SENATE SUBSTITUTE FOR

HOUSE BILL NO. 4348

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 may be cited as the "pharmacy benefit manager licensure and regulation act".

Sec. 5. As used in this act:

(a) "Affiliated pharmacy" means, except as otherwise provided in this subdivision, a network pharmacy that directly, or indirectly through 1 or more intermediaries, controls, is controlled by, or is under common control with, a pharmacy benefit

manager. As used in section 19, affiliated pharmacy does not include a pharmacy that controls, is controlled by, or is under common control with, a hospital as that term is defined in section 20106 of the public health code, 1978 PA 368, MCL 333.20106.

(b) "Aggregate retained rebate percentage" means the percentage of all rebates received by a pharmacy benefit manager from all manufacturers, that is not passed on to the pharmacy benefit manager's Michigan 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:

(*i*) 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 Michigan health plan or insurer clients.

(*ii*) Divide the result of the calculation under subparagraph (*i*) by the aggregate dollar amount of all rebates that the pharmacy benefit manager received during the prior calendar year from all manufacturers.

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

(d) "Claim" means 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.

(e) "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:

(*i*) Receiving payments for pharmacist services.

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

(*iii*) Receiving and making the payments described in subparagraphs (*i*) and (*ii*).

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

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

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

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

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

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

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

(k) "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.

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

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

(*ii*) A principal officer for a corporation or a partner or member for a partnership, association, or limited liability company.

(*iii*) 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.

(*iv*) Any person who exercises control over the affairs of the pharmacy benefit manager.

(m) "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. As used in this act:

(a) "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.

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

(c) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a network pharmacy for the ingredient cost for a generic drug.

(d) "Maximum allowable cost list" means a listing of drugs used by a pharmacy benefit manager, directly or indirectly, to set the maximum allowable cost.

(e) "Multiple source drug" means a therapeutically equivalent drug that is available from 1 or more of the following:

(*i*) At least 1 brand-named manufacturer and at least 1 generic manufacturer.

(*ii*) Two or more generic manufacturers.

(f) "Network pharmacy" means a retail pharmacy or other pharmacy that contracts directly or through a pharmacy services administration organization with a pharmacy benefit manager.

(g) "Nonaffiliated pharmacy" means a network pharmacy that directly, or indirectly through 1 or more intermediaries, does not control, is not controlled by, or is not under common control with, a pharmacy benefit manager.

(h) "Person" means an individual, partnership, corporation, association, governmental entity, or any other legal entity.

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

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

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

(*l*) Except as otherwise provided in subdivision (m), "pharmacy benefit manager" means an entity that contracts with a pharmacy or a pharmacy services administration organization on behalf of a health plan or carrier to provide pharmacy health services to individuals covered by the health plan or carrier or administration that includes, but is not limited to, any of the following:

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

(*ii*) Administering a drug benefit.

(*iii*) Processing or paying pharmacy claims.

(*iv*) Creating or updating drug formularies.

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

(*vi*) Administering rebates on drugs.

(*vii*) Establishing a pharmacy network.

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

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

(o) "Pharmacy services administration organization" means an entity that provides contracting and other administrative services relating to prescription drug benefits to pharmacies.

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

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

(r) "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. As used in this act:

(a) "Rebate" means a formulary discount or remuneration attributable to the use of prescription drugs 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 does not include a fee, including, but not limited to, a bona fide service fee or administrative fee, that is not a formulary discount or remuneration described in this subdivision.

(b) "Retail pharmacy" means a pharmacy that dispenses prescription drugs to the public at retail primarily to individuals that reside in close proximity to the pharmacy, typically by face-

to-face interaction with the individual or the individual's caregiver.

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

(d) "Specialty drug" means a drug to which all of the following apply:

(*i*) The cost of the drug exceeds the drug cost threshold established by the Centers for Medicare and Medicaid Services under the Medicare Part D program.

(*ii*) The drug requires special administration, including, but not limited to, injection, infusion, or inhalation.

(*iii*) The drug requires unique storage, handling, or distribution.

(*iv*) The drug requires special oversight, intensive monitoring, complex education and support, or care coordination with a person licensed under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838.

(*v*) The drug provides treatment for serious, chronic, or life-threatening diseases.

(*vi*) The drug is covered under a patient's health plan or by a patient's carrier.

