
THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 579 Session of
2021

INTRODUCED BY LAUGHLIN, STREET, KEARNEY, TARTAGLIONE, COLLETT,
PITTMAN, BAROLOTTA, HAYWOOD AND KANE, APRIL 20, 2021

REFERRED TO BANKING AND INSURANCE, APRIL 20, 2021

AN ACT

1 Providing for pharmaceutical transparency; establishing the
2 Pharmaceutical Transparency Review Board and providing for
3 its powers and duties; and establishing the Pharmaceutical
4 Transparency Review Fund.

5 The General Assembly of the Commonwealth of Pennsylvania
6 hereby enacts as follows:

7 Section 1. Short title.

8 This act shall be known and may be cited as the
9 Pharmaceutical Transparency Act.

10 Section 2. Definitions.

11 The following words and phrases when used in this act shall
12 have the meanings given to them in this section unless the
13 context clearly indicates otherwise:

14 "Board." The Pharmaceutical Transparency Review Board
15 established in section 3.

16 "Fund." The Pharmaceutical Transparency Review Fund
17 established in section 8.

18 "Manufacturer." An entity that:

19 (1) does the following:

1 (i) engages in the manufacture of a prescription
2 drug product; or
3 (ii) enters into a lease with another manufacturer
4 to market and distribute a prescription drug product
5 under the entity's own name; and
6 (2) sets or changes the wholesale acquisition cost of
7 the prescription drug product that the entity manufactures or
8 markets.

9 "Prescription drug product." Any of the following:

10 (1) A brand name drug licensed under a new drug
11 application.

12 (2) A generic drug licensed under an abbreviated new
13 drug application.

14 (3) A biologic licensed under a biologic license
15 application.

16 Section 3. Pharmaceutical Transparency Review Board.

17 (a) Establishment.--The Pharmaceutical Transparency Review
18 Board is established as an independent board. The board shall be
19 an instrumentality of the Commonwealth and a body corporate and
20 politic.

21 (b) Purpose.--The purpose of the board is to review high-
22 cost prescription drug products and develop recommendations for
23 addressing affordability burdens faced by residents, State and
24 local government agencies, commercial health plans, health care
25 providers, employers, pharmacies licensed in this Commonwealth
26 and other stakeholders.

27 (c) Composition.--The following shall apply:

28 (1) The board shall be composed of the following
29 individuals, who shall have expertise in health care
30 economics or clinical medicine:

1 (i) One member appointed by the Governor who shall
2 act as chair.

3 (ii) One member appointed by the President pro
4 tempore of the Senate.

5 (iii) One member appointed by the Majority Leader of
6 the Senate.

7 (iv) One member appointed by the Minority Leader of
8 the Senate.

9 (v) One member appointed by the Speaker of the House
10 of Representatives.

11 (vi) One member appointed by the Majority Leader of
12 the House of Representatives.

13 (vii) One member appointed by the Minority Leader of
14 the House of Representatives.

15 (2) A member may not be an employee of, a board member
16 of or a consultant to a manufacturer or trade association for
17 manufacturers.

18 (3) In appointing members to the board, an appointing
19 authority shall consider and disclose a conflict of interest,
20 including whether the individual has an association,
21 including a financial or personal association, that has the
22 potential to bias or has the appearance of biasing an
23 individual's decision in matters related to the board or the
24 conduct of the board's activities.

25 (d) Term of office.--The following shall apply:

26 (1) Except as set forth in paragraph (2), the term of a
27 member of the board is five years.

28 (2) The terms of the initial members of the board are as
29 follows:

30 (i) Members appointed under subsection (c) (1) (iii)

1 and (iv) shall serve initial terms of three years.

2 (ii) Members appointed under subsection (c) (1) (vi)
3 and (vii) shall serve initial terms of four years.

4 (iii) Members appointed under subsection (c) (1) (i),
5 (ii) and (v) shall serve initial terms of five years.

6 (e) Board staff.--The chair shall appoint an executive
7 director, general counsel and other staff for the board to the
8 extent funds are available to the board for this purpose.

9 (f) Compensation.--A member of the board:

10 (1) May receive compensation as a member of the board in
11 conformity with the rules of the Executive Board.

12 (2) Is entitled to reimbursement for expenses in
13 accordance with Commonwealth regulations.

