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PHARMACY BENEFIT MANAGERS

House Bill 4348 (H-1) as reported from committee
Sponsor: Rep. Julie Calley
Committee: Health Policy
Revised 6-9-21

SUMMARY:

House Bill 4348 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 or a pharmacy's agent 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, beginning January 1, 2023, a PBM that provides services to Michigan residents would have to apply for, obtain, and maintain a license to operate as a PBM from the director of the Department of Insurance and Financial Services (DIFS). A license under the proposed act would be renewable every two years and would be nontransferable.

An applicant for a license would have to submit to the DIFS director an application, including organizational documents and (if applicable) a power of attorney for the PBM, information about specified associated persons, recent financial statements, a description of the PBM, confirmation that the PBM's contracts comply with the proposed act, and an application fee.

Within 30 days of any significant modification of information included in the application, a PBM would have to file a notice of the modification with the DIFS director.

The DIFS director could refuse to issue a license upon determining that the PBM is not financially viable or that the PBM or an associated person has had a PBM certificate of authority or license denied or revoked for cause in another state.

Additionally, the DIFS director could suspend, deny, or revoke a license (or issue a cease and desist order if the PBM did not have a license) for a violation of any lawful rule or order or applicable Michigan law, for refusal to comply with financial or legal obligations, or for other specified violations. If the license were suspended or restricted, the director could allow the operation of the PBM for up to 60 days, or longer if the director determined continued operations to be in the interest of covered persons. (He or she could revoke the license thereafter.) The suspended or restricted PBM would be subject to a fine of up to $20,000 per month until the violation was remedied.

For the purpose of these licensing provisions, a PBM would have the same rights to notice and hearings as are provided to insurers under the Insurance Code. The DIFS director could investigate officers, directors, and owners of a PBM in the same manner as officers, directors, and owners of a business entity licensed 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 PMB 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. A PBM would have to notify all known covered persons of a cost share increase for a maintenance drug at least 60 days before it will take effect. A PBM would have to communicate the final reimbursement amount to the network pharmacy at the time of adjudication at the point of sale. Finally, a carrier, health plan, or PBM could not retroactively charge a network pharmacy a fee, charge, or other amount, whether based on performance metrics or otherwise, after communication of the final reimbursement amount at the time of adjudication at the point of sale.

A carrier, health plan, or PBM could not directly or indirectly reduce the amount of a claim payment to a network pharmacy after adjudication of the claim, except in accordance with an audit performed according to the requirements of the proposed act. Additionally, a PBM could not directly or indirectly, on behalf of itself, a carrier, or a health plan, charge or hold a pharmacy responsible for a fee for any step of or component or mechanism related to the claims adjudication process.

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 provides for convenient patient access to pharmacies within a reasonable distance from a patient's residence. (A PBM network is a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacist services.) A PBM would have to submit to the DIFS director a PBM network adequacy report describing the PBM network and its accessibility in Michigan.

If unable to comply with the adequacy requirements, a PBM could apply for a two-year renewable waiver from the DIFS director by submitting an application that demonstrates why the PBM is unable to meet the 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 it could be renewable depending on the steps taken by the PBM to address network adequacy over the waiver period.

A PBM could not conduct ***spread pricing*** in Michigan.

> ***Spread pricing*** would mean the model of prescription drug pricing in which a PBM charges a health plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the PBM directly or indirectly pays the pharmacist or pharmacy for pharmacy services.

Conflict of interest reporting

A PBM would have to disclose to a contracting carrier any difference between the amount paid to a network pharmacy and the amount charged to the carrier. A PBM could not discriminate against a nonaffiliated pharmacy and could not reimburse such a pharmacy less than was reimbursed to an affiliated pharmacy for the same services. For drug reimbursement, equivalent services would have to be evaluated on a per-unit basis using the identical generic product identifier or generic code number.

Prohibited actions

A PBM or carrier could not impose limits on an enrollee's access to medication, including quantity or refill frequency limits, that differ based solely on whether the carrier or PBM has an ownership interest in the pharmacy or the pharmacy has an ownership interest in the PBM.

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 solely because of its 340B association. A PBM or carrier could not reimburse one of those entities differently that other similarly situated pharmacies.

> ***340B Program entity*** would mean an entity authorized under section 340B of the federal 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 U.S. Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.[1]

A PBM could not transfer to or receive from an affiliated pharmacy a record containing patient- or prescriber-identifiable prescription information for a "commercial purpose" (which would not include pharmacy reimbursement, formulary compliance, pharmaceutical care, utilization review by a health care provider, or a public health activity authorized by law).

