Senate Fiscal Agency
P.O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

House Bill 4348 (Substitute H-1 as passed by the House)
Sponsor: Representative Julie Calley
House Committee: Health Policy
Senate Committee: Health Policy and Human Services

Date Completed: 6-17-21

CONTENT

The bill would enact the "Pharmacy Benefit Manager Licensure and Regulation Act" to do the following:

-- Provide for the licensure of pharmacy benefit managers (PBMs) in Michigan.
-- Require a person seeking licensure as a PBM to submit to the Director of the Department of Insurance and Financial Services (DIFS) an application containing specified information.
-- Allow the Director to refuse to issue a license if he or she determined that the PBM was not financially viable or that the PBM or any individual responsible for the conduct of the PBM's affairs had had a PBM certificate of authority or license denied or revoked for cause in another state.
-- Allow the Director to deny, suspend, or revoke a PBM license under certain circumstances.
-- Require an applicant seeking to renew a PBM license to submit to the Director a renewal application, a renewal fee, and a PBM network adequacy report.
-- Prescribe the duties and responsibilities of a PBM licensed in the State and prescribe certain prohibited actions.
-- Require a PBM to provide a reasonably adequate and accessible PBM network for the provision of drugs for a health plan that would have to provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence, and allow a PBM to apply for a waiver if it were unable to meet the network adequacy requirements.
-- Require a PBM to file an annual transparency report with the Director that contained specified information for the preceding calendar year unless the PBM had contracted with the Department of Health and Human Services (DHHS) under Medicaid.
-- Require the Director to conduct an annual review against all de-identified claims submitted to analyze if pharmacy payment and patient cost-sharing variations had occurred using certain specified information for each claim.
-- Prohibit a carrier, health plan, or PBM from reimbursing 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 when the drug was administered or dispensed, and require a PBM that established a maximum allowable cost to take certain actions.
-- Allow a carrier or a PBM to conduct an audit of a pharmacy in Michigan and prescribe the process for conducting an audit.
-- Prescribe certain record retention procedures.

-- Require the Director to promulgate rules that were necessary or required to implement the Act, which would have to include fines and suspension, restriction, and revocation of licensure.

The bill is tie-barred to House Bill 4347, which would enact the "Drug Manufacturer Data Reporting Act".

Definitions

The Act would define "carrier" as that term as defined in Section 3701 of the Insurance Code: a person that provides health benefits, coverage, or insurance in this state. For the purposes of Chapter 37 (Small Employer Group Health Coverage) of the Insurance Code, carrier includes a health insurance company authorized to do business in Michigan, a health maintenance organization, a multiple employer welfare arrangement, or any other person providing a plan of health benefits, coverage, or insurance subject to State insurance regulation.

"Claim" would mean a request for payment for administering, filling, or refilling a drug or for providing a pharmacy service or a medical supply or device to an enrollee.

"Covered person" would mean a person that is insured in a health plan. "Health plan" would mean a qualified health plan as that term is defined in Section 1261 of the Insurance Code: Under that section, "qualified health plan" means that term as defined in the Affordable Care Act.

"Enrollee" would mean that term as defined in Section 116 of the Insurance Code: an individual who is entitled to receive health services under a health insurance contract, unless the context requires otherwise.

"Insurer" would mean an insurer that delivers, issues for delivery, or renews in the State a health plan that provides drug coverage under the Insurance Code.

"Network pharmacy" would mean a retail pharmacy or other pharmacy that contracts directly or through a contracting agent with a PBM. "Retail pharmacy" would mean a pharmacy that dispenses drugs to the public at retail.

"Person" would mean an individual, partnership, corporation, association, or governmental entity.

"Pharmacist services" would mean products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy. "Practice of pharmacy" would mean that term as defined in Section 17707 of the Public Health Code: a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Practice of pharmacy includes the direct or indirect provision of professional functions and services associated with the practice of pharmacy. Professional functions associated with the practice of pharmacy include the interpretation and evaluation of the prescription; drug product selection; the compounding, dispensing, safe storage, and distribution of drugs and devices; the maintenance of legally required records; and advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs.

