SUBSTITUTE FOR

HOUSE BILL NO. 5938

A bill to license and regulate pharmacy benefit managers; to require reporting of certain data; to provide for the powers and duties of certain state governmental officers and entities; to provide remedies; to require the promulgation of rules; and to require and to provide sanctions for violation of this act.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known as and may be cited as the "pharmacy benefit manager licensure and regulation act".

Sec. 3. For purposes of this act, the words and phrases defined in sections 5 to 9 have the meanings ascribed to them in those sections.

Sec. 5. (1) "Aggregate retained rebate percentage" means the percentage of all rebates received by a pharmacy benefit manager

from all manufacturers, which is not passed on to the pharmacy benefit manager's health plan or insurer clients. Aggregate retained rebate percentage must be expressed without disclosing any identifying information regarding any health plan, drug, or therapeutic class, and must be calculated as follows:

(a) Calculate the aggregate dollar amount of all rebates that the pharmacy benefit manager received during the prior calendar year from all manufacturers and did not pass through to the pharmacy benefit manager's health plan or insurer clients.

(b) Divide the result of the calculation under subdivision (a) by the aggregate dollar amount of all rebates that the pharmacy benefit manager received during the prior calendar year from all manufacturers.

(2) "Carrier" means that term as defined in section 3701 of the insurance code of 1956, 1956 PA 218, MCL 500.3701.

(3) "Claim" means a request for payment for administering, filling, or refilling a drug or for providing a medical supply or device to an enrollee.

(4) "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include any of the following:

(a) Receiving payments for pharmacist services.

(b) Making payments to pharmacists or pharmacies for pharmacist services.

(c) Receiving and making the payments described in subdivisions (a) and (b).

(5) "Covered person" means a person that is insured in a health plan.

(6) "Department" means the department of insurance and financial services.

(7) "Director" means the director of the department.

(8) "Enrollee" means that term as defined in section 116 of the insurance code of 1956, 1956 PA 218, MCL 500.116.

(9) "Financially viable" means that 1 of the following conditions is met:

(a) The pharmacy benefit manager has received an unqualified opinion from an independent public accountant showing it is solvent based on generally accepted accounting principles.

(b) If no independent public accountant opinion is obtained, the pharmacy benefit manager remains solvent after adjusting for goodwill and intangible assets.

(10) "Health plan" means a qualified health plan as that term is defined in section 1261 of the insurance code of 1956, 1956 PA 218, MCL 500.1261.

(11) "Individual responsible for the conduct of affairs of the pharmacy benefit manager" means any of the following:

(a) A member of the board of directors, board of trustees, executive committee, or other governing board or committee.

(b) A principal officer in the case of a corporation or a partner or member in the case of a partnership, association, or limited liability company.

(c) A shareholder or member holding directly or indirectly 10% or more of the voting stock, voting securities, or voting interest of the pharmacy benefit manager.

(d) Any person who exercises control or influence over the affairs of the pharmacy benefit manager.

(12) "Insurer" means an insurer that delivers, issues for

delivery, or renews in this state a health plan that provides drug coverage under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

Sec. 7. (1) "Mail-order pharmacy" means 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.

(2) "Manufacturer" means that term as defined in section 17706 of the public health code, 1978 PA 368, MCL 333.17706.

(3) "Maximum allowable cost list" means a listing of drugs or other methodology used by a pharmacy benefit manager, directly or indirectly, to set the maximum allowable payment to a pharmacy or pharmacist for a drug, and includes, but is not limited to, any of the following:

(a) Average acquisition cost, including national average drug acquisition cost.

(b) Average manufacturer price.

(c) Average wholesale price.

(d) Brand effective rate or generic effective rate.

(e) Discount indexing.

(f) Federal upper limits.

(g) Wholesale acquisition cost.

(h) Any other term that a pharmacy benefit manager or an insurer may use to establish reimbursement rates to a pharmacist or pharmacy for a prescription drug.

(4) "Multiple source drug" means a therapeutically equivalent drug that is available from at least 2 manufacturers.

(5) "Network pharmacy" means a retail pharmacy or other pharmacy that directly contracts with a pharmacy benefit manager.

(6) "Other drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to, any of the following:

(a) Negotiating rebates, discounts, or other financial incentives and arrangements with manufacturers.

(b) Disbursing or distributing rebates.