(e) "Specialty pharmacy" means a pharmacy that dispenses specialty drugs to patients and that is nationally accredited by an independent third party.

(f) "Spread pricing" means the model of prescription drug pricing in which a pharmacy benefit manager charges a health plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefit manager directly or indirectly pays the pharmacist or

pharmacy for pharmacist services.

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

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

(i) "Wholesale distributor" means that term as defined in section 17709 of the public health code, 1978 PA 368, MCL 333.17709.

Sec. 11. (1) 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 individual responsible for the conduct or affairs 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 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.

(*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.

(*iv*) A copy of recent financial statements showing the pharmacy benefit manager's assets, liabilities, and sources of financial support that the director determines are sufficient to show that the pharmacy benefit manager is financially viable. If the pharmacy benefit manager's financial statements 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 this act.

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

(3) Within 30 days after 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 law of this state applicable to the pharmacy benefit manager.

(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 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 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 pharmacy benefit manager has failed to file a timely transparency report required under section 23.

(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 $20,000.00 per month, until the pharmacy benefit manager has remedied the violation leading 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 an insurer 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 officers, directors, and owners of 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 schedule and fee as provided by the director by rule.

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

(11) A pharmacy benefit manager license expires if a complete renewal filing and fee is not received by the due date as established in rule by the director.

Sec. 13. (1) The director shall promulgate rules that are necessary or required to implement this act.

(2) The rules promulgated by the director under subsection (1) must include fines, suspension of licensure, restriction of licensure, and revocation of licensure in accordance with this act.

Sec. 15. (1) A pharmacy benefit manager shall exercise good faith and fair dealing in the performance of its contractual duties to a health plan or network pharmacy. A provision in a contract

that attempts to waive or limit the obligation under this subsection is void.

(2) A pharmacy benefit manager shall notify a health plan 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) A pharmacy benefit manager shall not directly or indirectly, including indirectly through a pharmacy services administrative organization, charge or hold a pharmacist or pharmacy responsible for a fee related to a claim or reduce the amount of the claim at the time of the claim's adjudication or after the claim is adjudicated.

(4) This section does not apply to an audit under section 28 of a pharmacy's records if either of the following applies:

(a) The review of claims data or statements indicates fraud, abuse, other intentional misconduct, or waste.

(b) An investigative method, other than a review described in subdivision (a), indicates that the pharmacy is or has committed fraud or other intentional misrepresentation.

(5) Except for the recoupment of money under an audit conducted under section 28, a pharmacy benefit manager shall not recoup money from a pharmacist or pharmacy in connection with a claim for which the pharmacist or pharmacy has been paid unless the recoupment is required by law.

Sec. 17. (1) A pharmacy benefit manager shall provide a reasonably adequate and accessible retail pharmacy benefit manager network for the provision of drugs for a health plan that must provide for convenient enrollee access to pharmacies within a reasonable distance from an enrollee's residence, as determined by

the director. For purposes of this subsection, retail pharmacy benefit manager network does not include a mail-order pharmacy or specialty pharmacy.

(2) A pharmacy benefit manager shall submit to the director a retail pharmacy benefit manager network adequacy report that describes the retail pharmacy benefit manager network and the retail pharmacy benefit manager network's accessibility in this state. The report must categorize the network by urban, suburban, and rural geography and must include the applicable zip codes.

(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 must consider the steps that the pharmacy benefit manager has taken over the 2-year period covered by the waiver to address network adequacy.

(6) A pharmacy benefit manager shall not conduct spread pricing in this state. However, if a contract between a plan

sponsor and a health plan is in effect on the effective date of this act and the contract conflicts with this subsection, for that contract, this subsection applies to the pharmacy benefit manager beginning on the date the contract is amended, extended, or renewed, or before January 1, 2028, whichever is earlier.

(7) A pharmacy benefit manager shall not charge a pharmacy or pharmacist a fee to process a claim electronically.

Sec. 19. (1) A pharmacy benefit manager shall disclose to a carrier that contracts with the pharmacy benefit manager any difference between the amount paid to a network pharmacy and the amount charged to the carrier.