"Pharmacy" would mean that term as defined in Section 17707 of the Public Health Code: a facility or part of a facility that is licensed under Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to dispense prescription drugs or prepare prescription drugs for delivery or distribution. Pharmacy does not include the office of a dispensing prescriber or an automated device.

Except as otherwise provided, "pharmacy benefit manager" would mean a person that contracts 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 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.

"Pharmacy benefit manager" would not include the DHHS or an insurer. "Pharmacy benefit manager network" would mean a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacist services.

"Rebate" would mean a discount or other price concession based on use or price of a drug that is paid by a manufacturer or third party, directly or indirectly, to a PBM after a claim has been adjudicated at a pharmacy. Rebate would include incentives, disbursements, and reasonable estimates of volume-based or other discounts and price protection rebates. "Manufacturer" would mean that term as defined in Section 17706 of the Public Health Code: a person that prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and that supplies, distributes, sells, offers for sale, barters, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing. Manufacturer would not include a pharmacy unless it met the requirements described in Section 17748f of the Public Health Code. Except as otherwise provided, "third party" would mean a person that is not an enrollee or insured in a health plan. The term would not include a PBM.

Licensure

Under the Act, beginning January 1, 2023, 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 Act would be renewable biennially and nontransferable.

An applicant for a license to operate in Michigan as a PBM would have to submit to the Director an application in a form and manner prescribed by the Director that was signed by an officer or authorized representative of the PBM verifying that the contents of the application form and any attachments were correct and an application fee as provided by the Director by rule.

The application form would have to include all of the following:

-- A copy of all the PBM's basic organizational documents, including the articles of incorporation, bylaws, articles of association, trade name certificate, and other similar documents and all amendments to those documents.
-- A copy of a power of attorney duly executed by the PBM if not domiciled Michigan, appointing the director, the director's successors in office, and the director's authorized deputies as the attorney of the PBM in and for the State, on whom process in any legal action or proceeding against the PBM on a cause of action arising in the State could be served; the fee for service described in this provision would be $5, payable at the time of service.
-- The names, addresses, official positions, and professional qualifications of each individual who was responsible for the conduct of the affairs of the PBM, including each administrative services manager and each member of the board of directors, board of trustees, executive committee, or other governing board or committee and the officers and shareholders owning stock representing 10% or more of the voting shares of the PBM for a corporation and the partners or members for a partnership or association.
-- A description of the PBM, its services, facilities, and personnel.
-- A document in which the PBM confirmed that its business practices and each ongoing contract comply with the Act.
-- A copy of recent financial statements showing the PBM's assets, liabilities, and sources of financial support that the director, on the advice of the board, determined were sufficient to show that the PBM was financially viable.

"Financially viable" would mean that one of the following conditions is met:

-- The PBM has received an unqualified opinion from an independent public accountant showing it is solvent based on generally accepted accounting principles.
-- If no independent public accountant opinion is obtained, the PBM remains solvent after adjusting for goodwill and intangible assets.

If the PBM's financial affairs were prepared by an independent public accountant, a copy of the most recent regular financial statement would satisfy the requirement to show financial viability unless the Director determined that additional or more recent financial information was required for the proper administration of the Act.

Within 30 days after any significant modification of information submitted with the application for a license, a PBM would have to file a notice of the modification with the Director.

The Director could refuse to issue a license under the Act if he or she determined that the PBM was not financially viable or that the PBM or any individual responsible for the conduct of the PBM's affairs had had a PBM certificate of authority or license denied or revoked for cause in another state. "Individual responsible for the conduct of affairs of the PBM" would mean any of the following:

-- A member of the board of directors, board of trustees, executive committee, or other governing board or committee.
-- A principal officer for a corporation or a partner or member for a partnership, association, or limited liability company.
-- A shareholder or member holding directly or indirectly 10% or more of the voting stock, voting securities, or voting interest of the PBM.
-- Any person who exercises control or influence over the affairs of the PBM.