[1] https://www.hrsa.gov/opa/eligibility-and-registration/index.html

Generally, a carrier, health plan, or PBM could not steer or direct a patient to use only an affiliated pharmacy through any oral or written communication (including online messaging or patient-specific advertising or marketing). However, this would not prohibit inclusion of an affiliated pharmacy in a communication to a patient or prospective patient about the cost or service provided by pharmacies in the patient's health care network as long as the communication includes accurate comparable information about pharmacies in the network that are nonaffiliated.

A carrier, health plan, or PBM could not do any of the following:

- Require a patient to use only an affiliated pharmacy.
- Solicit a patient or prescriber to transfer a patient prescription to an affiliated pharmacy.
- Require a nonaffiliated pharmacy to transfer a patient's prescription to an affiliated pharmacy without the prior consent of the patient.
- Prohibit a pharmacy from mailing or delivering a drug to a patient upon the patient's request.
- Prohibit a pharmacy from charging a shipping and handling fee to a patient requesting mail or delivery as long as the pharmacy discloses the fee and that the fee may not be reimbursable.
- Require pharmacist or pharmacy accreditation or recertification that is inconsistent with, more stringent than, or in addition to federal and state requirements.
- Retaliate against a pharmacist or pharmacy based on the exercise of any right or remedy under the proposed act. Retaliation would include terminating or refusing to renew a contract, subjecting the pharmacy or pharmacist to increased audits, or failing to pay.

A PBM could not do any of the following:

- Cause or knowingly permit the use of any false or misleading advertising.
- Reverse and resubmit the claim of a network pharmacy without first notifying the pharmacy and attempting to reconcile the claim. (Additionally, a PBM could not do so more than 30 days after the claim was first affirmatively adjudicated.)

The provisions of the proposed act could not be waived, voided, or nullified by contract.

No limit on disclosing risks or alternatives

A contract between a PBM and a pharmacist or pharmacy that provides drug coverage for health plans could not prohibit or restrict or penalize a pharmacy's or pharmacist's disclosure of any of the following, as the pharmacy or pharmacist deems appropriate:

- The nature of the treatment or the risks of or alternatives to the treatment.
- The availability of alternative 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.

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 covered person or enrollee if one is available.

A carrier, health plan, or PBM could not require a covered person or enrollee to make a payment for a prescription drug at the point of sale in an amount greater than the applicable copayment or the final reimbursement amount to the network pharmacy, whichever is less.

Annual transparency report

Unless required more frequently by the DIFS director, beginning April 1, 2023, a PBM would have to file with the director an annual transparency report containing 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 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 the PBM received.
- The aggregate amount of all rebates the PBM received from all manufacturers that were not passed through to health plans or insurers.
- The aggregate amount of all fees 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 the Freedom of Information Act (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 legal 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 determines would cause financial, competitive, or proprietary harm to a PBM or a 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.

Reasonable reimbursement

A carrier, health plan, or PBM could not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed. (If the national average drug acquisition cost is not available, the floor would be the wholesale acquisition cost of the drug.)

The DIFS director could review and approve the network pharmacy compensation program of a carrier, health plan, or PBM to ensure that network pharmacy reimbursement is "fair and reasonable" to provide an adequate access to pharmacy services under standards issued by rule. ("Fair and reasonable" would mean to cover, at a minimum, the cost of the drug and the cost to dispense the drug.)

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 list.
- Establish and maintain a reasonable administrative appeals process to allow a pharmacy subject to the maximum allowable cost list, or an agent of such a pharmacy, to challenge a listed maximum allowable cost.
- Respond in writing to any appealing pharmacy within 10 days of receiving the appeal if the pharmacy appealed within 10 days after the pharmacy's claim for reimbursement was adjudicated, and respond within 30 days if the pharmacy appealed more than 10 days after the claim was adjudicated.
- If an appeal is denied, provide the appealing pharmacy the national drug code number and supplier that has the product available for purchase in Michigan at or below the appealed maximum allowable cost.
- If an appeal is granted, allow the pharmacy to reverse and rebill the claim and all subsequently submitted similar claims.

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, the drug could not be obsolete, and the drug would have to be a multiple source drug (a therapeutically equivalent drug that is available from at least two manufacturers).

All benefits payable by a carrier, health plan, or PBM to a pharmacy would have to be paid within 15 days after adjudication of an electronically submitted claim.