(2) A pharmacy benefit manager shall not discriminate against a nonaffiliated pharmacy that is a retail pharmacy. A pharmacy benefit manager shall not reimburse a nonaffiliated retail pharmacy that is a retail pharmacy an amount less than the amount that the pharmacy benefit manager reimburses an affiliated pharmacy for providing the same pharmacist services. For drug reimbursement, equivalent services must be evaluated on a per-unit basis using the identical generic product identifier or generic code number.

(3) A pharmacy benefit manager shall not impose limits, including quantity limits or refill frequency limits, on an enrollee's access to retail prescription drugs that differ based solely on whether the pharmacy benefit manager has an ownership interest in a pharmacy or the pharmacy has an ownership interest in the pharmacy benefit manager.

(4) 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.

(5) Unless required by applicable law or as required under Medicaid by the department of health and human services, a carrier, health plan, or pharmacy benefit manager shall not require an enrollee or covered person to use only a retail affiliated pharmacy that is a retail pharmacy.

(6) A carrier, health plan, or pharmacy benefit manager shall not financially induce an enrollee or covered person or prescriber to transfer an enrollee or covered person prescription to a retail affiliated pharmacy. As used in this subsection, "prescriber" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.

(7) A carrier, health plan, or pharmacy benefit manager shall not require a retail nonaffiliated pharmacy to transfer an enrollee's or covered person's retail prescription to a retail affiliated pharmacy without the prior consent of the enrollee or patient.

(8) A pharmacy benefit manager shall not unreasonably restrict an enrollee or covered person from using a particular retail pharmacy for the purposes of receiving pharmacist services covered by the enrollee's or covered person's health plan.

(9) Before a prescription is dispensed, an affiliated pharmacy

shall disclose to an enrollee or covered person that the affiliated pharmacy is an affiliated pharmacy and that the enrollee or covered person is not obligated to use the affiliated pharmacy.

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 or enrollee 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.

(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 covered person or enrollee if a more affordable alternative is available.

(3) A carrier, health plan, or pharmacy benefit manager shall 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:

(a) The applicable copayment, coinsurance, and deductible.

(b) The final reimbursement amount to the network pharmacy.

Sec. 23. (1) Unless otherwise required more frequently by the director, by April 1, 2025 and each April 1 after that date, except as otherwise provided in subsection (5), a pharmacy benefit manager shall file a transparency report with the director that contains the information required under subsection (2) from the preceding

calendar year. The transparency report must not disclose any of the following information:

(a) The identity of a specific health plan or enrollee.

(b) The price the pharmacy benefit manager charged a pharmacy for a specific drug or class of prescription drugs.

(c) The amount of any rebate or fee provided to the pharmacy benefit manager for a prescription drug or class of prescription drugs.

(2) 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 distributor for each therapeutic category of drugs for the pharmacy benefit manager's Michigan plan sponsors, net of rebates and other fees and payments, direct or indirect, from all sources.

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

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

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

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

(f) The aggregate retained rebate percentage from business

conducted in this state.

(g) All of the following information attributable to patient use of prescription drugs covered by Michigan health plans:

(*i*) The aggregate amount of rebates and fees that the pharmacy benefit manager received from manufacturers.

(*ii*) The aggregate amount of rebates and fees that the pharmacy benefit manager received from manufacturers that were either of the following:

(A) Passed through to Michigan health plans or enrollees at the point of sale of a prescription drug.

(B) Retained by the pharmacy benefit manager.

(3) Except to the extent to prepare the report under subsection (4), all information submitted to the director in a transparency report under this section is exempt from disclosure under section 13 of the freedom of information act, 1976 PA 442, MCL 15.243.

(4) By August 1, 2025 and each August 1 after that date, the director shall prepare a report based on the information received by the director under this act and submit the report to the legislature. 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 department shall post the report required under this subsection on the department's website.

(5) This section does not apply to a contract between a pharmacy benefit manager and 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-6, and administered by the department of health and human services under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.

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 or an agent of a pharmacy subject to the maximum allowable cost list to challenge the adjudication of a pharmacy's claim.

(e) Investigate and resolve an appeal under this subsection within 14 calendar days after the pharmacy benefit manager receives the appeal. An appeal under this subsection must be submitted to the pharmacy benefit manager not later than 14 days after the date the pharmacy's claim for reimbursement has been adjudicated.

(f) Respond in writing to any appealing pharmacy or an appealing pharmacy's agent 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.

