SENATE BILL No. 287

March 30, 2017, Introduced by Senators SCHUITMAKER, KNEZEK and GREEN and referred to the Committee on Insurance.

A bill to provide for the regulation of the management of pharmacy benefits; to require the licensing of pharmacy benefit managers; to provide for the regulation of certain other entities under certain circumstances; to provide for the powers and duties of certain state governmental officers and entities; to prescribe penalties and provide remedies; and to allow for the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 101. This act shall be known and may be cited as the "pharmacy benefit management act".

Sec. 103. For purposes of this act, the words and phrases defined in sections 105 to 111 have the meanings ascribed to them in those sections.

Sec. 105. (1) "Board of pharmacy" means the Michigan board of

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pharmacy created in part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780.

(2) "Claim" means an attempt to cause a health benefit payer or a pharmacy benefit manager to make a payment to cover a service that is provided by a pharmacy benefit.

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

(4) "Director" means the director of the department or his or her designee.

Sec. 107. (1) "Federal act" means the federal food, drug, and cosmetic act, 21 USC 301 to 399f.

(2) "Food and Drug Administration" means the United States Food and Drug Administration.

(3) "Health benefit payer" means a public or private entity that offers, provides, administers, or manages a health care benefit plan, including, but not limited to, all of the following:

(a) An insurer or health maintenance organization regulated under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, or a dental care corporation regulated under 1963 PA 125, MCL 550.351 to 550.373.

(b) A nonprofit health care corporation.

(c) A preferred provider organization.

(d) The medical services administration in the department of health and human services.

(e) A person acting in a contractual relationship with an entity described in subdivisions (a) to (d) to perform any activity on behalf of the entity described in subdivisions (a) to (d).

Sec. 109. (1) "Maximum allowable cost price" means a maximum reimbursement amount for a multiple source drug.

(2) "Multiple source drug" means a drug for which there are 2 or more prescription drugs, each of which meets both of the following requirements, as determined by the director:

(a) Is considered to be pharmaceutically equivalent or otherwise interchangeable by the Food and Drug Administration.

(b) Is generally and readily available for purchase by pharmacies in this state from national or regional wholesalers and is not obsolete.

(3) "Obsolete" means that the prescription drug may be listed in the national pricing compendia but is no longer actively marketed by the manufacturer or labeler.

Sec. 111. (1) "Person" means an individual, sole proprietorship, partnership, corporation, association, or any other legal entity.

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

(3) "Pharmacy benefit" means a health care benefit plan that is offered by a health benefit payer and provides coverage for a pharmacy service to a covered individual. Coverage under a pharmacy benefit includes, but is not limited to, coverage for a prescription drug that is dispensed to a covered individual.

(4) "Pharmacy benefit manager" means a person that manages a pharmacy benefit on behalf of a health benefit payer. A person that engages in, or subcontracts for, 3 or more of the following activities is considered a pharmacy benefit manager that is subject

to this act:

(a) Claims processing.

(b) Pharmacy network management.

(c) Pharmacy discount card management.

(d) Payment of claims to pharmacies for prescription drugs dispensed to individuals covered by a pharmacy benefit.

(e) Clinical formulary development and management services, including, but not limited to, utilization management and quality assurance programs.

(f) Rebate contracting and administration.

(g) Conducting audits of network pharmacies.

(h) Setting pharmacy reimbursement pricing and methodologies, including maximum allowable cost price and other prescription drug pricing standards, and determining single source drugs or multiple source drugs.

(i) Retention of any spread or differential between what is received under a pharmacy benefit as reimbursement for a prescription drug and what is paid to pharmacies by the pharmacy benefit manager for the prescription drug.

(5) "Prescription drug" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.

(6) "Prescription drug pricing standard" means a standard for reimbursing a prescription drug that is based on the cost of the prescription drug or an industry-recognized benchmark for the pricing of the prescription drug. Prescription drug pricing standard includes, but is not limited to, the average wholesale price, the wholesale acquisition cost, the maximum allowable cost,

the national average drug acquisition cost, and the average manufacturer price.

(7) "Temporarily unavailable" means that the prescription drug is experiencing short-term supply interruptions and only inconsistent or intermittent supply is available in the current marketplace.

Sec. 113. (1) A pharmacy benefit manager that provides services to residents of this state shall apply for, obtain, and maintain a certificate of authority to operate as a pharmacy benefit manager from the department. A certificate of authority under this act is renewable annually.

