HOUSE BILL No. 5772

January 27, 2010, Introduced by Reps. Calley, Liss, Kurtz, McMillin, Ball and Opsommer and referred to the Committee on Health Policy.

A bill to define and regulate certain persons managing pharmacy benefits for certain governmental entities; to provide for certain powers and duties for state departments and agencies; to provide for the certification of and imposition of regulatory and other requirements upon certain persons; and to provide for remedies and penalties.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "transparency in government pharmacy benefit manager act".

Sec. 3. As used in this act:

(a) "Board" means the Michigan board of pharmacy created in part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780.

HOUSE BILL No. 5772

(b) "Commissioner" means the commissioner of the office of financial and insurance regulation.

(c) "Covered entity" means a nonprofit hospital or medical service organization; insurer; health coverage plan or health maintenance organization; a health program administered by OFIR or the state in the capacity of provider of health coverage; or other group of persons that is a governmental entity and that provides health coverage to covered individuals who are employed or reside in the state and includes any person, corporation, business, company, association, health care group, network, or any governmental entity that provides prescription drugs or medical supplies, or both. Covered entity does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, long-term care, or other limited benefit health insurance policies and contracts.

(d) "Covered individual" means a dependent or other individual provided health coverage through a policy, contract, or plan by a covered entity.

(e) "Covered person" means a member, participant, enrollee, contract holder, or policyholder or beneficiary of a covered entity who is provided health coverage by the covered entity.

(f) "Governmental entity" means the state of Michigan, a school district, a state university, a county, a city, a village, and a township.

(g) "Health benefit plan" means a policy, certificate, contract, or a certificate or agreement issued by a covered entity

to provide, deliver, arrange for, pay for, or reimburse any of the cost of health care services, including prescription drug benefits.

(h) "Maintenance drug" means a drug prescribed by a practitioner who is licensed to prescribe drugs and used to treat a medical condition for a period greater than 30 days.

(i) "Multisource drug" means a drug that is stocked and is available from 3 or more suppliers.

(j) "OFIR" means the office of financial and insurance regulation.

(k) "Person" means an individual, sole proprietorship, partnership, corporation, association, organization, limited liability company, or other entity.

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

(m) "Pharmacist services" includes drug therapy and other patient care services provided by a licensed pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules promulgated by the board.

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

(o) "Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, including, but not limited to, construction and management of formularies, negotiation with and management of provider networks, determination of consumer

cost-sharing requirements, communication of benefit status to consumers, claims processing, and negotiated rebates and discounts.

(p) "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management for covered individuals who are employed by a governmental entity. PBM includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management regarding a covered entity.

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

(r) "Usual and customary price" means the price the pharmacist would have charged a cash paying patient for the same services on the same date inclusive of any discounts applicable, but does not include a patient where reimbursement rates are set by a contract.

Sec. 5. (1) A person shall not act or operate, or offer to act or operate, as a PBM in this state regarding prescription drugs for a covered entity whose covered individuals are employed by a governmental entity without a valid certificate of authority issued under this act. A person failing to hold such a certificate while acting as a PBM is subject to a civil fine as provided for in section 31.

(2) A person applying for a certificate of authority to act as a PBM shall file a completed application with the commissioner, which application shall include or attach the following:

(a) All basic organizational documents of the PBM.

(b) The names, addresses, official positions, and professional

qualifications of the individuals who are responsible for the conduct of the affairs of the PBM, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association, and any other person who exercises control or influence over the affairs of the PBM.

(c) Annual statements or reports for the 3 most recent years, or such other information as the commissioner may require in order to review the current financial condition of the applicant.

(d) If the applicant is not currently acting as a PBM, a statement of the amounts and sources of funds available for organization expenses, and the proposed arrangements for reimbursement and compensation of officers or other principals.

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

(f) A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies, or other administrative services to be provided.

(g) All incentive arrangements or programs such as rebates, discounts, disbursements, or any other similar financial program, or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company, that relates to prescription drug or device services, including, at a minimum, information on the formula or other method for calculation and amount of the incentive arrangements, rebates,

or other disbursements, the identity of the associated drug or device, and the dates and amounts of such disbursements.

(h) Such other information as the commissioner may require.

(i) A certificate of compliance from the board.