14 (g) Quorum.--A majority of the members of the board shall
15 constitute a quorum for the purposes of conducting the business
16 of the board.

17 (h) Meetings.--The following shall apply:

18 (1) The board shall meet for the following purposes:

19 (i) Subject to subparagraphs (ii) and (iv), the
20 board shall meet in open session at least once each
21 quarter to review prescription drug product information.

22 (ii) The following actions of the board shall be
23 made in open session:

24 (A) Deliberations on whether to subject a
25 prescription drug product to a review under
26 subsection (b).

27 (B) Decisions by the board, including agreeing
28 to reports created by the board under section 9.

29 (iii) The chair may cancel or postpone a meeting if
30 the board has no prescription drug products before it to

1 review.

2 (iv) The board may meet in closed session to discuss
3 proprietary data and information.

4 (2) The board shall provide public notice of each board
5 meeting at least two weeks prior to the meeting.

6 (3) Materials for each board meeting shall be made
7 available to the public at least one week prior to the
8 meeting.

9 (4) The board shall provide an opportunity for public
10 comment at each open meeting of the board and shall provide
11 the public with the opportunity to provide written comments
12 to the board.

13 (5) The board may allow expert testimony at board
14 meetings, including when the board meets in closed session.

15 Section 4. Conflict of interest.

16 (a) Recusal.--Board members shall recuse themselves from
17 decisions related to a prescription drug product where a
18 conflict of interest exists. A conflict of interest exists if
19 the member, or an immediate family member of the member, has
20 received or could receive any of the following:

21 (1) A direct financial benefit of any amount deriving
22 from the result or finding of a study or determination by or
23 for the board.

24 (2) A financial benefit from a person that owns,
25 manufactures or provides prescription drug products, services
26 or items to be studied by the board that, in the aggregate,
27 exceeds \$5,000 per year.

28 (b) Duty to disclose.--A conflict of interest shall be
29 disclosed:

30 (1) by the board when hiring board staff;

1 (2) by the appointing authority when appointing members
2 to the board; and

3 (3) by the board when a member of the board is recused
4 from a final decision resulting from a review of a
5 prescription drug product.

6 (c) Time for disclosure.--A conflict of interest shall be
7 disclosed:

8 (1) in advance of the first open meeting after the
9 conflict is identified; or

10 (2) within five days after the conflict is identified.

11 (d) Public disclosure.--The following shall apply:

12 (1) A conflict of interest disclosed under subsection

13 (a) shall be posted on the publicly accessible Internet
14 website of the board unless the chair recuses the member from
15 a final decision resulting from a review of a prescription
16 drug product.

17 (2) A posting under paragraph (1) shall include the
18 type, nature and magnitude of the interests of the member
19 involved.

20 (e) Prohibition.--Members of the board, board staff and
21 third-party contractors of the board may not accept a gift or
22 donation of services or property that indicates a potential
23 conflict of interest or has the appearance of biasing the work
24 of the board.

25 (f) Definition.--As used in this section, the term
26 "financial benefit" includes honoraria, fees, stock, the value
27 of the member's or immediate family member's stock holdings and
28 any direct financial benefit deriving from the findings of a
29 review conducted under this act.

30 Section 5. Powers and duties of board.

1 (a) General.--The board shall assess and issue a report as
2 provided under section 9(a) on how to make prescription drugs
3 affordable for residents of this Commonwealth.

4 (b) Pricing information.--To the extent practicable, the
5 board may access pricing information for prescription drug
6 products by:

7 (1) Entering into a memorandum of understanding with
8 another state to which manufacturers already report pricing
9 information.

10 (2) Accessing other available pricing information.

11 (c) Independent contractors.--The following shall apply:

12 (1) The board may enter into a contract with a
13 qualified, independent third party for any service necessary
14 to carry out the powers and duties of the board.

15 (2) Unless permission is granted by the board, a third
16 party hired by the board may not release, publish or
17 otherwise use any information to which the third party has
18 access under the third party's contract.

19 (d) Penalty.--The board may assess a fee of \$20,000 per day
20 per drug on a manufacturer that fails to comply with the
21 provisions of this act.

22 Section 6. Board assessment of prescription drug affordability.

23 (a) General rule.--After receiving information about
24 prescription drug products reported under section 7, the board
25 shall analyze the reported data and any other relevant data in
26 order to publish reports on the prescription drug products
27 subject to reporting.

