

SENATE BILL NO. 889

February 24, 2022, Introduced by Senators BRINKS, MCMORROW, POLEHANKI, BAYER, GEISS, CHANG, BULLOCK, WOJNO, ANANICH, MOSS and IRWIN and referred to the Committee on Health Policy and Human Services.

An act 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
5 accordance with a biologics license application approved under 42
6 CFR 447.502.

7 (b) "Biosimilar" means a drug that is produced or distributed
8 in accordance with a biologics license application approved under
9 42 USC 262(k).

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

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

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

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

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

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

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

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

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

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

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

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

4 (i) An insurer authorized under the insurance code of 1956,
5 1956 PA 218, MCL 500.100 to 500.8302, to deliver, issue for
6 delivery, or renew in this state a health insurance policy.

7 (ii) A health maintenance organization as that term is defined
8 in section 3501 of the insurance code of 1956, 1956 PA 218, MCL
9 500.3501.

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

12 (m) "Prescription drug product" means a brand name drug, a
13 generic drug, a biologic, or a biosimilar.

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

17 (o) "Third-party payer" means a health insurer, a state
18 department or agency administering a plan of medical assistance
19 under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, a
20 person administering a self-funded plan, or a pharmacy benefit
21 manager.

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

24 (2) The board consists of 5 members, appointed by the governor
25 with the advice and consent of the senate. The members of the board
26 must include individuals who have expertise in health care
27 economics and clinical medicine. The governor shall not appoint an
28 individual to the board if the individual is employed by, a
29 consultant to, or a board member of a manufacturer or a trade

1 association for a manufacturer or otherwise has a personal or
2 financial interest that has the potential to bias or has the
3 appearance of biasing the individual's decision in matters related
4 to the board or in conducting the board's activities.

5 (3) The governor shall appoint the first members of the board
6 within 90 days after the effective date of this act.

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

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

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

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

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

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

3 (10) Except as otherwise provided in this subsection, a
4 writing that is prepared, owned, used, in the possession of, or
5 retained by the board in performing an official function is subject
6 to the freedom of information act, 1976 PA 442, MCL 15.231 to
7 15.246. A writing containing a trade secret or proprietary
8 information is confidential and is not subject to disclosure under
9 the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

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

13 Sec. 7. A member of the board is subject to 1968 PA 317, MCL
14 15.321 to 15.330, and 1973 PA 196, MCL 15.341 to 15.348.

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

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

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

20 (i) One individual representing manufacturers of brand name
21 drugs.

22 (ii) One individual representing manufacturers of generic
23 drugs.

24 (iii) One individual representing employers.

25 (iv) One individual representing pharmacy benefit managers.

26 (v) One individual representing pharmacists.

27 (vi) A pharmacologist.

28 (vii) A member of the public.

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

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

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

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

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

9 (iv) A labor union.

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

11 (vi) The public.

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

16 (i) Physicians.

17 (ii) Nurses.

18 (iii) Hospitals.

19 (iv) Health insurers.

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 the first members of the
4 council within 90 days after the effective date of this act.

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

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

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

16 (8) The first meeting of the council must occur within 6 weeks
17 after the final member is appointed to the council. At the first
18 meeting, the council shall elect from among its members a
19 chairperson and other officers as it considers necessary or
20 appropriate. After the first meeting, the council shall meet at
21 least quarterly, or more frequently at the call of the chairperson
22 or if requested by 7 or more members.

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

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

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

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

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

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

11 Sec. 11. (1) The board shall identify any prescription drug
12 product that meets any of the following requirements:

13 (a) Is a brand name drug or a biologic that, as adjusted
14 annually for inflation in accordance with the Consumer Price Index,
15 has a launch wholesale acquisition cost of \$30,000.00 or more per
16 year or course of treatment or has a wholesale acquisition cost
17 increase of \$3,000.00 or more in any 12-month period.

18 (b) Is a biosimilar that has a launch wholesale acquisition
19 cost that is not at least 15% lower than the referenced brand
20 biologic at the time the biosimilar is launched.

21 (c) Is a generic drug that, as adjusted annually for inflation
22 in accordance with the Consumer Price Index, has a wholesale
23 acquisition cost that meets both of 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) Is a prescription drug product that may create
10 affordability challenges for health care systems in this state and
11 patients, including, but not limited to, a prescription drug
12 product needed to address a public health emergency.

13 (2) The board shall determine whether to conduct a cost and
14 affordability review for each prescription drug product that is
15 identified under subsection (1). In making a determination under
16 this subsection, the board shall consider input from the council
17 and the average patient cost share for each prescription drug
18 product.

19 (3) If the board determines to conduct a cost and
20 affordability review of a prescription drug product under
21 subsection (2), the board may consider when conducting the review
22 any document or research related to the manufacturer's selection of
23 the introductory price or price increase of the prescription drug
24 product, including life cycle management, net average price in this
25 state, market competition, projected revenue, and, subject to
26 subsection (6), the estimated cost effectiveness of the
27 prescription drug product. In its review, the board shall determine
28 whether the use of a prescription drug product that is fully
29 consistent with the labeling approved by the United States Food and

1 Drug Administration or standard medical practice for the
2 prescription drug product has led to or will lead to affordability
3 challenges to health care systems in this state or high out-of-
4 pocket costs for patients in this state. In making its
5 determination under this subsection, the board shall consider any
6 information that a manufacturer chooses to provide to the board and
7 all of the following factors, to the extent practicable:

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

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

15 (c) The total amount of the price concession, discount, or
16 rebate the manufacturer provides to each pharmacy benefit manager
17 operating in this state for the prescription drug product,
18 expressed as a percent of the wholesale acquisition cost.

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

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

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

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

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

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

9 (4) 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 (5), establish an upper payment limit for the
14 prescription drug product. In establishing an upper payment limit
15 under this subsection, the following apply:

16 (a) The board shall consider all of the following:

17 (i) The administrative costs of drug suppliers.

18 (ii) The cost of pharmacy stocking.

19 (iii) Other relevant administrative costs related to supplying,
20 administering, or dispensing the prescription drug product.

21 (b) The board may consider international reference rates.

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

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

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

1 severity of illness, age, or preexisting disability.

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

7 (7) An upper payment limit established under this section
8 takes effect on the date prescribed by the board but no sooner than
9 6 months after the date the upper payment limit is 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 commence a civil action against a
26 person for appropriate relief, including, but not limited to,
27 injunctive relief, for a violation of this section.

28 (4) This section does not prohibit any other sanction against
29 a prescription drug product purchaser or third-party payer as

1 provided by law.

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

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

8 (2) The state treasurer shall deposit money received under
9 section 16315(14) of the public health code, 1978 PA 368, MCL
10 333.16315, 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. (1) 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 (2) The board shall conduct a study on all of the following
2 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 generic drug prices affect yearly
5 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 generic drug prices affect yearly
10 Medicaid spending in this state.

11 (f) The impact of an upper payment limit on 340B Program
12 entities. As used in this subdivision, "340B Program entities"
13 means entities authorized to participate in the federal 340B
14 Program under section 340B of the public health service act, 42 USC
15 256b.

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

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

20 Sec. 23. This act takes effect 180 days after the date it is
21 enacted into law.

22 Enacting section 1. This act does not take effect unless
23 Senate Bill No. 890 of the 101st Legislature is enacted into law.