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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 321 Session of 2021

INTRODUCED BY PUSKARIC, BOBACK, HERSHEY, CIRESI, STRUZZI AND MOUL, JANUARY 28, 2021

REFERRED TO COMMITTEE ON INSURANCE, JANUARY 28, 2021

AN ACT

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

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

Section 1. Short title.

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

Section 2. Definitions.

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

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

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

"Manufacturer." An entity that:

(1) does the following:

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

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

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

"Prescription drug product." Any of the following:

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

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

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

Section 3. Pharmaceutical Transparency Review Board.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

review.

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

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

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

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

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

Section 4. Conflict of interest.

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

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

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

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

(1) by the board when hiring board staff;

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

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

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

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

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

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

(1) A conflict of interest disclosed under subsection (a) shall be posted on the publicly accessible Internet website of the board unless the chair recuses the member from a final decision resulting from a review of a prescription drug product.

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

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

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

Section 5. Powers and duties of board.

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

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

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

(2) Accessing other available pricing information.

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

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

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

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

Section 6. Board assessment of prescription drug affordability.

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

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

about a particular drug product.

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

Section 7. Pharmaceutical transparency.

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

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

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

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

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

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

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

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

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

(iii) The total costs of materials, manufacturing

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

(iv) The costs accrued in the United States and paid by an entity other than the manufacturer for research and development, including any amount from Federal, State or other governmental programs or any form of subsidies, grants or other support.

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

(vi) The marketing and advertising costs accrued in the United States for the promotion of the drug directly to consumers for each of the previous three years, including:

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

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

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

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

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

(i) in dollars; and

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

(4) The aggregate amount of all rebates that the manufacturer provided to all payers, including insurers and pharmacy benefit managers, for the sale of the drug within this Commonwealth for each of the previous three years.

(5) A description of the manufacturer's patient prescription assistance programs available in the United States that include a drug under subsection (a), including:

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

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

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

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

(6) Payments or financial incentives, direct or indirect, to hospitals, health care providers or physicians located in this Commonwealth attributable to a drug under subsection (a), including speaking fees, dinners, research, consulting, charitable donations, grants or other incentives, discounts or rebates for each of the previous three years.

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

(1) For a drug described under subsection (a)(1),

filings must be submitted to the board by March 31.

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

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

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

Section 8. Pharmaceutical Transparency Review Fund.

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

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

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

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

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

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

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

Section 9. Reports by board.

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

(1) The Governor.

(2) The President pro tempore of the Senate.

(3) The Majority Leader of the Senate.

(4) The Minority Leader of the Senate.

(5) The Speaker of the House of Representatives.

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

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

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

(9) The chairperson and minority chairperson of the Appropriations Committee of the House of Representatives.

(10) The chairperson and minority chairperson of the Banking and Insurance Committee of the Senate.

(11) The chairperson and minority chairperson of the Insurance Committee of the House of Representatives.

(12) The chairperson and minority chairperson of the Health and Human Services Committee of the Senate.

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

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

(1) By January 2024, the board shall submit a report on recommendations as to how to make prescription drugs more

affordable for all individuals, providers and health plans in this Commonwealth.

(2) The report shall include:

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

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

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

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

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

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

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

(1) Price trends for prescription drug products.

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

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

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

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

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

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

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

(6) Any other information relevant to the study.

Section 10. Effective date.

This act shall take effect in 60 days.