(2) The director shall collect, and the persons affected shall pay to the director, the following fees that, on appropriation, the department shall use to cover the costs incurred by the department in administering this act:

(a) Filing fee to accompany application for pharmacy benefit manager's certificate of authority..... $ 200.00.

(b) Certificate of authority for a pharmacy benefit manager..... $ 25.00.

(3) Subject to this section, an applicant for a certificate of authority to operate in this state as a pharmacy benefit manager shall submit to the department an application in a form and manner prescribed by the director. An officer or authorized representative of the pharmacy benefit manager shall verify the application form.

(4) An applicant shall include with an application form all of

the following:

(a) All organizational documents, including, but not limited to, articles of incorporation, bylaws, and other similar documents, and any amendments to the organizational documents.

(b) The names, addresses, titles, and qualifications of the members and officers of the board of directors, board of trustees, or other governing body or committee of the applicant, or the partners, members, or owners if the applicant is a partnership or other entity or association.

(c) A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, or other administrative services provided by the applicant.

(d) The name and address of the agent for service of process in this state.

(e) Financial statements for the current year and the preceding year that show the assets, liabilities, direct or indirect income, and any other sources of financial support considered sufficient by the director that demonstrate financial stability and viability of the pharmacy benefit manager to meet its full obligations to covered individuals and network pharmacies. The director may allow a recent financial statement prepared by an independent certified public accountant to meet the requirement of this subdivision.

(f) Any other information the director requires. However, the director shall not demand trade secret information from an applicant.

(5) The director may revoke, suspend, deny, or restrict a certificate of authority of a pharmacy benefit manager for a violation of this act or on other grounds or violations of state or federal laws as determined necessary or appropriate by the director. A pharmacy benefit manager has the same rights to notice, hearings, and other provisions that are provided to insurers under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302. If a certificate of authority is revoked, suspended, or denied, the director may permit the operation of the pharmacy benefit manager for a limited time not to exceed 60 days under conditions and restrictions as determined necessary by the director for the beneficial interests of the covered individuals and network pharmacies.

(6) The director may renew a certificate of authority of a pharmacy benefit manager, subject to any restrictions considered necessary or appropriate by the director.

Sec. 115. (1) Both of the following apply to a contract between a pharmacy benefit manager and a pharmacy or between a pharmacy benefit manager and a pharmacy's contracting representative or agent, including, but not limited to, a pharmacy services administrative organization:

(a) If a pharmacy benefit manager uses a prescription drug pricing standard to reimburse a pharmacy or a health facility, both of the following apply:

(*i*) The contract entered into by the pharmacy benefit manager must include a current list of the sources used to determine the prescription drug pricing standard. The pharmacy benefit manager

shall update the prescription drug pricing standard not less often than every 7 days and provide a means by which the pharmacy may promptly review the updates in a format that is readily available and accessible.

(*ii*) The pharmacy benefit manager shall use the same prescription drug pricing standard or set of prescription drug pricing standards for all covered individuals and pharmacies participating in the same pharmacy benefit. This subparagraph does not prohibit a pharmacy benefit manager from managing multiple pharmacy benefits for 1 or more health benefit payers.

(b) The pharmacy benefit manager shall include in the contract a process to appeal, investigate, and resolve disputes regarding a prescription drug pricing standard, which process must include all of the following:

(*i*) A 21-day limit on the right to appeal following the initial claim.

(*ii*) A requirement that the appeal be investigated and resolved within 10 business days after the appeal.

(*iii*) A telephone number at which the pharmacy may contact the pharmacy benefit manager to speak to an individual responsible for processing appeals.

(*iv*) A requirement that the pharmacy benefit manager provide a reason for any appeal denial and the identification of the national drug code of a prescription drug that may be purchased by the pharmacy at a price at or below the prescription drug pricing standard used by the pharmacy benefit manager.

(*v*) A requirement that the pharmacy benefit manager do all of

the following if the appeal is successful:

(A) Adjust the prescription drug pricing standard that is the subject of the appeal. The adjustment under this sub-subparagraph shall take effect on the day after the date the appeal is resolved.

(B) Apply the prescription drug pricing standard that is adjusted under sub-subparagraph (A) to all pharmacies and covered individuals participating in the pharmacy benefit to which the appeal was made.

