SUBSTITUTE FOR

SENATE BILL NO. 483

A bill to provide for a cost and affordability review of certain prescription drug products; to create the prescription drug pricing board and prescription drug affordability stakeholder council and to prescribe their powers and duties; to provide for the powers and duties of certain state governmental officers and entities; to establish upper payment limits for certain prescription drug products and provide remedies; and to provide for the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act may be cited as the "prescription drug cost and affordability review act".

Sec. 3. As used in this act:

(a) "Biologic" means a drug that is produced or distributed in

accordance with a biologics license application approved by the United States Food and Drug Administration.

(b) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 USC 262(k).

(c) "Board" means the prescription drug affordability board created in section 5.

(d) "Brand-name drug" means a drug other than an authorized generic that is produced or distributed in accordance with an original new drug application approved under 21 USC 355.

(e) "Consumer Price Index" means the United States Consumer Price Index for all urban consumers as defined and reported by the United States Department of Labor, Bureau of Labor Statistics.

(f) "Council" means the prescription drug affordability stakeholder council created in section 9.

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

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

(i) "Fund" means the prescription drug affordability fund created in section 17.

(j) "Generic drug" means any of the following:

(*i*) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355.

(*ii*) An authorized generic drug as that term is defined in 42 CFR 447.502.

(*iii*) A drug that entered the market before 1962 that was not originally marketed under a new drug application.

(k) "Health insurer" means any of the following:

(*i*) An insurer authorized under the insurance code of 1956,

1956 PA 218, MCL 500.100 to 500.8302, to deliver, issue for delivery, or renew in this state a health insurance policy.

(*ii*) A health maintenance organization as that term is defined in section 3501 of the insurance code of 1956, 1956 PA 218, MCL 500.3501.

(*l*) "Manufacturer" means an entity that meets any of the following:

(*i*) Owns the patent to a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name.

(*ii*) Is the labeled entity of a generic drug at the point of manufacture and the entity does 1 of the following:

(A) Sets or changes the wholesale acquisition cost of a brand-name drug that it manufactures or has leased the right to market.

(B) Sets or changes the wholesale acquisition cost of a generic drug that it manufactures.

(m) "Person" means an individual and includes a body politic and corporate.

(n) "Prescription drug product" means a brand-name drug, a generic drug, a biologic, or a biosimilar.

(o) "Prescription drug product purchaser" means an entity that purchases and takes ownership of a prescription drug product for resale or providing to patients.

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

(q) "Third-party payer" means a health insurer, a state department or agency administering a plan of medical assistance under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, a

person administering a self-funded plan, or a pharmacy benefit manager.

(r) "Wholesale acquisition cost" means that term as defined in 42 USC 1395w-3a(c)(6)(B).

(s) "340B Program entity" means an entity authorized to participate in the federal 340B Program under section 340B of the public health service act, 42 USC 256b.

Sec. 5. (1) The prescription drug affordability board is created as an autonomous entity within the department.

(2) The board consists of 5 members, appointed by the governor with the advice and consent of the senate. The members of the board must include individuals who have expertise in health care economics, health policy, health equity, and clinical medicine. The governor shall not appoint an individual to the board if the individual is employed by, a consultant to, or a board member of a manufacturer or a trade association for a manufacturer or otherwise has a personal or financial interest that has the potential to bias or has the appearance of biasing the individual's decision in matters related to the board or in conducting the board's activities. The governor shall not appoint an individual to the board if the individual is a lobbyist who is registered in this state. An individual who is appointed to the board shall not register as a lobbyist in this state for a period of 5 years after the individual's term on the board expires.

(3) The governor shall appoint 2 of the first members to 1-year terms and 3 of the first members to 2-year terms. After the first appointments, the term of a member of the board is 4 years or until a successor is appointed, whichever is later.

(4) If a vacancy occurs on the board, the governor shall

appoint an individual to fill the vacancy for the balance of the term in the same manner as the original appointment.

(5) The governor may remove a member of the board for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

(6) The governor shall call the first meeting of the board. At the first meeting, the board shall elect from among its members a chairperson and other officers as it considers necessary or appropriate. After the first meeting, the board shall meet at least quarterly, or more frequently at the call of the chairperson or if requested by 3 or more members.

(7) A majority of the members of the board constitute a quorum for transacting business. Except as otherwise provided in this subsection, a majority of the members present and serving are required for official action of the board. If 1 or more members of the board recuse themselves, 2/3 of the members present and serving are required for official action of the board.

(8) The board shall conduct its business in compliance with the open meetings act, 1976 PA 267, MCL 15.261 to 15.275.

(9) Except as otherwise provided in this subsection, a writing that is prepared, owned, used, in the possession of, or retained by the board in performing an official function is subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246. A writing containing a trade secret or proprietary information is confidential and is not subject to disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(10) The salaries and other expenses incurred by members of the board are subject to an annual appropriation as provided by law.

(11) As used in this section, "health equity" means attaining the highest level of health for all individuals, in which an individual has a fair and just opportunity to attain the individual's optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factor that affects access to health care and health outcomes.