(3) The applicant shall make available for inspection by the commissioner copies of all contracts with insurers, pharmaceutical manufacturers, or other persons utilizing the services of the PBM for pharmacy benefit management services. Certain contracts are subject to approval as provided in section 9.

(4) The commissioner shall not issue a certificate of authority if he or she determines that the PBM or any of its principals or officers is not competent, trustworthy, financially responsible, or of good personal and business reputation or has had an insurance license or pharmacy license denied for cause by any state.

(5) A PBM shall maintain a fidelity bond equal to at least 10% of the amount of the funds handled or managed annually by the PBM. However, the commissioner may require an amount in excess of $500,000.00, but not more than 10% of the amount of the funds handled or managed annually by the PBM. A copy shall be provided to the commissioner.

Sec. 7. (1) Each PBM seeking to become certificated in the state must submit its plan of operation for review in a format to be furnished by the commissioner. The commissioner may promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, to set minimum standards regarding the format required, the filing fee for the certificate of compliance, the

requirements for recertification, and any other information that it may require.

(2) Upon review of the submission of the plan of operation, the commissioner shall determine if it complies with the rules adopted under subsection (1).

(3) If the filing under subsection (2) meets with the commissioner's approval, the commissioner shall issue a certificate of compliance to the PBM. Subsequent material changes in the plan of operation, as determined by the commissioner, must be filed with the commissioner.

Sec. 9. (1) Each PBM shall disclose to the commissioner any ownership interest or affiliation of any kind with any of the following:

(a) Any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the PBM provides services.

(b) Any parent companies, subsidiaries, other entities or businesses relative to the provision of pharmacy services, other prescription drug or device services, or a pharmaceutical manufacturer.

(2) A PBM must notify the commissioner in writing within 5 calendar days of any material change in its ownership.

(3) A PBM shall disclose the following agreements:

(a) Any agreement with a pharmaceutical or device manufacturer to favor the manufacturer's products or devices over a competitor's products or to place the manufacturer's drug or device on any of the PBM's lists or formularies, or to switch the drug or device

prescribed by the patient's health care provider with a drug or device agreed to by the PBM and the manufacturer.

(b) Any agreement with a pharmaceutical manufacturer to share manufacturer rebates and discounts with the PBM or to pay money or other economic benefits to the PBM.

(c) Any agreement or practice to bill the health benefit plan for prescription drugs or devices at a cost higher than that which the PBM pays the pharmacy.

(d) Any agreement to share revenue with a mail order or internet pharmacy company.

(e) Any agreement to sell prescription drug data, including data concerning the prescribing practices of the health care providers in the state.

(4) A PBM shall disclose all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug or device manufacturer or labeler, including, but not limited to, rebates, formulary management and drug-switch or substitution programs, education support, claims processing or pharmacy network fees that are charged from retail pharmacies, and data sales fees.

Sec. 11. (1) A PBM shall maintain, for the duration of the written agreement and for 2 years thereafter, books and records of all transactions between the PBM, insurers, covered persons, pharmacists, and pharmacies.

(2) The commissioner shall have access to books and records maintained by the PBM for the purposes of examination, audit, and inspection. The information contained in the books and records is

confidential. However, the commissioner may use the information in any proceeding instituted against the PBM or an insurer.

(3) The commissioner shall conduct periodic financial examinations of every PBM in this state to ensure an appropriate level of regulatory oversight. The PBM shall pay the cost of the examination, which shall be deposited in a special fund to provide all expenses for the regulation, supervision, and examination of all entities subject to regulation under this act.

Sec. 13. (1) Each PBM holding a certificate of authority shall file with the commissioner an annual statement on or before March 1 of each year. The statement shall be in such form and contain such matters as the commissioner prescribes and include the filing fee established by rule of the commissioner. The statement shall include the total number of persons subject to management by the PBM during the year, the number of persons terminated during the year, the number of persons covered at the end of the year, and the dollar value of claims processed.

(2) The statement filed under subsection (1) shall disclose all incentive arrangements or programs, including, at a minimum, information on the formula or other method for calculation and amount of the incentive arrangements, rebates, or other disbursements, the identity of the associated drug or device, and the dates and amounts of such disbursements. The incentive arrangements include, but are not limited to, rebates, discounts, disbursements, or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical

company, involving prescription drug or device services.