The Director could deny, suspend, or revoke a PBM license, or could issue a cease and desist order if the PBM were not licensed, if the Director found, after notice and opportunity for hearing, any of the following:

-- That the PBM had violated any lawful rule or order of the Director or any Michigan law applicable to the PBM.
-- That the PBM had refused to be examined or to produce its accounts, records, and files for examination, or if any individual responsible for the conduct of the PBM's affairs had refused to give information with respect to its affairs or had refused to perform any other legal obligation as to an examination when required by the Director.
-- That the PBM had, without just cause, refused to pay proper claims or perform services arising under its contracts or had, without just cause, caused covered persons or enrollees to accept less than the amount due them or caused covered persons or enrollees to employ attorneys or bring suit against the PBM or a payor that it represented to secure full payment or settlement of the claims.
-- That the PBM was required under the Act to have a license and failed at any time to meet any qualification for which issuance of a license could have been refused had the failure then existed and been known to the Director, unless the Director issued a license with knowledge of the ground for disqualification and had the authority to waive it.
-- That any individual responsible for the conduct of affairs of the PBM had been convicted of, or had entered a plea of guilty or nolo contendere to, a felony without regard to whether adjudication was withheld.
-- That the PBM's license had been suspended or revoked in another state.
-- That a resident PBM had failed to file a timely report, or a timely renewal application and renewal fee, as applicable.

If a PBM's license were suspended or restricted, the Director could permit the PBM to operate for a limited time not exceeding 60 days. However, the Director could permit a PBM whose license had been suspended or restricted to operate for a period that exceeded 60 days if the Director determined that the PBM's continued operation was in the beneficial interests of covered persons by ensuring minimal disruptions to the continuity of care. A PBM whose license had been suspended or restricted would be subject to a fine each month, as determined by the Director, not exceeding $20,000 per month, until the PBM had remedied the violation leading to the suspension or restriction.

The Director could revoke the license of a PBM if the PBM had been operating under a suspended license for a period of more than 60 days.

For purposes of the Act, a PBM would have the same rights to notice and hearings that were provided to an insurer under the Insurance Code.

The 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.

To renew a license as a PBM, an applicant would have to submit to the Director all of the following:

-- A renewal application in a form and manner prescribed by the Director that was signed by an officer or authorized representative of the PBM verifying that the contents of the renewal form were correct.
-- A renewal fee as provided by the Director by rule.
-- A PBM network adequacy report.

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

Duties & Responsibilities

The Act would require a PBM to exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a PBM and a carrier or a network pharmacy that attempted to waive or limit this obligation would be void. A PBM would have to notify a carrier in writing of any activity, policy, or practice of the PBM that directly or indirectly presented a conflict of interest with the duties imposed in the Act. If a PBM planned to increase the patient's cost share amount on a drug that was a maintenance drug, the PBM would have to notify all known covered people currently taking the maintenance drug of the cost share increase 60 days before it went into effect.

The PBM would have to communicate the final reimbursement amount to the network pharmacy at the time of adjudication at the point of sale. A carrier, health plan, or PBM could not retroactively charge a network pharmacy any 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 including through the use of fees in the form of an aggregated effective rate, quality assurance program, other direct or indirect remuneration fee, or otherwise, except in accordance with an audit performed in accordance with the Act. A PBM could not directly or indirectly, on behalf of the PBM, 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, including any of the following:

-- Adjudicating a pharmacy benefit claim.
-- Processing or transmitting a pharmacy benefit claim.
-- Developing or managing a claims processing or adjudication network.
-- Participating in, admission into, or credentialing for a claims processing or adjudication network.