Sec. 7. A member of the board is subject to 1968 PA 317, MCL 15.321 to 15.330, and 1973 PA 196, MCL 15.341 to 15.348.

Sec. 9. (1) The prescription drug affordability stakeholder council is created within the department.

(2) Subject to subsection (3), the council consists of the following 21 members:

(a) Seven members appointed by the governor as follows:

(*i*) One individual representing manufacturers of brand-name drugs.

(*ii*) One individual representing manufacturers of generic drugs.

(*iii*) One individual representing employers.

(*iv*) One individual representing pharmacy benefit managers.

(*v*) One individual representing pharmacists.

(*vi*) One individual representing a mutual insurance company. The mutual insurance company under this subparagraph must not be an entity that, directly or indirectly, through 1 or more intermediaries, controls, is controlled by, or is under common control with the managed care organization under subdivision (c)(*iv*).

(*vii*) One member of the public.

(b) Seven members appointed by the governor from a list of

nominees submitted by the speaker of the house of representatives. The list of nominees must include individuals who represent the following:

(*i*) A statewide organization that advocates for senior citizens.

(*ii*) A statewide organization that advocates for health care.

(*iii*) A statewide organization that advocates for diversity within communities.

(*iv*) A labor union.

(*v*) Researchers who specialize in prescription drug products.

(*vi*) The public.

(c) Seven members appointed by the governor from a list of nominees submitted by the senate majority leader. The list of nominees must include individuals who represent each of the following:

(*i*) Physicians.

(*ii*) Nurses.

(*iii*) Hospitals.

(*iv*) Managed care organizations. The managed care organization under this subparagraph must not be an entity that, directly or indirectly, through 1 or more intermediaries, controls, is controlled by, or is under common control with the mutual insurance company under subdivision (a)(*vi*).

(*v*) The department of management and budget.

(*vi*) Clinical researchers.

(*vii*) The public.

(3) The governor shall ensure that the members appointed to the council have knowledge in 1 or more of the following areas:

(a) The pharmaceutical business model.

(b) Supply chain business models.

(c) The practice of medicine or clinical training.

(d) Consumer or patient perspectives.

(e) Health care costs trends.

(f) Clinical and health services research.

(4) The governor shall appoint 7 of the first members to 1-year terms, 7 of the first members to 2-year terms, and 7 of the first members to 3-year terms. After the first appointments, the term of a member of the council is 3 years or until a successor is appointed, whichever is later.

(5) If a vacancy occurs on the council, the governor shall appoint an individual to fill the vacancy for the balance of the term in the same manner as the original appointment.

(6) The governor may remove a member of the council for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

(7) At the first meeting of the council, the council shall elect from among its members a chairperson and other officers as it considers necessary or appropriate. After the first meeting, the council shall meet at least quarterly, or more frequently at the call of the chairperson or if requested by 7 or more members.

(8) A majority of the members of the council constitute a quorum for transacting business. A majority of the members present and serving are required for official action of the council.

(9) The council shall conduct its business in compliance with the open meetings act, 1976 PA 267, MCL 15.261 to 15.275.

(10) Except as otherwise provided in this subsection, a writing that is prepared, owned, used, in the possession of, or

retained by the council in performing an official function is subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246. A writing containing a trade secret or proprietary information is confidential and is not subject to disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(11) A member of the council is not entitled to compensation for service on the council, but may be reimbursed for actual and necessary expenses incurred in serving.

(12) The council shall assist the board in making decisions required under this act.

Sec. 11. (1) Beginning 18 months after the effective date of this act, subject to subsection (2), the board, in consultation with the council, shall select 1 or more prescription drug products based on any of the following criteria:

(a) The prescription drug product is a brand-name drug or a biologic that, as adjusted annually for inflation in accordance with the Consumer Price Index, has a wholesale acquisition cost of $60,000.00 or more per year or course of treatment or has a wholesale acquisition cost increase of $3,000.00 or more in any 12-month period.

(b) The prescription drug product is a biosimilar that has a wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic.

(c) The prescription drug product is a generic drug that, as adjusted annually for inflation in accordance with the Consumer Price Index, has a wholesale acquisition cost that meets both of the following requirements:

(*i*) Is $100.00 or more for any of the following:

(A) A 30-day supply that lasts a patient for a period of 30

consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration.

(B) A supply that lasts a patient for fewer than 30 days based on the recommended dosage approved for labeling by the United States Food and Drug Administration.

(C) One unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage.

(*ii*) Increased by 200% or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average wholesale acquisition cost reported over the immediately preceding 12 months.

(d) The prescription drug product is a prescription drug product that may create affordability challenges for health care systems in this state and patients, including, but not limited to, a prescription drug product needed to address a public health emergency.

(2) In selecting 1 or more prescription drug products under subsection (1), the board is not required to identify each prescription drug product that meets the criteria described in subsection (1).

(3) The board shall determine whether to conduct a cost and affordability review for each prescription drug product that is selected under subsection (1). In making a determination under this subsection, the board shall consider input from the council and the average patient cost share for each prescription drug product.

