

**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:

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

3 Sec. 3. As used in this act:

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



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

3 (b) "Biosimilar" means a drug that is produced or distributed
4 in accordance with a biologics license application approved under
5 42 USC 262(k).

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

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

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

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

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

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

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

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

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

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

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

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

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



1 1956 PA 218, MCL 500.100 to 500.8302, to deliver, issue for
2 delivery, or renew in this state a health insurance policy.

3 (ii) A health maintenance organization as that term is defined
4 in section 3501 of the insurance code of 1956, 1956 PA 218, MCL
5 500.3501.

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

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

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

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

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

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

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

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

24 (p) "Rule" means a rule promulgated pursuant to the
25 administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to
26 24.328.

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



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

3 (r) "Wholesale acquisition cost" means that term as defined in
4 42 USC 1395w-3a(c) (6) (B).

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

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

10 (2) The board consists of 5 members, appointed by the governor
11 with the advice and consent of the senate. The members of the board
12 must include individuals who have expertise in health care
13 economics, health policy, health equity, and clinical medicine. The
14 governor shall not appoint an individual to the board if the
15 individual is employed by, a consultant to, or a board member of a
16 manufacturer or a trade association for a manufacturer or otherwise
17 has a personal or financial interest that has the potential to bias
18 or has the appearance of biasing the individual's decision in
19 matters related to the board or in conducting the board's
20 activities.

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

25 (4) If a vacancy occurs on the board, the governor shall
26 appoint an individual to fill the vacancy for the balance of the
27 term in the same manner as the original appointment.

28 (5) The governor may remove a member of the board for
29 incompetence, dereliction of duty, malfeasance, misfeasance, or



1 nonfeasance in office, or any other good cause.

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

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

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

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

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

26 (11) As used in this section, "health equity" means attaining
27 the highest level of health for all individuals, in which an
28 individual has a fair and just opportunity to attain the
29 individual's optimal health regardless of race, ethnicity,



1 disability, sexual orientation, gender identity, socioeconomic
 2 status, geography, preferred language, or other factor that affects
 3 access to health care and health outcomes.

4 Sec. 7. A member of the board is subject to 1968 PA 317, MCL
 5 15.321 to 15.330, and 1973 PA 196, MCL 15.341 to 15.348.

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

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

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

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

13 (ii) One individual representing manufacturers of generic
 14 drugs.

15 (iii) One individual representing employers.

16 (iv) One individual representing pharmacy benefit managers.

17 (v) One individual representing pharmacists.

18 (vi) One individual representing a mutual insurance company.

19 The mutual insurance company under this subparagraph must not be an
 20 entity that, directly or indirectly, through 1 or more
 21 intermediaries, controls, is controlled by, or is under common
 22 control with the managed care organization under subdivision

23 (c) (iv) .

24 (vii) One member of the public.

25 (b) Seven members appointed by the governor from a list of
 26 nominees submitted by the speaker of the house of representatives.

27 The list of nominees must include individuals who represent the
 28 following:

29 (i) A statewide organization that advocates for senior



1 citizens.

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

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

5 (iv) A labor union.

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

7 (vi) The public.

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

12 (i) Physicians.

13 (ii) Nurses.

14 (iii) Hospitals.

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

20 (v) The department of management and budget.

21 (vi) Clinical researchers.

22 (vii) The public.

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

25 (a) The pharmaceutical business model.

26 (b) Supply chain business models.

27 (c) The practice of medicine or clinical training.

28 (d) Consumer or patient perspectives.



1 (e) Health care costs trends.

2 (f) Clinical and health services research.

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

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

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

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

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

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

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



1 the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

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

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

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

11 (a) The prescription drug product is a brand-name drug or a
12 biologic that, as adjusted annually for inflation in accordance
13 with the Consumer Price Index, has a wholesale acquisition cost of
14 \$60,000.00 or more per year or course of treatment or has a
15 wholesale acquisition cost increase of \$3,000.00 or more in any 12-
16 month period.

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

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

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

25 (A) A 30-day supply that lasts a patient for a period of 30
26 consecutive days based on the recommended dosage approved for
27 labeling by the United States Food and Drug Administration.

28 (B) A supply that lasts a patient for fewer than 30 days based
29 on the recommended dosage approved for labeling by the United



1 States Food and Drug Administration.

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

5 (ii) Increased by 200% or more during the immediately preceding
6 12-month period, as determined by the difference between the
7 resulting wholesale acquisition cost and the average wholesale
8 acquisition cost reported over the immediately preceding 12 months.

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

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

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

23 (4) If the board conducts a cost and affordability review of a
24 prescription drug product, the board may consider when conducting
25 the review any document or research related to the manufacturer's
26 selection of the introductory price or price increase of the
27 prescription drug product, including life cycle management, net
28 average price in this state, market competition, projected revenue,
29 and, subject to subsection (7), the estimated cost effectiveness of



1 the prescription drug product. In its review, the board shall
2 determine whether the use of a prescription drug product that is
3 fully consistent with the labeling approved by the United States
4 Food and Drug Administration or standard medical practice for the
5 prescription drug product has led to or will lead to affordability
6 challenges to health care systems in this state or high out-of-
7 pocket costs for patients in this state. In making its
8 determination under this subsection, the board shall consider any
9 information that a manufacturer chooses to provide to the board and
10 all of the following factors, to the extent practicable:

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

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

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

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

25 (e) The cost to health insurers based on patient access
26 consistent with United States Food and Drug Administration labeled
27 indications or recognized standard medical practice.

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



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

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

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

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

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

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

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

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

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

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



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

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

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

19 (2) A prescription drug product purchaser or third-party payer
 20 shall not reimburse an independent pharmacy licensed under article
 21 15 of the public health code, 1978 PA 368, MCL 333.16101 to
 22 333.18838, for a prescription drug product in an amount less than
 23 an upper payment limit established under section 11 for the
 24 prescription drug product.

25 (3) The attorney general may investigate a violation of this
 26 section and may commence a civil action against a person for
 27 appropriate relief, including, but not limited to, injunctive
 28 relief, for a violation of this section.

29 (4) This section does not prohibit any other sanction against



1 a prescription drug product purchaser or third-party payer as
2 provided by law.

3 Sec. 13. A person aggrieved by a decision of the board under
4 this act may request an appeal within 30 days. A hearing and appeal
5 is subject to the administrative procedures act of 1969, 1969 PA
6 306, MCL 24.201 to 24.328.

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

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

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

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

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

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

23 (a) Price trends for prescription drug products.

24 (b) The number of prescription drug products that were subject
25 to board review, including the results of the review and the number
26 and disposition of appeals of board decisions.

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



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

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

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

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

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

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

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

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

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

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