(c) Managing or participating in incentive programs or arrangements for pharmacist services.

(d) Negotiating or entering into contractual arrangements with pharmacists or pharmacies.

(e) Developing drug formularies.

(f) Designing prescription drug benefit programs.

(g) Advertising or promoting services.

(7) "Person" means an individual, partnership, corporation, association, or governmental entity.

(8) "Pharmacist" means that term as defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

(9) "Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy.

(10) "Pharmacy" means that term as defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

(11) Except as otherwise provided in subsection (12), "pharmacy benefit manager" means a person that contracts 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:

(a) Contracting directly or indirectly with pharmacies to provide drugs to enrollees or other covered persons.

(b) Administering a drug benefit.

(c) Processing or paying pharmacy claims.

(d) Creating or updating drug formularies.

(e) Making or assisting in making prior authorization determinations on drugs.

(f) Administering rebates on drugs.

(g) Establishing a pharmacy network.

(12) "Pharmacy benefit manager" does not include the department of health and human services or an insurer.

(13) "Pharmacy benefit manager network" means a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacist services.

(14) "Plan sponsor" means that term as defined in section 7705 of the insurance code of 1956, 1956 PA 218, MCL 500.7705.

(15) "Practice of pharmacy" means that term as defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

(16) "Preferred pharmacy" means 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.

Sec. 9. (1) "Rebate" means 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 pharmacy benefit manager after a claim has been adjudicated at a pharmacy.

Rebate includes, but is not limited to, incentives, disbursements, and reasonable estimates of volume-based or other discounts and price protection rebates.

(2) "Retail pharmacy" means a pharmacy that dispenses drugs to the public at retail.

(3) "Rule" means a rule promulgated pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

(4) Except as otherwise provided in subsection (5), "third party" means a person that is not an enrollee or insured in a health plan.

(5) "Third party" does not include a pharmacy benefit manager.

Sec. 11. (1) Beginning January 1, 2021, a pharmacy benefit manager that provides services to residents of this state shall apply for, obtain, and maintain a license to operate as a pharmacy benefit manager from the director. A license under this act is renewable biennially and is nontransferable.

(2) Subject to this section, an applicant for a license to operate in this state as a pharmacy benefit manager shall submit to the director both of the following:

(a) An application in a form and manner prescribed by the director that is signed by an officer or authorized representative of the pharmacy benefit manager verifying that the contents of the application form and any attachments are correct. The application form must include, but is not limited to, all of the following:

(*i*) A copy of all basic organizational documents of the pharmacy benefit manager, including, but not limited to, the articles of incorporation, bylaws, articles of association, trade name certificate, and other similar documents and all amendments to

those documents.

(*ii*) A copy of a power of attorney duly executed by the pharmacy benefit manager if not domiciled in this state, appointing the director, the director's successors in office, and the director's duly authorized deputies as the attorney of the pharmacy benefit manager in and for this state, on whom process in any legal action or proceeding against the pharmacy benefit manager on a cause of action arising in this state may be served. The fee for such service is $5.00, payable at the time of service.

(*iii*) The names, addresses, official positions, and professional qualifications of each individual who is responsible for the conduct of the affairs of the pharmacy benefit manager, including the following:

(A) Each administrative services manager and each member of the board of directors, board of trustees, executive committee, or other governing board or committee.

(B) The officers and shareholders owning stock representing 10% or more of the voting shares of the pharmacy benefit manager in the case of a corporation and the partners or members in the case of a partnership or association.

(*iv*) A copy of recent financial statements showing the pharmacy benefit manager's assets, liabilities, and sources of financial support that the director, on the advice of the board, determines are sufficient to show that the pharmacy benefit manager is financially viable. If the pharmacy benefit manager's financial affairs are prepared by an independent public accountant, a copy of the most recent regular financial statement satisfies the requirement to show financial viability unless the director determines that additional or more recent financial information is

required for the proper administration of this act.

(*v*) A description of the pharmacy benefit manager, its services, facilities, and personnel.

(*vi*) A document in which the pharmacy benefit manager confirms that its business practices and each ongoing contract comply with the provisions of this act.

(b) An application fee as provided by the director by rule.

(3) Within 30 days following any significant modification of information submitted with the application for a license under subsection (2), a pharmacy benefit manager shall file a notice of the modification with the director.