Audit of a pharmacy

A carrier or PBM conducting an audit of a Michigan pharmacy would have to describe the audit process, comply with specified notice and scheduling requirements for the audit, minimize inconvenience to the pharmacy and ensure that the delivery of pharmacy services is not disrupted, and adhere to certain standards in judgment. The carrier or PBM would have to allow the use of certain electronic records or prescriptions to validate pharmacy records.

The bill also specifies the standards for determining and addressing overpayment, underpayment, recoupment, reimbursement, and payment adjustments. The time frame for the audit would generally be limited to one year, and the carrier or PBM could not receive payment or compensate the auditor based on the amount recovered. The carrier or PBM would have to establish an appeals process for the preliminary and final audit reports.

Upon completion of an audit, the carrier or PBM would have to deliver a preliminary audit report to the pharmacy within 60 days and allow the pharmacy at least 30 days to appeal before delivering the final report.

A carrier or PBM could not use an "extrapolation audit," or a sample of claims, to estimate the audit results for a larger group of claims not reviewed during the audit.

A clerical error found during an audit would not, on its face, constitute fraud, or subject the individual to criminal penalties, absent proof of intent.

The above provisions would not apply to an audit conducted to investigate fraud, misrepresentation, or abuse, or an audit based on a criminal investigation. Similarly, they would not impair or supersede rules regarding carrier pharmacy audits in the Insurance Code (which would control in any conflict between the two acts).

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 whether the PBM is 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 be used only to ensure 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.

Record retention

Generally, the DIFS director could destroy or dispose of records and data on file with DIFS that in his or her opinion, and on the advice of the Attorney General, have no further material value to Michigan. However, the DIFS director could not order the destruction or disposal of documents required to be retained for 10 years, those filed during the director's administration, or copies of certain important business documents.

Rule promulgation

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

Tie-bar

The bill is tie-barred to HB 4347, which means that it could not take effect unless HB 4347 were also enacted. (HB 4347 would create a new act to require drug manufacturers to disclose annually to DIFS certain information regarding costs and pricing.)

FISCAL IMPACT:

House Bill 4348 would have a significant fiscal impact on DIFS. The bill would increase departmental costs for regulating pharmacy benefit managers (PBMs). However, revenues would also increase from fees and fines assessed on PBMs. It is presently indeterminate whether revenue under the bill would sufficiently offset departmental costs.

Under the bill, DIFS would be charged with licensing and regulating PBMs, which would lead to an increase in departmental costs. The department's responsibilities would include processing applications and renewals and reviewing application and renewal materials (which include various financial and legal documents); reviewing notices of modification; monitoring the conduct of PBMs, conducting hearings for alleged violations, and taking adverse licensure action against licensees and issuing cease and desist orders for unlicensed activity; processing waivers for network adequacy requirements (including reviewing data contained in waiver applications); reviewing PBM network adequacy reports and annual transparency reports; reviewing and approving network pharmacy compensation programs; conducting audits, examinations, and annual reviews to enforce the act; and preparing an annual report based on the information DIFS receives under the act. Initial estimates from DIFS indicated that the changes under the bill would necessitate 3.0 additional FTE positions (two analysts and a technician) at an annual cost of approximately $209,000. There would also likely be information technology costs, but the department does not have a definitive estimate for those costs.

The bill would allow the DIFS director to set application and renewal fees via administrative rule. The bill would also allow for fines to be established through the administrative rules process. Presumably, application and renewal fees would be set at a level sufficient to offset departmental costs for those activities. However, since the various fees would be set via rule, the fee levels are currently indeterminate and it cannot be determined if revenues under the bill would sufficiently offset departmental costs. A $5 fee would be established in the bill for attorney services provided by DIFS related to the serving of process in legal proceedings. The bill also stipulates that a PBM whose license has been suspended or restricted may be fined each month at an amount not to exceed $20,000 per month until the PBM has remedied the situation leading to the suspension or restriction. It is unclear where revenue from these fines would be deposited.

POSITIONS:

Representatives of the following entities testified in support of the bill (3-10-21):
Michigan Pharmacists Association
American Pharmacies

The following entities indicated support for the bill (3-10-21):
NFIB
National Community Pharmacists Association

Representatives of the following entities testified in opposition to the bill (3-10-21):
Pharmaceutical Care Management Association
Michigan Chamber
Blue Cross Blue Shield of Michigan

The following entities indicated opposition to the bill:

CVS/Aetna (3-10-21)
Cigna (3-10-21)
Economic Alliance for Michigan (3-10-21)
Michigan Manufacturers Association (3-17-21)

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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.