PBM Network

Under the Act, a PBM would have to provide a reasonably adequate and accessible PBM network for the provision of drugs for a health plan that would have to provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence. A PBM would have to submit to the Director a PBM network adequacy report that described the PBM network and its accessibility in the State in the time and manner prescribed by the Director. A PBM could apply for a waiver from the Director if it were unable to meet the network adequacy requirements. To apply for a waiver, a PBM would have to submit to the Director an application in a form and manner prescribed by the Director that did both of the following:

-- Demonstrated with specific data why the PBM was not able to meet the network adequacy requirements.
-- Included information as to the steps that the PBM had taken and would take to address network adequacy.

If the Director granted a waiver, it would expire after two years. If a PBM sought a renewal of the waiver, the Director would have to consider the steps that the PBM had taken over the two-year period covered by the waiver to address network adequacy.

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.

Reporting Conflicts of Interest

Under the Act, a PBM would have to disclose to a carrier that contracted with the PBM 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. A PBM could not reimburse a nonaffiliated pharmacy an amount less than the amount that the PBM reimburses an affiliated pharmacy for providing the same pharmacy 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. "Nonaffiliated pharmacy" would mean a network pharmacy that directly, or indirectly through one or more intermediaries, does not control, is not controlled by, or is not under common control with, a PBM. "Affiliated pharmacy" as a network pharmacy that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, a PBM.

Prohibited Actions

The Act would prohibit a PBM or carrier from imposing limits, including quantity limits 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 a pharmacy or the pharmacy had an ownership interest in the PBM.

A PBM or carrier could not prohibit a 340B Program entity or a pharmacy that had a license in good standing in Michigan under contract with a 340B Program entity from participating in the PBM's or carrier's provider network solely because it was a 340B Program entity or a pharmacy under contract with a 340B Program entity. A PBM or carrier could not reimburse a 340B Program entity or a pharmacy under contract with a 340B Program entity differently than other similarly situated pharmacies. As used in these provisions, "340B Program entity" would mean an entity authorized to participate in the Federal 340B Program under Section 340B of the Federal Public Health Service Act.

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. As used in this provision, "commercial purpose" would not include pharmacy reimbursement, formulary compliance, pharmaceutical care, utilization review by a heath care provider, or a public health activity authorized by law.

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 regarding the pharmacy or patient- or prospective patient-specific advertising, marketing, or promotion of the pharmacy. This provision would not prohibit a carrier or PBM from including an affiliated pharmacy in a patient or prospective patient communication if both of the following apply:

-- The communication was regarding information about the cost or service provided by pharmacies in the network of a health plan in which the patient was enrolled.
-- The communication included accurate comparable information regarding the pharmacies in the network that were nonaffiliated pharmacies.

A carrier, health plan, or PBM could not require a patient to use only an affiliated pharmacy.

A carrier, health plan, or PBM could not solicit a patient or prescriber to transfer a patient prescription to an affiliated pharmacy. As used in this provision, "prescriber" would mean that term as defined in Section 17708 of the Public Health Code: a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed physician's assistant, a licensed optometrist certified under Part 174 (Optometry) of the Public Health Code to administer and prescribe therapeutic pharmaceutical agents, an advanced practice registered nurse as that term is defined in the Code who meets certain requirements, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.

A carrier, health plan, or PBM could not require a nonaffiliated pharmacy to transfer a patient's prescription to an affiliated pharmacy without the prior consent of the patient.

A contract between a PBM and a pharmacist or a pharmacy that provided drug coverage for health plans could not prohibit or restrict a pharmacy or pharmacist from, or penalize a pharmacy or pharmacist for, disclosing to a covered person or enrollee health care information that the pharmacy or pharmacist considered appropriate regarding any of the following:

-- 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 that was used to authorize or deny health care services or benefits.

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 a more affordable alternative were 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 lesser of the following:

-- The applicable copayment, coinsurance, and deductible.
-- The final reimbursement amount to the network pharmacy.