28 (b) Posting.--The board shall post information about
29 prescription drug products on its publicly accessible Internet
30 website in a manner that does not reveal specific trade secrets

1 about a particular drug product.

2 (c) Regulations.--The board may promulgate regulations on
3 what can be considered a trade secret for purposes of
4 publication of reported data.

5 Section 7. Pharmaceutical transparency.

6 (a) Application.--This section shall only apply to a
7 prescription drug product that meets one of the following
8 criteria:

9 (1) The drug has an average wholesale acquisition cost
10 of at least \$5,000 annually or per course of treatment if
11 less than a year, adjusted annually to the Consumer Price
12 Index for All Urban Consumers, and which:

13 (i) the average wholesale acquisition cost has
14 increased by 50% or more over the past five years; or

15 (ii) the average wholesale acquisition cost has
16 increased by 15% or more over the past 12 months.

17 (2) The board has determined that the drug has created
18 an affordability burden in this Commonwealth.

19 (b) Information from manufacturer.--A manufacturer of a
20 prescription drug product shall file with the board the
21 following information on a form prescribed by the board:

22 (1) The costs for the development and manufacturing of
23 the drug, including the following:

24 (i) The total research and development costs accrued
25 in the United States and paid by the manufacturer in the
26 development of the drug.

27 (ii) The total costs of clinical trials and other
28 regulatory costs accrued in the United States and paid by
29 the manufacturer.

30 (iii) The total costs of materials, manufacturing

1 and distribution attributable to the drug for each of the
2 previous three years.

3 (iv) The costs accrued in the United States and paid
4 by an entity other than the manufacturer for research and
5 development, including, but not limited to, any amount
6 from Federal, State or other governmental programs or any
7 form of subsidies, grants or other support.

8 (v) Other costs to acquire the drug, including costs
9 for the purchase of or leasing the rights to patents,
10 licensing or acquisition of a corporate entity owning
11 rights to the drug while in development.

12 (vi) The marketing and advertising costs accrued in
13 the United States for the promotion of the drug directly
14 to consumers for each of the previous three years,
15 including, but not limited to:

16 (A) Costs associated with coupons or discounts
17 that are directed to consumers and the amount
18 redeemed in the United States.

19 (B) Marketing and advertising costs accrued in
20 the United States for promotion of the drug directly
21 or indirectly to prescribers.

22 (C) All other advertising costs accrued in the
23 United States for the drug.

24 (2) A five-year history of average wholesale acquisition
25 cost increases for the drug expressed as percentages,
26 including the months each average wholesale acquisition cost
27 increase took effect.

28 (3) The total profit attributable to the drug and
29 realized in the United States as represented:

30 (i) in dollars; and

1 (ii) as a percentage of the total company profits
2 realized in the United States that were derived from the
3 sale of the drug for each of the previous three years.

4 (4) The aggregate amount of all rebates that the
5 manufacturer provided to all payers, including, but not
6 limited to, insurers and pharmacy benefit managers, for the
7 sale of the drug within this Commonwealth for each of the
8 previous three years.

9 (5) A description of the manufacturer's patient
10 prescription assistance programs available in the United
11 States that include a drug under subsection (a), including,
12 but not limited to:

13 (i) The amount of financial assistance provided for
14 each of the previous three years.

15 (ii) The amount of financial assistance provided to
16 residents of this Commonwealth for each of the previous
17 three years.

18 (iii) The average per capita amount of assistance to
19 residents of this Commonwealth and the drugs for which
20 assistance was provided for each of the previous three
21 years.

22 (iv) The eligibility and benefit structure of the
23 patient prescription assistance programs, including
24 coupons.

25 (6) Payments or financial incentives, direct or
26 indirect, to hospitals, health care providers or physicians
27 located in this Commonwealth attributable to a drug under
28 subsection (a), including, but not limited to, speaking fees,
29 dinners, research, consulting, charitable donations, grants
30 or other incentives, discounts or rebates for each of the

1 previous three years.

2 (c) Filing deadlines.--The following shall apply:

3 (1) For a drug described under subsection (a)(1),
4 filings must be submitted to the board by March 31.

