
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2426 Session of
2020

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REFERRED TO COMMITTEE ON INSURANCE, APRIL 21, 2020

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:

1 (1) does the following:

2 (i) engages in the manufacture of a prescription
3 drug product; or

4 (ii) enters into a lease with another manufacturer
5 to market and distribute a prescription drug product
6 under the entity's own name; and

7 (2) sets or changes the wholesale acquisition cost of
8 the prescription drug product that the entity manufactures or
9 markets.

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

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

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

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

17 Section 3. Pharmaceutical Transparency Review Board.

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

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

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

29 (1) The board shall be composed of the following
30 individuals, who shall have expertise in health care

1 economics or clinical medicine:

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

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

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

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

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

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

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

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

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

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

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

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

1 (i) Members appointed under subsection (c) (1) (iii)
2 and (iv) shall serve initial terms of three years.

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

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

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

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

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

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

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

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

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

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

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

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

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

30 (iii) The chair may cancel or postpone a meeting if

1 the board has no prescription drug products before it to
2 review.

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

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

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

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

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

16 Section 4. Conflict of interest.

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

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

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

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

- 1 (1) by the board when hiring board staff;
- 2 (2) by the appointing authority when appointing members
3 to the board; and
- 4 (3) by the board when a member of the board is recused
5 from a final decision resulting from a review of a
6 prescription drug product.

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

- 9 (1) in advance of the first open meeting after the
10 conflict is identified; or
- 11 (2) within five days after the conflict is identified.

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

- 13 (1) A conflict of interest disclosed under subsection
14 (a) shall be posted on the publicly accessible Internet
15 website of the board unless the chair recuses the member from
16 a final decision resulting from a review of a prescription
17 drug product.
- 18 (2) A posting under paragraph (1) shall include the
19 type, nature and magnitude of the interests of the member
20 involved.

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

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

1 Section 5. Powers and duties of board.

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

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

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

11 (2) Accessing other available pricing information.

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

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

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

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

23 Section 6. Board assessment of prescription drug affordability.

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

29 (b) Posting.--The board shall post information about
30 prescription drug products on its publicly accessible Internet

1 website in a manner that does not reveal specific trade secrets
2 about a particular drug product.

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

6 Section 7. Pharmaceutical transparency.

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

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

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

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

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

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

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

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

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

1 (iii) The total costs of materials, manufacturing
2 and distribution attributable to the drug for each of the
3 previous three years.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 or other incentives, discounts or rebates for each of the
2 previous three years.

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

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

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

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

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

15 Section 8. Pharmaceutical Transparency Review Fund.

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

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

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

30 (2) Annually, the board shall assess and collect fees

1 from manufacturers as provided for in this subsection.

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

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

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

10 Section 9. Reports by board.

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

13 (1) The Governor.

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

15 (3) The Majority Leader of the Senate.

16 (4) The Minority Leader of the Senate.

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

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

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

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

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

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

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

28 (12) The chairperson and minority chairperson of the
29 Health Committee of the House of Representatives.

30 (13) The chairperson and minority chairperson of the

1 Insurance Committee of the House of Representatives.

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

3 (1) By January 2023, the board shall submit a report on
4 recommendations as to how to make prescription drugs more
5 affordable for all individuals, providers and health plans in
6 this Commonwealth.

7 (2) The report shall include:

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

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

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

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

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

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

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

25 (1) Price trends for prescription drug products.

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

28 (d) Study.--By June 2021, the board shall submit a study of
29 the operation of the generic drug market that includes a review
30 of physician-administered drugs. The study shall include:

1 (1) The prices of generic drugs on a year-over-year
2 basis.

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

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

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

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

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

11 Section 10. Effective date.

12 This act shall take effect in 60 days.