A carrier, health plan, or PBM could not prohibit a pharmacy from doing either of the following:

-- Mailing or delivering a drug to a patient on the patient's request.
-- Charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered if the pharmacist or pharmacy disclosed to the patient before the delivery the fee that would be charged and that the fee could not be reimbursable.

A carrier, health plan, or PBM could not require pharmacist or pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to Federal and State requirements.

A PBM could not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that was untrue, deceptive, or misleading.

A PBM could not reverse and resubmit the claim of a network pharmacy without prior and proper notification to the network pharmacy; without just cause or attempt to first reconcile

the claim with the pharmacy; and more than 30 days after the claim was first affirmatively adjudicated.

The termination of a pharmacy from a PBM network would not release the PBM from the obligation to make any payment due to the pharmacy for an affirmatively adjudicated claim.

A carrier, health plan, or PBM could not retaliate against a pharmacist or pharmacy based on the pharmacist's or pharmacy's exercise of any right or remedy under the Act. Retaliation prohibited by this provision would include any of the following:

-- Terminating or refusing to renew a contract with the pharmacist or pharmacy.
-- Subjecting the pharmacist or pharmacy to increased audits.
-- Failing to promptly pay the pharmacist or pharmacy any money owed by the PBM to the pharmacist or pharmacy.

Transparency Report

Under the Act, unless otherwise required more frequently by the Director, beginning April 1, 2023, except as otherwise provided, a PBM would have to file an annual transparency report with the Director that contained the information required in the Act from the preceding calendar year. This provision would not apply if the PBM had contracted with the DHHS under Medicaid. As used in this provision, "Medicaid" would mean benefits under the program of medical assistance established under Title XIX of the Social Security Act and administered by the DHHS under the Social Welfare Act.

The transparency report would have to include all of the following information:

-- 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 of rebates 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.

"Plan sponsor" would mean that term as defined in Section 7705 of the Insurance Code:

-- For a benefit plan established or maintained by a single employer, the single employer.
-- For a benefit plan established or maintained by an employee organization, the employee or organization.
-- For a benefit plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the benefit plan.

"Aggregate retained rebate percentage" would mean the percentage of all rebates received by a PBM from all manufacturers, that is not passed on to the PBM's health plan or insurer clients. Aggregate retained rebate percentage would have to be expressed without disclosing

any identifying information regarding any health plan, drug, or therapeutic class, and would have to be calculated as follows:

-- Calculate the aggregate dollar amount of all rebates that the PBM received during the prior calendar year from all manufacturers and did not pass through to the PBM's health plan or insurer clients.
-- Divide the result of the calculation above by the aggregate dollar amount of all rebates that the PBM received during the prior calendar year from all manufacturers.

Annual Review

The Act would require the Director to conduct an annual review against all de-identified claims submitted to analyze if pharmacy payment and patient cost-sharing variations had occurred using the following information for each claim:

-- The drug and quantity for each prescription.
-- Whether the claim required prior authorization.
-- Patient cost-sharing paid on each prescription.
-- The amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges.
-- The identity of the pharmacy that filled each prescription.
-- Whether the pharmacy was under common control or ownership with the PBM.
-- Whether the pharmacy was a preferred pharmacy under the health plan.
-- Whether the pharmacy was a mail-order pharmacy.
-- Whether the health plan required enrollees to use the pharmacy.

"Preferred pharmacy" would mean a network pharmacy that offers covered drugs to health plan members at lower out-of-pocket costs than what the member would pay at a nonpreferred network pharmacy.

"Mail-order pharmacy" would mean a pharmacy whose primary business is to receive prescriptions by mail, fax, or through electronic submissions, dispense drugs to enrollees through the use of the United States Postal Service or other common carrier services, and provide consultation with patients electronically rather than face-to-face.

The report would have to be filed with DIFS in a form and manner required by the Department.