(C) Allow the appealing pharmacy to resubmit the claim to the pharmacy benefit manager for reimbursement using the prescription drug pricing standard adjusted under sub-subparagraph (A).

Sec. 117. A pharmacy shall be reimbursed for a legally valid claim at a rate of not less than the rate in effect at the time of original claim adjudication as submitted at the point of sale.

Sec. 119. (1) A pharmacy benefit manager shall not do any of the following:

(a) Mandate that a covered individual use a specific pharmacy, mail-order pharmacy, specialty pharmacy, or any other pharmacy, if the pharmacy benefit manager has an ownership interest in the pharmacy or if the pharmacy has an ownership interest in the pharmacy benefit manager.

(b) Except as otherwise provided in this subdivision, provide an incentive to a covered individual to encourage the use of a specific pharmacy if the incentive only applies to a pharmacy in which the pharmacy benefit manager has an ownership interest or provide an incentive to a covered individual to encourage the use of a specific pharmacy if the incentive only applies to a pharmacy

that has an ownership interest in the pharmacy benefit manager. This subdivision does not apply if the covered individual willingly designates as the covered individual's primary pharmacy a pharmacy in which the pharmacy benefit manager has an ownership interest or that has an ownership interest in the pharmacy benefit manager.

(c) Require that a pharmacist or pharmacy participate in a network managed by the pharmacy benefit manager as a condition for the pharmacy to participate in another network managed by the same pharmacy benefit manager.

(d) Automatically enroll or disenroll a pharmacy in a contract or modify an existing agreement without written agreement of the pharmacist, pharmacy, or person acting on behalf of the pharmacist or pharmacy.

(e) Prohibit a covered individual from receiving a prescription drug benefit, including a 90-day supply of a prescription drug, at a network pharmacy of the pharmacy benefit manager.

(f) Impose on a covered individual who uses a pharmacy a copayment, deductible, fee, limitation on benefits, or other condition or requirement that is not otherwise imposed on the covered individual when the covered individual uses a mail-order pharmacy.

(g) Distribute to a pharmacy a prescription, or a copy of a prescription, to dispense a drug utilizing information submitted to the pharmacy benefit manager for the purpose of obtaining a prior authorization or to complete any other nondispensing or administrative function that is conducted by the pharmacy benefit

manager.

(h) Solicit a covered individual utilizing information submitted to the pharmacy benefit manager for the purpose of obtaining a prior authorization or to complete any other nondispensing or administrative function that is conducted by the pharmacy benefit manager.

(2) This section does not mandate the inclusion of a pharmacy in a health benefit payer network or pharmacy benefit manager's network or the exclusion of a pharmacy from a health benefit payer network or pharmacy benefit manager's network.

Sec. 121. (1) Except as otherwise provided in this subsection, a pharmacy benefit manager shall not sell, lease, or rent utilization or claims data that the pharmacy benefit manager possesses as a result of a contract between the pharmacy benefit manager and the health benefit payer. A pharmacy benefit manager may sell, lease, or rent the data described in this subsection if the pharmacy benefit manager obtains the covered individual's consent before selling, leasing, or renting the data.

(2) A pharmacy benefit manager shall not directly contact a covered individual on behalf of a health benefit payer without the express written permission of the health benefit payer and the covered individual. A health benefit payer may make a request of a covered individual for permission under this subsection.

(3) A pharmacy benefit manager shall not transmit to a pharmacy any personally identifiable utilization or claims data that is related to a covered individual unless the covered individual has voluntarily elected to fill a prescription at that

pharmacy.

Sec. 123. Each pharmacy benefit manager shall maintain a current formulary list by major therapeutic category and make the list available to prescribers and pharmacies that are participating in the pharmacy benefit manager's network or have contracted with a health benefit payer that utilizes the pharmacy benefit manager for the management of the health benefit payer's pharmacy benefit.

Sec. 125. (1) Except as otherwise provided in subsection (2), if a pharmacy benefit manager makes or approves a change in a formulary that causes a prescription drug to not be covered, applies a new or revised dose restriction that causes a prescription drug to not be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a prescription drug to not be covered until the step therapy or prior authorization requirement has been met, the pharmacy benefit manager shall do 1 of the following:

(a) At least 60 days before the effective date of the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement, provide notice of the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement to each covered individual who is currently receiving benefits for the prescription drug. The notice described in this subdivision must be provided in writing or, if the covered individual has agreed to receive information in this manner, by electronic means.