(4) The director may refuse to issue a license under this act if the director determines that the pharmacy benefit manager is not financially viable or that the pharmacy benefit manager or any individual responsible for the conduct of the affairs of the pharmacy benefit manager has had a pharmacy benefit manager certificate of authority or license denied or revoked for cause in another state.

(5) The director may deny, suspend, or revoke the license of a pharmacy benefit manager, or may issue a cease and desist order if the pharmacy benefit manager is not licensed, if the director finds, after notice and opportunity for hearing, any of the following:

(a) That the pharmacy benefit manager has violated any lawful rule or order of the director or any provision of law applicable to the pharmacy benefit manager of this state.

(b) That the pharmacy benefit manager has refused to be examined or to produce its accounts, records, and files for examination, or if any individual responsible for the conduct of

affairs of the pharmacy benefit manager has refused to give information with respect to its affairs or has refused to perform any other legal obligation as to an examination when required by the director.

(c) That the pharmacy benefit manager has, without just cause, refused to pay proper claims or perform services arising under its contracts or has, without just cause, caused covered individuals to accept less than the amount due them or caused covered individuals to employ attorneys or bring suit against the pharmacy benefit manager or a payor that it represents to secure full payment or settlement of the claims.

(d) That the pharmacy benefit manager is required under this act to have a license and fails 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.

(e) That any individual responsible for the conduct of affairs of the pharmacy benefit manager has been convicted of, or has entered a plea of guilty or nolo contendere to, a felony without regard to whether adjudication was withheld.

(f) That the pharmacy benefit manager's license has been suspended or revoked in another state.

(g) That a resident pharmacy benefit manager has failed to file a timely annual report required under section 23, or a timely renewal application and renewal fee, as applicable, required under subsection (10).

(6) If a pharmacy benefit manager's license is suspended or restricted, the director may permit the operation of the pharmacy

benefit manager for a limited time not to exceed 60 days. However, the director may permit a pharmacy benefit manager whose license has been suspended or restricted to operate for a period that exceeds 60 days if the director determines that the continued operation of the pharmacy benefit manager is in the beneficial interests of covered persons by ensuring minimal disruptions to the continuity of care. A pharmacy benefit manager whose license has been suspended or restricted is subject to a fine each month, as determined by the director, not to exceed $5,000.00 per month, until the pharmacy benefit manager has remedied the violation leading up to the suspension or restriction.

(7) The director may revoke the license of a pharmacy benefit manager if the pharmacy benefit manager has been operating under a suspended license for a period of more than 60 days.

(8) For purposes of this section, a pharmacy benefit manager has the same rights to notice and hearings that are provided to insurers under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

(9) The director may investigate officers, directors, and owners of a pharmacy benefit manager in the same manner as a business entity licensed under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

(10) To renew a license as a pharmacy benefit manager, an applicant shall submit to the director all of the following:

(a) A renewal application in a form and manner prescribed by the director that is signed by an officer or authorized representative of the pharmacy benefit manager verifying that the contents of the renewal form are correct.

(b) A renewal fee as provided by the director by rule.

(c) A pharmacy benefit manager network adequacy report required under section 17.

Sec. 13. (1) The director shall promulgate rules to implement this act.

(2) The rules promulgated by the director under subsection (1) shall include, but are not limited to, fines, suspension of licensure, restriction of licensure, and revocation of licensure.

Sec. 15. (1) A pharmacy benefit manager shall exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a pharmacy benefit manager and a carrier or a network pharmacy that attempts to waive or limit this obligation is void.

(2) A pharmacy benefit manager shall notify a carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the duties imposed in this section.

(3) If a pharmacy benefit manager plans to increase the patient's cost share amount on a drug that is a maintenance drug, the pharmacy benefit manager shall notify all known covered persons currently taking the maintenance drug of the cost share increase 60 days before it goes into effect.

(4) The pharmacy benefit manager shall communicate the final reimbursement amount to the network pharmacy at the time of adjudication at the point of sale.

(5) The pharmacy benefit manager may 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.

Sec. 17. (1) A pharmacy benefit manager shall provide a reasonably adequate and accessible pharmacy benefit manager 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.

(2) A pharmacy benefit manager shall submit to the director a pharmacy benefit manager network adequacy report that describes the pharmacy benefit manager network and the pharmacy benefit manager network's accessibility in this state in the time and manner prescribed by the director.