(4) If the board conducts a cost and affordability review of a prescription drug product, the board may consider when conducting the review any document or research related to the manufacturer's

selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in this state, market competition, projected revenue, and, subject to subsection (7), the estimated cost effectiveness of the prescription drug product. In its review, the board shall determine whether the use of a prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice for the prescription drug product has led to or will lead to affordability challenges to health care systems in this state or high out-of-pocket costs for patients in this state. In making its determination under this subsection, the board shall consider any information that a manufacturer chooses to provide to the board and all of the following factors, to the extent practicable:

(a) The wholesale acquisition cost for the prescription drug product sold in this state.

(b) The average monetary price concession, discount, or rebate that the manufacturer provides to health insurers and pharmacy benefit managers in this state or is expected to provide to health insurers and pharmacy benefit managers in this state, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review.

(c) The price at which therapeutic alternatives for the prescription drug product have been sold in this state.

(d) The average monetary concession, discount, or rebate that another manufacturer provides or is expected to provide to health insurers and pharmacy benefit managers in this state for therapeutic alternatives.

(e) The cost to health insurers based on patient access

consistent with United States Food and Drug Administration labeled indications or recognized standard medical practice.

(f) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design.

(g) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer.

(h) The relative financial impact to health, medical, or social service costs as can be quantified and compared to baseline effects of existing therapeutic alternatives.

(i) The average patient co-pay or other cost-sharing for the prescription drug product in this state.

(j) Any other factor established by the board by rule.

(5) If the board determines that spending on a prescription drug product reviewed under this section has led to or will lead to affordability challenges to health care systems in this state or high out-of-pocket costs for patients in this state, the board may, subject to subsection (6), establish by rule an upper payment limit for the prescription drug product. In establishing an upper payment limit under this subsection, the board shall consider all of the following:

(a) Relevant administrative costs related to supplying or stocking the prescription drug product.

(b) The impact of an upper payment limit for the prescription drug product on 340B Program entities.

(6) An upper payment limit established under this section must not include professional dispensing fees.

(7) If the board considers the estimated cost effectiveness of a prescription drug product under this section, the board shall comply with both of the following:

(a) The board shall not use a cost-per-quality adjusted life year, or a similar measure, to identify a subpopulation for which a prescription drug product would be less cost effective due to severity of illness, age, or preexisting disability.

(b) If the board uses a cost-effectiveness analysis for a prescription drug product that extends an individual's life, the board must use a cost-effectiveness analysis that weighs the value of all additional lifetime gained equally for any individual, no matter the severity of illness, age, or preexisting disability.

(8) An upper payment limit established under this section takes effect on the date prescribed by the board by rule but no sooner than 6 months after the date the upper payment limit is established.

Sec. 12. (1) Except as otherwise provided in subsection (2), if the board establishes an upper payment limit under section 11 for a prescription drug product intended for use by individuals in this state, beginning on the effective date of the upper payment limit, a prescription drug product purchaser or third-party payer shall not purchase, bill, or reimburse for the prescription drug product in an amount that exceeds the upper payment limit, regardless of whether the prescription drug product is dispensed or distributed in person, by mail, or by other means.

(2) A prescription drug product purchaser or third-party payer shall not reimburse an independent pharmacy licensed under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, for a prescription drug product in an amount less than an upper payment limit established under section 11 for the prescription drug product.

(3) The attorney general may investigate a violation of this

section and may commence a civil action against a person for appropriate relief, including, but not limited to, injunctive relief, for a violation of this section.

(4) This section does not prohibit any other sanction against a prescription drug product purchaser or third-party payer as provided by law.

Sec. 13. A person aggrieved by a decision of the board under this act may request an appeal within 30 days. A hearing and appeal is subject to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

Sec. 17. (1) The prescription drug affordability fund is created within the state treasury.

(2) The state treasurer shall deposit money and other assets from any source into the fund. The state treasurer shall direct the investment of money in the fund and credit interest and earnings from fund investments to the fund.

(3) Money in the fund at the close of the fiscal year must remain in the fund and must not lapse to the general fund.

(4) The department is the administrator of the fund for audits of the fund.

(5) The department shall expend money from the fund, on appropriation, only to fund the board and for costs expended by the department to implement this act.

Sec. 19. On or before December 31 of each year, the board shall submit a written report to the legislature that includes all of the following information:

(a) Price trends for prescription drug products.

(b) The number of prescription drug products that were subject to board review, including the results of the review and the number

and disposition of appeals of board decisions.

(c) Any recommendations that the board may have on further legislation to make prescription drug products more affordable in this state.

Sec. 20. The board shall conduct a 1-time study on all of the following and report its findings to the legislature:

(a) The prices of generic drugs on a year-to-year basis.

(b) The degree to which the prices of generic drugs affect yearly insurance premium charges.

(c) Annual changes in insurance cost-sharing for generic drugs.

(d) The potential for and history of drug shortages.

(e) The degree to which the prices of generic drugs affect yearly Medicaid spending in this state.

(f) The impact of an upper payment limit on 340B Program entities.

(g) Any other issue that the board considers relevant.

Sec. 21. The board may promulgate rules to implement this act and enter into contracts with third parties to assist the board in carrying out its functions under this act.

Sec. 23. The implementation of this act is subject to appropriation.