(b) If a covered individual who is currently receiving

benefits for the prescription drug requests a refill of the prescription drug, cover up to a 60-day supply of the prescription drug on the same terms as covered previously if the prescription drug continues to be prescribed for the covered individual during that time period and inform the covered individual of the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement, unless either of the following applies:

(*i*) The covered individual's prescriber agrees to a request from the health benefit payer or the pharmacist to change the prescription in accordance with the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement.

(*ii*) If the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement pertains to generic substitution, the prescription does not prohibit generic substitution or the covered individual agrees at the pharmacy to generic substitution.

(2) A pharmacy benefit manager is not required to provide the notice described in subsection (1) or cover up to a 60-day supply of a prescription drug under subsection (1) if either of the following applies:

(a) The prescription drug is being discontinued from coverage on the formulary for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.

(b) The formulary change, new or revised dose restriction, or

new or revised step therapy or prior authorization requirement for the prescription drug is made, approved, or applied for safety reasons.

Sec. 127. (1) Except as otherwise provided in subsection (2), if a pharmacy benefit manager makes or approves a change in a formulary that causes a prescription drug to not be covered, applies a new or revised dose restriction that causes a prescription for a prescription drug to not be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a prescription drug to not be covered until the requirements of the step therapy or prior authorization requirement have been met, the pharmacy benefit manager shall provide notice of the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement to all of the following in the following time frames:

(a) Except as otherwise provided in this subdivision, to prescribers at least 60 days before the effective date of the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement. A pharmacy benefit manager is not required to provide notice to a prescriber under this subdivision if the pharmacy benefit manager provides coverage of up to a 60-day supply of the prescription drug as provided in section 125.

(b) To pharmacies participating in the pharmacy benefit manager's network, by the effective date of the formulary change, new or revised dose restriction, or new or revised step therapy or

prior authorization requirement.

(c) To prescribers who did not receive advance notice of the change under subdivision (a), by the effective date of the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement.

(2) Subsection (1) does not apply if the formulary change, new or revised dose restriction, or new or revised step therapy or prior authorization requirement is being made, approved, or applied for safety reasons or because the prescription drug cannot be supplied by, or has been withdrawn from the market by, the drug's manufacturer.

Sec. 129. (1) A pharmacy benefit manager shall secure the participation in its network of a sufficient number of pharmacies that dispense, other than by mail order, prescription drugs directly to covered individuals to ensure convenient access to those pharmacies that are within 30 miles of a covered individual's residence.

(2) If a covered individual wishes to use an out-of-network pharmacy that is geographically closer to the covered individual's residence than the closest in-network pharmacy, a pharmacy benefit manager shall allow the covered individual to designate the out-of-network pharmacy as the covered individual's primary pharmacy and shall treat the out-of-network pharmacy as though it were in-network for the purpose of providing services under a pharmacy benefit. A covered individual who designates an out-of-network pharmacy as the covered individual's primary pharmacy under this subsection is eligible for all incentives, reductions, and cost

sharing that he or she would otherwise be eligible to receive if the covered individual had designated an in-network pharmacy as his or her primary pharmacy.

Sec. 131. (1) Subject to this section, a health benefit payer or a pharmacy benefit manager may conduct an audit of a pharmacy in this state. A health benefit payer or a pharmacy benefit manager that conducts an audit of a pharmacy in this state shall do all of the following:

(a) In its pharmacy contract, identify and describe in detail the audit procedures including the appeals process described in subdivision (m). A health benefit payer or pharmacy benefit manager shall update its pharmacy contract and communicate any changes to the pharmacy as changes to the contract occur.

(b) Provide written notice to the pharmacy at least 2 weeks before initiating and scheduling the initial on-site audit for each audit cycle. Unless otherwise consented to by the pharmacist, a health benefit payer or pharmacy benefit manager shall not initiate or schedule an on-site audit during the first 6 calendar days of a month, a holiday time frame, a weekend, or a Monday. A health benefit payer or pharmacy benefit manager shall be flexible in initiating and scheduling an audit at a time that is reasonably convenient to the pharmacy and the health benefit payer or pharmacy benefit manager.

(c) Utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process. A health benefit payer or pharmacy benefit manager that conducts an audit of a pharmacy in this state shall not interfere with the

delivery of pharmacy services to a patient.