(3) A pharmacy benefit manager may apply for a waiver from the director if the pharmacy benefit manager is unable to meet the network adequacy requirements under subsection (1).

(4) To apply for a waiver under subsection (3), a pharmacy benefit manager must submit to the director an application in a form and manner prescribed by the director that does both of the following:

(a) Demonstrates with specific data why the pharmacy benefit manager is not able to meet the network adequacy requirements under subsection (1).

(b) Includes information as to the steps that the pharmacy benefit manager has taken and will take to address network adequacy.

(5) If the director grants a waiver under subsection (3), the waiver expires after 2 years. If a pharmacy benefit manager seeks a renewal of the waiver, the director shall consider the steps that the pharmacy benefit manager has taken over the 2-year period covered by the waiver to address network adequacy.

Sec. 19. (1) A pharmacy benefit manager that has an ownership

interest, either directly or indirectly, or through an affiliate or subsidiary, in a pharmacy must disclose to a carrier that contracts with the pharmacy benefit manager any difference between the amount paid to that pharmacy and the amount charged to the carrier.

(2) A pharmacy benefit manager shall not discriminate against a pharmacy in which the pharmacy benefit manager does not have an ownership interest.

(3) Except as otherwise provided in subsection (4), a pharmacy benefit manager or carrier shall not impose limits, including quantity limits or refill frequency limits, on an enrollee's access to medication that differ based solely on whether the carrier or pharmacy benefit manager has an ownership interest in a pharmacy or the pharmacy has an ownership interest in the pharmacy benefit manager.

(4) Subsection (3) does not prohibit a pharmacy benefit manager from imposing different limits, including quantity limits or refill frequency limits, on an enrollee's access to medication based on whether the enrollee uses a mail-order pharmacy or retail pharmacy if the enrollee has the option to use a mail-order pharmacy or retail pharmacy with the same limits imposed in which the pharmacy benefit manager or carrier does not have an ownership interest unless the pharmacy's status within the pharmacy network is identified as a preferred pharmacy.

(5) A pharmacy benefit manager or carrier shall not prohibit a 340B Program entity or a pharmacy that has a license in good standing in this state under contract with a 340B Program entity from participating in the pharmacy benefit manager's or carrier's provider network solely because it is a 340B Program entity or a pharmacy under contract with a 340B Program entity. A pharmacy

benefit manager or carrier shall 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 this subsection, "340B Program entity" means an entity authorized to participate in the federal 340B Program under section 340B of the public health service act, 42 USC 256b.

Sec. 21. (1) A contract between a pharmacy benefit manager and a pharmacist or a pharmacy that provides drug coverage for health plans must not prohibit or restrict a pharmacy or pharmacist from, or penalize a pharmacy or pharmacist for, disclosing to a covered person health care information that the pharmacy or pharmacist considers appropriate regarding any of the following:

(a) The nature of the treatment or the risks or the alternatives to the treatment.

(b) The availability of alternate therapies, consultations, or tests.

(c) The decision of utilization reviewers or similar persons to authorize or deny services.

(d) The process that is used to authorize or deny health care services or benefits.

(2) A pharmacy benefit manager shall 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 a more affordable alternative is available.

(3) A contract between a pharmacy benefit manager and a pharmacist shall require the pharmacist to refund a patient if the price of the drug without insurance is less than the cost of the patient's insurance copayment price.

Sec. 23. (1) Unless otherwise required more frequently by the director, beginning January 1, 2022, except as otherwise provided in subsection (2), a pharmacy benefit manager shall file an annual transparency report with the director that contains the information required under this section from the immediately preceding calendar year.

(2) This section does not apply if the pharmacy benefit manager has contracted with the department of health and human services under Medicaid. As used in this subsection, "Medicaid" means benefits under the program of medical assistance established under title XIX of the social security act, 42 USC 1396 to 1396w-5, and administered by the department of health and human services under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.

(3) The transparency report required under subsection (1) must include all of the following information:

(a) The aggregate wholesale acquisition costs from a manufacturer or wholesale drug distributor for each therapeutic category of drugs for all of the pharmacy benefit manager's plan sponsors, net of all rebates and other fees and payments, direct or indirect, from all sources.

(b) The aggregate amount of all rebates that the pharmacy benefit manager received from all manufacturers for all of the pharmacy benefit manager's plan sponsors. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a manufacturer or wholesale drug distributor.

