefore potentially increase caseloads and personnel work hours for the AG or 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 \$200,000.

A fiscal analysis for the Department of Insurance and Financial Services is in progress.

House Bill 5944 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. The number of convictions that would result under this provision is not known. New felony convictions would result in increased costs related to state prisons and state probation supervision. In fiscal year 2019, the average cost of prison incarceration in a state facility was roughly \$39,400 per prisoner, a figure that includes various fixed administrative and operational costs. State costs for parole and felony probation supervision averaged about \$3,800 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.

Legislative Analyst: Jenny McNerney
Fiscal Analysts: Michael Cnossen
Marcus Coffin
Robin Risko

■ 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.