Sec. 15. (1) A person shall not act as a PBM for a person without a written agreement between that person and the PBM.

(2) A PBM shall not require a pharmacist or a pharmacy to participate in 1 contract in order to participate in another contract and shall not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network solely because the pharmacist or pharmacy declined to participate in another plan or network managed by the PBM.

(3) A PBM shall file a copy with the commissioner of all agreements with pharmacies for approval by the commissioner not less than 30 days before the execution of the agreement. The agreement is considered approved unless the commissioner disapproves it within the 30-day period.

(4) The written agreement between the covered entity and the PBM shall not provide that the pharmacist or pharmacy is responsible for the actions of the covered entity or the PBM. All agreements shall provide that, when the PBM receives payment for the services of the pharmacist or pharmacy, the PBM shall act as a fiduciary of the pharmacy or pharmacist providing the services. The PBM shall distribute the funds in accordance with the time frames provided in this act and rules promulgated under this act.

Sec. 17. (1) When the services of a PBM are utilized, the PBM shall provide a written notice approved by the covered entity to covered persons advising them of the identity of, and relationship between, the PBM, the covered entity, and the covered person.

(2) The notice in subsection (1) shall comply with all of the

following:

(a) Contain a statement advising the covered person that the PBM is regulated by the OFIR and has the right to file a complaint, appeal, or grievance with the commissioner concerning the PBM.

(b) Include the toll-free telephone number, mailing address, and electronic mail address of the OFIR.

(c) Be written in plain English, using terms that will be generally understood by the prudent layperson, and a copy must be provided to the OFIR and each pharmacist or pharmacy participating in the network.

(3) When a PBM requests a substitute prescription for a prescribed drug to a covered individual, the following provisions apply:

(a) The PBM may substitute a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug.

(b) With regard to substitutions in which the substitute drug costs more than the prescribed drug, the substitution must be made for medical reasons that benefit the covered individual. If a substitution is being made under this subdivision, the PBM, after disclosing to the covered individual the cost of both drugs and any benefit or payment directly or indirectly accruing to the PBM as a result of the substitution and any potential effects on a patient's health and safety including side effects, shall obtain the approval of the prescribing health professional or of that person's authorized representative.

(c) The PBM shall transfer in full to the covered entity any

benefit or payment received in any form by the PBM as a result of a prescription drug substitution under subdivision (a) or (b).

Sec. 19. (1) A PBM shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A PBM providing information under this section may designate that material as confidential. Information designated as confidential by a PBM and provided to a covered entity under this section shall not be disclosed by the covered entity to any person without the consent to the PBM, except that disclosure may be made when authorized by an order of a court of competent jurisdiction.

(2) A PBM shall disclose to the covered entity the following:

(a) All financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler, including, but not limited to, rebates, formulary management and drug-switch or substitution programs, educational support, claims processing, and pharmacy network fees that are charged from retail pharmacies and data sales fees.

(b) Whether there is a difference between the price paid to retail pharmacy and the amount billed to the covered entity for a prescription drug purchase.

(3) The covered entity may audit the PBM's books and records related to the rebates or other information provided in subsections (1) and (2).

(4) A PBM shall exercise good faith and fair dealing toward

the covered entity performing its duties.

Sec. 21. (1) A PBM shall not terminate or penalize a pharmacist or pharmacy for doing any of the following:

(a) Filing a complaint, grievance, or appeal as permitted under this act.

(b) Expressing disagreement with the PBM's decision to deny or limit benefits to a covered person.

(c) Assisting a covered person to seek reconsideration of the PBM's decision to deny or limit benefits.

(d) Discussing alternative medications.

(2) Prior to terminating a pharmacy or pharmacist from the network, the PBM shall provide the pharmacy or pharmacist a written explanation of the reason for the termination. The notice described in this subsection shall be provided at least 30 days before the termination date unless the termination is based on any of the following:

(a) The loss of the pharmacy's license to practice pharmacy.

(b) The cancellation of the pharmacy's professional liability insurance.

(c) Conviction of fraud as reported to the board.

(3) Termination of a contract between a PBM and a pharmacy or pharmacist, or termination of a pharmacy or pharmacist from a PBM's provider network, does not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services rendered.