(c) The aggregate amount of all fees that the pharmacy benefit manager received.

(d) The aggregate amount of all rebates that the pharmacy benefit manager received from all manufacturers that were not

passed through to health plans or insurers.

(e) The aggregate amount of all fees that the pharmacy benefit manager received from all manufacturers that were not passed through to health plans or insurers.

(f) The aggregate retained rebate percentage.

(4) The director shall conduct an annual review against all de-identified claims submitted to analyze if pharmacy payment and patient cost-sharing variations have occurred using the following information for each claim:

(a) The drug and quantity for each prescription.

(b) Whether the claim required prior authorization.

(c) Subject to subsection (6), patient cost-sharing paid on each prescription.

(d) Subject to subsection (6), 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.

(e) Subject to subsection (6), any spread between the net amount paid to the pharmacy in subdivision (d) and the amount charged to the plan sponsor.

(f) The identity of the pharmacy that filled each prescription.

(g) Whether the pharmacy is under common control or ownership with the pharmacy benefit manager.

(h) Whether the pharmacy is a preferred pharmacy under the health plan.

(i) Whether the pharmacy is a mail-order pharmacy.

(j) Whether the health plan requires enrollees to use the pharmacy.

(5) The report required under this section must be filed with the department in a form and manner required by the department.

(6) Data, documents, materials, or other information in the possession or control of the director that are obtained by, created by, or disclosed to the director under subsection (4)(c) to (e) is confidential by law and privileged, is not subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246, is not subject to subpoena, and is not subject to discovery or admissible in evidence in any private civil action. However, the director is 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 director's duties. The director shall not otherwise make the data, documents, materials, or other information public.

Sec. 25. The department shall prepare an annual report based on the information received by it under this act. The report must contain aggregate data and must not contain any information that the director determines would cause financial, competitive, or proprietary harm to a pharmacy benefit manager or carrier that the pharmacy benefit manager services. The director shall file the report described in this section with each of the following:

(a) The house and senate standing committees on health policy.

(b) The house and senate fiscal agencies.

(c) The house and senate policy offices.

Sec. 27. (1) For each drug that a pharmacy benefit manager establishes a maximum allowable cost, the pharmacy benefit manager shall do all of the following:

(a) 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.

(b) Update its maximum allowable cost list at least once every 7 calendar days.

(c) 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.

(d) 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.

(e) Respond in writing to any appealing pharmacy not later than 10 calendar days after receipt of an appeal if the pharmacy filed the appeal within 10 calendar days after the date the pharmacy's claim for reimbursement is adjudicated.

(f) Respond in writing to any appealing pharmacy not later than 30 calendar days after receipt of an appeal if the pharmacy filed the appeal more than 10 calendar days after the date the pharmacy's claim for reimbursement is adjudicated.

(2) Before a pharmacy benefit manager places or continues a drug on a maximum allowable cost list, both of the following requirements must be met:

(a) The drug is available for purchase by each pharmacy in this state from national or regional wholesale drug distributors operating in this state.

(b) The drug is not obsolete.

Sec. 29. (1) The director shall enforce this act.

(2) The director may examine or audit the books and records of a pharmacy benefit manager providing claims processing services or other drug or device services for a health plan to determine if the pharmacy benefit manager is in compliance with this act.

(3) All of the following apply to information or data acquired during an examination under subsection (2), or otherwise acquired under this act:

(a) The information or data is considered proprietary and confidential.

(b) The information or data is not subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(c) The information or data is only to be used for purposes of ensuring a pharmacy benefit manager's compliance with this act.

Sec. 31. A contract between a pharmacy benefit manager and an insurer that exists on the date of licensure of the pharmacy benefit manager must comply with the requirements of this act as a condition of licensure for the pharmacy benefit manager.

Sec. 33. (1) Except as otherwise provided in subsection (2), the director may destroy or otherwise dispose of a record, book, paper, or other data on file with the department that, in his or her opinion, and on the advice of the attorney general, is of no further material value to this state.

(2) The director shall not order the destruction or other disposal of a record, book, paper, or other data that is any of the following:

(a) Required by law to be filed or kept on file with the department until the expiration of a period of 10 years.

(b) Filed during the director's administration or administrations.

(c) 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.

(3) The director shall promulgate rules to implement this section.

Enacting section 1. This act does not take effect unless House Bill No. 5937 of the 100th Legislature is enacted into law.