Data, documents, materials, or other information in the possession or control of the Director that were obtained by, created by, or disclosed to the Director regarding patient cost-sharing paid on each prescription and the amount paid for each prescription would be confidential by law and privileged, would not be subject to the Freedom of Information Act, would not be subject to subpoena, and would not be subject to discovery or admissible in evidence in any private civil action. However, the Director would be authorized to use the data, documents, materials, or other information in the furtherance of any regulatory or legal action brought as a part of the his or her duties. The Director could not otherwise make the data, documents, materials, or other information public.

Annual Report

The Act would require DIFS to prepare an annual report based on the information it received under the Act. The report would have to contain aggregate data and could not contain any information that the Director determined would cause financial, competitive, or proprietary

harm to a PBM or carrier that the PBM services. The Director would have to file the report with each of the following:

-- The Senate and House of Representatives standing committees on health policy.
-- The Senate and House Fiscal Agencies.
-- The Senate and House policy offices.

Reimbursement & Maximum Allowable Cost

Under the Act, 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 was administered or dispensed. If the national average drug acquisition cost were not available at the time a drug is administered or dispensed, a carrier, health plan, or PBM could not reimburse in an amount that was less than the wholesale acquisition cost of the drug, as defined under Federal law.

The Director could review and approve the network pharmacy compensation program of a carrier, health plan, or PBM to ensure that network pharmacy reimbursement was fair and reasonable to provide an adequate access to pharmacy services under standards issued by rule. As used in this provision, "fair and reasonable" would mean to cover at a minimum the cost of the drug and the cost to dispense the drug.

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

-- Provide each pharmacy subject to a maximum allowable cost list with access to the maximum allowable cost 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 calendar 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 or an agent of a pharmacy subject to the maximum allowable cost list to challenge a listed maximum allowable cost.
-- Respond in writing to any appealing pharmacy or an appealing pharmacy's agent within 10 calendar days after receiving an appeal if the pharmacy filed the appeal within 10 calendar days after the date the pharmacy's claim for reimbursement was adjudicated.
-- Respond in writing to any appealing pharmacy or an appealing pharmacy's agent within 30 calendar days after receiving an appeal if the pharmacy filed the appeal more than 10 calendar days after the date the pharmacy's claim for reimbursement was adjudicated.
-- If an appeal were denied, provide the appealing pharmacy or the appealing pharmacy's agent the national drug code number and supplier that had the product available for purchase in the State at or below the appealed maximum allowable cost.
-- If an appeal were granted, permit the pharmacy to reverse and rebill the claim and all subsequently submitted similar claims.

"Maximum allowable cost" would mean the maximum amount that a PBM will reimburse a network pharmacy for the ingredient cost for a generic drug.

Before a PBM placed or continued a drug on a maximum allowable cost list, all of the following conditions would have to be met:

-- The drug was available for purchase by each pharmacy in Michigan from national or regional wholesale drug distributors operating in the State.
-- The drug was not obsolete.
-- The drug was a multiple source drug.

"Maximum allowable cost list" would mean a listing of drugs used by a PBM, directly or indirectly, to set the maximum allowable cost. "Multiple source drug" would mean 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 a claim in which claims were submitted electronically.

Pharmacy Audit

The Act would allow a carrier or a PBM to conduct an audit of a pharmacy in Michigan. A carrier or a PBM that conducted an audit of a pharmacy in Michigan would have to do all of the following:

-- In its pharmacy contract, identify and describe in detail the audit procedures, including the appeals process; a carrier or PBM would have to update its pharmacy contract and communicate any changes to the pharmacy as changes to the contract occurred.
-- Use every effort to minimize inconvenience and disruption to pharmacy operations during the audit process; a carrier or PBM that conducted an audit of a pharmacy in the State could not interfere with the delivery of pharmacy services to a patient.
-- Conduct an audit that involved clinical or professional judgment by or in consultation with a pharmacist.
-- Subject to the requirements of Article 15 (Occupations) of the Public Health Code, for the purpose of validating a pharmacy record with respect to orders, refills, or changes in prescriptions, allow the use of hospital or physician records that were written or that were transmitted or stored electronically, including file annotations, document images, and other supporting documentation that was date- and time-stamped, or a prescription that complied with the requirements of the Board of Pharmacy and State and Federal law.
-- Base any finding of an overpayment or underpayment on the actual overpayment or underpayment of claims.
-- Base any recoupment or payment adjustments of claims on a calculation that was reasonable and proportional in relation to the type of error detected.
-- If there were a finding of an underpayment, reimburse the pharmacy as soon as possible after detection.
-- Conduct its audit of each pharmacy under the same sampling standards, parameters, and procedures that the carrier or PBM used when auditing other similarly licensed pharmacies; the carrier would have to provide to the pharmacy samples of the standards, parameters, and procedures for the audit being conducted.
-- Only audit claims submitted or adjudicated within the one-year period preceding the initiation of the audit unless a longer period was permitted under Federal or State law.
-- Not receive payment and not compensate the auditor based on the amount recovered.
-- Not include the dispensing fee amount in a finding of an overpayment.
-- Establish a written appeals process that included a process to appeal preliminary audit reports and final audit reports prepared under the Act; if either party were not satisfied with the results of the appeal, that party could seek mediation.
-- Not limit the days' supply for unit-of-use items, such as topicals, drops, vials, and inhalants, beyond manufacturer recommendations.
-- If the only commercially available package size exceeded the maximum days' supply, not use the dispensing of the package size as the basis for recoupment.

-- If the only commercially available package size exceeded the maximum days' supply and the claim was affirmatively adjudicated, not recoup the claim as an early refill.
-- Provide written notice to the pharmacy at least four weeks before initiating and scheduling the initial on-site audit for each audit cycle.

Unless otherwise consented to by a network pharmacy, a carrier or PBM could not initiate or schedule an on-site audit during the first six calendar days of a month, a holiday time frame, a weekend, or a Monday. A carrier or PBM would have to be flexible in initiating and scheduling an audit at a time that was reasonably convenient to the pharmacy and the carrier or PBM. In conducting an audit of wholesale invoices, a carrier or a PBM that conducted an audit of a pharmacy in Michigan would have to do all of the following:

-- Not audit the claims of another carrier or PBM.
-- Within five business days after a request by the audited pharmacy, provide supporting documentation provided to the carrier or PBM by the audited pharmacy's suppliers.
-- Not use any of the following as a basis for recoupment: the national drug code for the dispensed drug was in a quantity that was a subunit or multiple of the purchased drug as reflected on a supporting wholesale invoice; the correct quantity dispensed was reflected on the audited pharmacy claim; or the drug dispensed by the pharmacy on an audited pharmacy claim is identical to the strength and dosage form of the drug purchased.
-- Accept as evidence each of the following: supplier invoices issued before the date of dispensing the drug underlying the audited claim; invoices from any supplier permitted by law to transfer ownership of the drug acquired by the audited pharmacy; or copies of supplier invoices in the possession of the audited pharmacy.

After completing an audit of a pharmacy, the carrier or PBM would have to do all of the following:

-- Deliver a preliminary written audit report to the pharmacy within 60 days; the report would have to include contact information for the person performing the audit and a description of the established appeals process.
-- Allow the pharmacy at least 30 days after receiving the preliminary written audit report to produce documentation to address any discrepancy found during the audit.
-- If an appeal were not filed, deliver a final written audit report to the pharmacy within 90 days after the time described in the Act had elapsed; and if an appeal were filed, deliver a final written audit report to the pharmacy within 90 days after concluding the appeal.
-- Except as otherwise provided, recoup disputed funds or overpayments or restore underpayments only after the final written audit report was delivered to the pharmacy.