(d) Conduct an audit that involves clinical or professional judgment by or in consultation with a pharmacist.

(e) Subject to the requirements of article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, for the purpose of validating a pharmacy record with respect to orders, refills, or changes in prescriptions, allow the use of either of the following:

(*i*) Hospital or physician records that are written or that are transmitted or stored electronically, including file annotations, document images, and other supporting documentation that is date- and time-stamped.

(*ii*) A prescription that complies with the requirements of the board of pharmacy and state and federal law.

(f) Base any finding of an overpayment or underpayment on the actual overpayment or underpayment of claims.

(g) Subject to subsection (4), base any recoupment or payment adjustments of claims on a calculation that is reasonable and proportional in relation to the type of error detected.

(h) If there is a finding of an underpayment, reimburse the pharmacy as soon as possible after detection.

(i) Conduct its audit of each pharmacy under the same sampling standards, parameters, and procedures that the health benefit payer or pharmacy benefit manager uses when auditing other similarly licensed pharmacies. The health benefit payer shall provide to the pharmacy samples of the standards, parameters, and procedures for the audit being conducted.

(j) Audit only claims submitted or adjudicated within the 1-year period immediately preceding the initiation of the audit unless a longer period is permitted under federal or state law.

(k) Not receive payment based on a percentage of the amount recovered.

(*l*) Not include the dispensing fee amount in a finding of an overpayment.

(m) Establish a written appeals process that includes a process to appeal preliminary audit reports and final audit reports prepared under this section. If either party is not satisfied with the results of the appeal, that party may seek mediation.

(2) On completion of an audit of a pharmacy, the health benefit payer or pharmacy benefit manager shall do all of the following:

(a) Deliver a preliminary written audit report to the pharmacy on or before the expiration of 60 days after the completion of the audit. The preliminary written audit report must include contact information for the person performing the audit and a description of the appeal process established under subsection (1)(m).

(b) Allow the pharmacy at least 30 days following its receipt of the preliminary written audit report under subdivision (a) to produce documentation to address any discrepancy found during the audit.

(c) If an appeal is not filed, deliver a final written audit report to the pharmacy within 90 days after the time described in subdivision (b) has elapsed. If an appeal is filed, deliver a final written audit report to the pharmacy within 90 days after the

conclusion of the appeal.

(d) Except as otherwise provided in this section, only recoup disputed funds or overpayments or restore underpayments after the final written audit report is delivered to the pharmacy under subdivision (c).

(e) On request, provide to the sponsor of the health care benefit plan a copy of the final written audit report delivered to the pharmacy under subdivision (c).

(3) A health benefit payer or pharmacy benefit manager shall not conduct an extrapolation audit in calculating recoupments, restoration, or penalties for an audit under this section. As used in this subsection, "extrapolation audit" means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the health benefit payer that is then used to estimate audit results for a larger batch or group of claims not reviewed during the audit.

(4) 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 is found during an audit under this section does not, on its face, constitute fraud. An error described in this subsection does 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 is not subject to recoupment of funds by the health benefit payer or pharmacy benefit

manager unless the health benefit payer can provide proof of intent to commit fraud or the error results in actual financial harm to the health benefit payer, pharmacy benefit manager, or a covered individual.

(5) This section does not apply to any of the following:

(a) An audit conducted to investigate fraud, willful misrepresentation, or abuse, including, but not limited to, investigative audits or audits conducted under any other statutory provision that authorizes investigation relating to insurance fraud.

(b) An audit based on a criminal investigation.

(6) This section does not impair or supersede a provision regarding health benefit payer pharmacy audits in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302. If any provision of this section conflicts with a provision of the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, with regard to health benefit payer pharmacy audits, the provision in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, controls.

Sec. 133. (1) The director is responsible for the enforcement of this act. The director shall take action or impose sanctions to bring noncomplying entities into full compliance with this act. The director has the same authority to examine and investigate entities regulated by this act and may enforce this act in the same manner as provided for insurers under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

(2) The department may promulgate rules under the

administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, that it considers necessary to implement, administer, and enforce this act.

Enacting section 1. This act takes effect 90 days after the date it is enacted into law.

Enacting section 2. This act applies to contracts delivered, executed, issued, amended, adjusted, or renewed in this state beginning January 1, 2019.