Sec. 23. (1) PBMs shall use a current and nationally recognized benchmark to base the reimbursement paid to network

pharmacies for medications and products. The reimbursement shall be determined as follows:

(a) For brand or single source products, the average wholesale price as listed in first data bank (Hearst publications) or facts and comparisons (formerly medispan), correct and current on the date of service provided, for use as an index.

(b) For generic drug or multisource products, maximum allowable cost shall be established by referencing first data bank/facts and comparisons baseline price.

(2) If a multisource product has no first data bank/facts and comparisons baseline price, then it shall be treated as a single source branded drug for the purpose of determining reimbursement.

Sec. 25. (1) If a PBM processes claims via electronic review, then it shall electronically transmit payment within 7 calendar days of that claim's transmission to the pharmacist or pharmacy. Specific time limits for the PBM to pay the pharmacist for all other services rendered must be set forth in the agreement.

(2) Within 24 hours after a price increase notification by a manufacturer or supplier, the PBM shall adjust its payments to the pharmacist or pharmacy consistent with the price increase.

(3) Claims paid by the PBM shall not be retroactively denied or adjusted after 7 days from adjudication of those claims except as provided in subsection (4). In no case shall acknowledgment of eligibility be retroactively reversed.

(4) The PBM may retroactively deny or adjust under any of the following circumstances:

(a) The original claim was submitted fraudulently.

(b) The original claim payment was incorrect because the provider was already paid for services rendered.

(c) The services were not rendered by the pharmacist or pharmacy.

(5) The PBM may not require extrapolation audits as a condition of participating in the contract, network, or program.

(6) The PBM shall not recoup any money that it believes is due as a result of the audit by setoff until the pharmacist or pharmacy has the opportunity to review the PBM's findings and concurs with the results. If the parties cannot agree, then the audit shall be subject to review by the commission.

Sec. 27. (1) A PBM shall not intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of doing any of the following:

(a) Influencing the prescriber's choice of therapy.

(b) Influencing the patient's choice of pharmacist or pharmacy.

(c) Altering the prescription information, including, but not limited to, switching the prescribed drug without the express authorization of the prescriber.

(2) An agreement shall not mandate that a pharmacist or pharmacy change a covered person's prescription unless the prescribing physician and the covered person authorize the pharmacist to make the change.

(3) The covered entity and the PBM may not discriminate with respect to participation in the network or reimbursement as to any pharmacist or pharmacy that is acting within the scope of its

license.

(4) The PBM may not transfer a health benefit plan to another payment network unless it receives written authorization from the insurer.

(5) A PBM shall not discriminate when contracting with pharmacies on the basis of copayments or days of supply. A contract shall apply the same coinsurance, copayment, and deductible to covered drug prescriptions filled by any pharmacy, including a mail order pharmacy or pharmacist who participates in the network.

(6) A PBM shall not discriminate when advertising the names of pharmacies that are participating. Any list of participating pharmacies shall be complete and all-inclusive.

(7) A PBM shall not mandate on any pharmacist or pharmacy basic record keeping that is more stringent than that required by state or federal laws, rules, or regulations.

Sec. 29. (1) The commission shall promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, for formal investigation of complaints concerning the failure of a PBM to comply with this act.

(2) Any complaint shall be resolved and determined under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

Sec. 31. A person failing to hold a certificate of authority issued under this act while acting as a PBM is subject to a civil fine of not less than $5,000.00 or more than $10,000.00 for each violation.

Sec. 33. (1) All benefits payable under a pharmacy benefits

management plan shall be paid as soon as feasible but not less than 7 days after receipt of a clean claim when the claim is submitted electronically.

(2) Payments to the pharmacy or pharmacist for clean claims are considered to be overdue if not paid within 7 days. If any clean claim is not timely paid, the pharmacy benefits manager must pay the pharmacy or pharmacist interest at the rate of 10% per annum commencing the day after any claim payment or portion thereof was due until the claim is finally settled or adjudicated in full.

Sec. 35. Compensation to a PBM for any claims that the PBM adjusts or settles on behalf of an insurer is not contingent on claims experience. This section does not prohibit the compensation of a PBM based on total number of claims paid or processed.

Sec. 37. The commissioner may promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, to carry out the provisions of this act. The rules may include the definition of terms, use of prescribed forms, reporting requirements, prohibited practices, administrative fines, license sanctions, and enforcement procedures.

Sec. 39. This act takes effect October 1, 2011.