(g) If an appeal is denied, provide the appealing pharmacy or

the appealing pharmacy's agent the national drug code number available for purchase in this state at or below the appealed maximum allowable cost.

(h) If an appeal is granted, permit the pharmacy to reverse and rebill the claim and all claims for the drug.

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

(a) The drug is available for purchase by pharmacies in this state from wholesale distributors operating in this state.

(b) The drug is not obsolete.

(c) The drug is a multiple source drug.

(3) All benefits payable by a carrier, health plan, or pharmacy benefit manager to a pharmacy must be paid within 14 days after adjudication of a claim if claims are submitted electronically.

Sec. 28. (1) Subject to this section, a carrier or a pharmacy benefit manager may conduct an audit of a pharmacy in this state. A carrier 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 carrier 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. If the pharmacy on average dispenses more than 600 prescriptions per week, a carrier or pharmacy benefit manager shall

not initiate or schedule an audit under this subsection during the first 5 business days of a month without the express consent of the pharmacy. A carrier or pharmacy benefit manager shall be flexible in initiating and scheduling an audit at a time that is reasonably convenient to the pharmacy. Within 3 business days after the pharmacy receives notice of an on-site audit, the pharmacy may reschedule the audit to a date not more than 10 business days after the date proposed by the carrier or pharmacy benefit manager.

(c) Utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process. A carrier 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 Michigan board of pharmacy created under section 17721 of the public health code, 1978 PA 368, MCL 333.17721, 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 the pharmacy under the same standards and parameters that the carrier or pharmacy benefit manager uses when auditing other similarly situated pharmacies.

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

(k) Not receive payment and not compensate the auditor based on the amount recovered.

(*l*) Not include the dispensing fee amount in a finding of an overpayment unless any of the following apply:

(*i*) The prescription was not dispensed. As used in this subparagraph, "dispense" means that term as defined in section 17703 of the public health code, 1978 PA 368, MCL 333.17703.

(*ii*) The prescription was not delivered to the patient. As used in this subparagraph, "deliver" means that term as defined in section 17703 of the public health code, 1978 PA 368, MCL 333.17703.

(*iii*) The prescriber denied prior authorization.

(*iv*) The prescription was a medication error by the pharmacy.

(*v*) The overpayment is solely based on an extra dispensing fee.

(m) Establish a written appeals process that includes a process to appeal preliminary audit reports and final audit reports prepared under this section. A pharmacy has 30 days after the

pharmacy receives the final audit report to file an appeal under this section.

(n) Not limit the days' supply for unit-of-use items, such as topicals, drops, vials, and inhalants, beyond manufacturer recommendations.

(o) If the only commercially available package size exceeds the maximum days' supply, not use the dispensing of the package size as the basis for recoupment.

(p) If the only commercially available package size exceeds the maximum days' supply and the claim was affirmatively adjudicated, not recoup the claim as an early refill.

(q) In conducting an audit of wholesale invoices, all of the following:

(*i*) Not audit the claims of another carrier or pharmacy benefit manager.

(*ii*) Within 5 business days after a request by the audited pharmacy, provide supporting documentation provided to the carrier or pharmacy benefit manager by the audited pharmacy's suppliers.

(*iii*) Not utilize any of the following as a basis for recoupment:

(A) The national drug code for the dispensed drug is in a quantity that is a subunit or multiple of the purchased drug as reflected on a supporting wholesale invoice.

(B) The correct quantity dispensed is reflected on the audited pharmacy claim.

(C) The drug dispensed by the pharmacy on an audited pharmacy claim is identical to the labeler and product code section under the national drug code. A difference in the package code under the national drug code is not subject to recoupment.

(*iv*) Accept as evidence each of the following:

(A) Supplier invoices issued to the audited pharmacy before the date of dispensing the drug underlying the audited claim.

(B) Invoices issued to the audited pharmacy from any supplier permitted by law to transfer ownership of the drug acquired by the audited pharmacy, subject to validation by the supplier.

(C) Copies of supplier invoices in the possession of the audited pharmacy.

(2) Upon completion of an audit of a pharmacy, the carrier or pharmacy benefit manager shall do all of the following:

(a) Deliver a preliminary written audit report to the pharmacy not later than 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 appeals process established under subsection (1)(m).