A carrier or PBM could not conduct an extrapolation audit in calculating recoupments, restoration, or penalties for an audit. "Extrapolation audit" would mean an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the carrier that is then used to estimate audit results for a larger batch or group of claims not reviewed during the audit.

Any clerical or record-keeping error, including a typographical error, a scrivener's error, or a computer error, regarding a required document or record that was found during an audit would not, on its face, constitute fraud. An error described in this provision would not subject the individual involved to criminal penalties without proof of intent to commit fraud. To the extent that an audit results in the identification of a clerical or record-keeping error, including a typographical error, a scrivener's error, or a computer error, in a required document or record, the pharmacy would not be subject to recoupment of money by the carrier or PBM unless the carrier could provide proof of intent to commit fraud or the error resulted in actual financial harm to the carrier, PBM, or a covered person or enrollee.

The audit provisions would not apply to either of the following:

-- An audit conducted to investigate fraud, willful misrepresentation, or abuse, including investigative audits or audits conducted under any other statute that authorized investigation relating to insurance fraud.
-- An audit based on a criminal investigation.

The audit provisions also would not impair or supersede a provision regarding carrier pharmacy audits in the Insurance Code. If any provision conflicted with a provision of the Insurance Code with regard to carrier pharmacy audits, the provision in the Insurance Code would control.

PBM Examination & Audit

Under the Act, the Director could examine or audit the books and records of a PBM providing claims processing services or other drug or device services for a health plan to determine if the PBM were in compliance with the Act. "Claims processing services" would mean the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include any of the following:

-- Receiving payments for pharmacist services.
-- Making payments to pharmacists or pharmacies for pharmacist services.
-- Receiving and making the payments described above.

"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 arrangements with pharmacists or pharmacies.
-- Developing drug formularies.
-- Designing prescription drug benefit programs.
-- Advertising or promoting services.

All of the following would apply to information or data acquired during an examination described above, or otherwise acquired under the Act:

-- The information or data was considered proprietary and confidential.
-- The information or data was not subject to the Freedom of Information Act.
-- The information or data was to be used only for purposes of ensuring a PBM's compliance with the Act.

Record Retention

Except as otherwise provided, the Director could destroy or otherwise dispose of a record, book, paper, or other data on file with DIFS that, in the Director's opinion, and on the advice of the Attorney General, was of no further material value to the State. The Director could not order the destruction or other disposal of a record, book, paper, or other data that was any of the following:

-- Required by law to be filed or kept on file with DIFS until 10 years had passed.

-- Filed during the Director's administration or administrations.
-- A copy of bylaws, articles of incorporation, a copy of a certificate, any other written evidence of authorization to transact business or of approval of articles of incorporation and bylaws, or any amendment to those documents.

Rule Promulgation & Other Provisions

The Act would require the Director to promulgate rules that were necessary or required to implement the Act. The rules promulgated by the Director would have to include fines, suspension of licensure, restriction of licensure, and revocation of licensure in accordance with the Act. The Act would require the Director to enforce the Act.

The Act's provisions could not be waived, voided, or nullified by contract.

Legislative Analyst: Stephen Jackson

FISCAL IMPACT

The bill would have a significant fiscal impact on State government and no fiscal impact on local units of government. The Department of Insurance and Financial Services would be required to implement and administer the PBM licensure program. The Department estimates that 3.0 additional FTEs would be required to perform this work. The standard estimate for the annual cost of an FTE is approximately $110,000, but exact costs vary. Two FTEs would be Departmental Analyst positions while the remaining 1.0 FTE would be a Departmental Technician. Cost estimates for information technology required by the bill currently are not available.

It is unknown if revenue from the program would be sufficient to fully offset the additional costs to the Department. The bill would allow many of fines and fees associated with the PBM program to be set through administrative rules. The costs for promulgation of these rules would be covered by existing appropriations.

Fiscal Analyst: Elizabeth Raczkowski

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