5 (2) For a drug described under subsection (a)(2),
6 filings must be submitted to the board within 90 days of the
7 board making a formal determination to review.

8 (d) Audit and certification.--A filing under this section
9 shall be audited and certified by an independent third-party
10 auditor prior to filing.

11 (e) Regulations.--The board may promulgate regulations as
12 may be necessary and appropriate to carry out the provisions of
13 this section.

14 Section 8. Pharmaceutical Transparency Review Fund.

15 (a) Establishment.--The Pharmaceutical Transparency Review
16 Fund is established as a special fund in the State Treasury. The
17 fund shall be used only to provide funding for the board and for
18 the purposes authorized under this act, including any costs
19 expended by any State agency to implement this act. The fund
20 shall be invested and reinvested in the same manner as other
21 State funds. Any investment earnings shall be retained to the
22 credit of the fund. The fund shall be subject to an audit by the
23 Auditor General. This subsection may not be construed to
24 prohibit the fund from receiving money from any other source.

25 (b) Assessment.--The following shall apply:

26 (1) The board shall be funded by an assessment on
27 manufacturers. A manufacturer shall pay the assessment within
28 the time prescribed by the board.

29 (2) Annually, the board shall assess and collect fees
30 from manufacturers as provided for in this subsection.

1 (3) The board shall assess each manufacturer based on
2 the manufacturer's relative share of gross revenue from
3 prescription drug sales in this Commonwealth.

4 (4) The board shall pay all money collected from the
5 assessment into the fund.

6 (c) Repayment.--Any appropriation to the board from the
7 General Fund shall be repaid to the General Fund from the
8 assessments collected under this section.

9 Section 9. Reports by board.

10 (a) Submission.--A report created by the board shall be
11 submitted to the following:

12 (1) The Governor.

13 (2) The President pro tempore of the Senate.

14 (3) The Majority Leader of the Senate.

15 (4) The Minority Leader of the Senate.

16 (5) The Speaker of the House of Representatives.

17 (6) The Majority Leader of the House of Representatives.

18 (7) The Minority Leader of the House of Representatives.

19 (8) The chairperson and minority chairperson of the
20 Appropriations Committee of the Senate.

21 (9) The chairperson and minority chairperson of the
22 Banking and Insurance Committee of the Senate.

23 (10) The chairperson and minority chairperson of the
24 Health and Human Services Committee of the Senate.

25 (11) The chairperson and minority chairperson of the
26 Appropriations Committee of the House of Representatives.

27 (12) The chairperson and minority chairperson of the
28 Insurance Committee of the House of Representatives.

29 (13) The chairperson and minority chairperson of the
30 Health Committee of the House of Representatives.

1 (b) Report.--The following shall apply:

2 (1) By January 2024, the board shall submit a report on
3 recommendations as to how to make prescription drugs more
4 affordable for all individuals, providers and health plans in
5 this Commonwealth.

6 (2) The report shall include:

7 (i) An analysis of the role of the supply chain in
8 prescription drug costs.

9 (ii) The role of price transparency in lowering
10 costs.

11 (iii) How high patient out-of-pocket costs relate to
12 prescription drug costs and affordability.

13 (3) The report shall review pricing from the
14 manufacturer through the supply chain to the point of service
15 and the patient.

16 (4) The report shall examine the role of health plans
17 and pharmacy benefit management contractors in prescription
18 drug costs.

19 (5) The report shall examine actions undertaken by other
20 states to make prescription drugs more affordable and the
21 impact of those actions.

22 (c) Further reporting.--On or before December 31 of each
23 year, the board shall submit a report that includes:

24 (1) Price trends for prescription drug products.

25 (2) Specific information about prescription drug
26 products and price increases that were reported to the board.

27 (d) Study.--By June 2022, the board shall submit a study of
28 the operation of the generic drug market that includes a review
29 of physician-administered drugs. The study shall include:

30 (1) The prices of generic drugs on a year-over-year

1 basis.

2 (2) The degree to which generic drug prices affect
3 yearly insurance premium changes.

4 (3) Annual changes in insurance cost-sharing for generic
5 drugs.

6 (4) The potential for and history of drug shortages.

7 (5) The degree to which generic drug prices affect
8 yearly State Medicaid spending.

9 (6) Any other information relevant to the study.

10 Section 10. Effective date.

11 This act shall take effect in 60 days.