(b) Allow the pharmacy at least 30 days after 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, recoup disputed money or overpayments or restore underpayments only after the final written audit report is delivered to the pharmacy under subdivision (c).

(3) Except as required by federal law, a carrier or pharmacy

benefit manager shall not conduct an extrapolation audit in calculating recoupments, restoration, or penalties for an audit under this section. For the purposes of this subsection, "extrapolation audit" means 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.

(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 money by the carrier or pharmacy benefit manager unless clerical error or record-keeping error surpasses the statistical threshold established by the Centers for Medicare and Medicaid Services or the carrier can provide proof of intent to commit fraud or the error results in actual financial harm to the carrier, pharmacy benefit manager, or a covered person or enrollee.

(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 statute 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 carrier 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 carrier pharmacy audits, the provision in the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302, controls.

Sec. 29. (1) A contract between a retail pharmacy and a pharmacy benefit manager or plan sponsor must not prohibit the retail pharmacy from offering either of the following as an ancillary service of the retail pharmacy:

(a) The delivery of a prescription drug by mail or common carrier to a patient or patient representative on request of the patient or patient representative if the request is made before the drug is delivered.

(b) The delivery of a prescription to a patient or patient representative by an employee or contractor of the retail pharmacy.

(2) Except as otherwise provided in a contract described in subsection (1), the retail pharmacy shall not charge a plan sponsor or pharmacy benefit manager for the delivery service described in subsection (1).

(3) If a retail pharmacy provides a delivery service described in subsection (1) to a patient, the retail pharmacy must disclose both of the following to the patient:

(a) Any fee charged to the patient for the delivery of a prescription drug.

(b) The plan sponsor or pharmacy benefit manager may not reimburse the patient for the fee described in subdivision (a).

(4) Except as otherwise provided in a contract between a mail-

order pharmacy or specialty pharmacy and a carrier, health plan, or pharmacy benefit manager, the carrier, health plan, or pharmacy benefit manager shall not require pharmacist or pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements to obtain reimbursement for a covered drug.

(5) A pharmacy benefit manager shall not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.

(6) A pharmacy benefit manager shall not reverse and resubmit the claim of a network pharmacy:

(a) Without prior and proper notification to the network pharmacy.

(b) Without just cause or attempt to first reconcile the claim with the pharmacy.

(c) More than 90 days after the claim was first affirmatively adjudicated.

(7) The termination of a pharmacy from a pharmacy benefit manager network must not release the retail pharmacy benefit manager from the obligation to make any payment due to the pharmacy for an affirmatively adjudicated claim unless payments are withheld because of an investigation relating to insurance fraud.

(8) A carrier, health plan, or pharmacy benefit manager shall not retaliate against a pharmacist or pharmacy based on the pharmacist's or pharmacy's exercise of any right or remedy under this act. Retaliation prohibited by this subsection includes any of the following:

(a) Terminating or refusing to renew a contract with the

pharmacist or pharmacy.

(b) Subjecting the pharmacist or pharmacy to increased audits.

(c) Failing to promptly pay the pharmacist or pharmacy any money owed by the pharmacy benefit manager to the pharmacist or pharmacy.

(9) This section does not prohibit the use of remote pharmacies, secure locker systems, or other types of pickup stations if such services are otherwise permitted by law.

(10) The provisions of this act may not be waived, voided, or nullified by contract.

(11) As used in this section:

(a) "Guardian" means a person with the powers and duties to make medical treatment decisions on behalf of a patient to the extent granted by court order under section 5314 of the estates and protected individuals code, 1998 PA 386, MCL 700.5314.

(b) "Patient advocate" means an individual presently authorized to make medical treatment decisions on behalf of a patient under sections 5506 to 5515 of the estates and protected individuals code, 1998 PA 386, MCL 700.5506 to 700.5515.

(c) "Patient representative" means a guardian or patient advocate.

Sec. 30. (1) The director shall enforce this act.

(2) The director may examine or audit the relevant 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) The director shall establish a retention schedule for all records, books, papers, and other data on file with the department related to the enforcement of this act.

(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 10 years have passed.

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

Sec. 35. This act does not apply with respect to a claim that is entirely preempted by federal law, including Medicare Part D or the employee retirement income security act of 1974, Public Law 93-406.

Enacting section 1. This act takes effect January 1, 2024.