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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2212 Session of 2020

INTRODUCED BY FRANKEL, RABB, HILL-EVANS, KINSEY, ZABEL, MADDEN, SCHLOSSBERG, McNEILL, DeLUCA, WILLIAMS, HOWARD, JOHNSON-HARRELL, A. DAVIS, READSHAW, DEASY, YOUNGBLOOD, FREEMAN, CIRESI, HANBIDGE, GALLOWAY, ULLMAN, INNAMORATO, BURNS, PASHINSKI, LEE, KULIK, MALAGARI, KORTZ, HARKINS, RAVENSTAHL, BIZZARRO, MERSKI, DALEY AND WARREN, JANUARY 21, 2020

REFERRED TO COMMITTEE ON HEALTH, JANUARY 21, 2020

AN ACT

Providing for prescription drug affordability; establishing the Prescription Drug Affordability Board, the Prescription Drug Affordability Stakeholder Council and the Prescription Drug Affordability 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 Prescription Drug Affordability 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:

"Biologic." A drug that is produced or distributed in accordance with a biologics license issued under 21 C.F.R. 601.4 (relating to issuance and denial of license).

"Biosimilar." A drug that is produced or distributed in

accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3) (relating to regulation of biological products).

"Board." The Prescription Drug Affordability Board established under section 3.

"Brand name drug." A drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(c). The term does not include an authorized generic drug as defined under 42 C.F.R. 447.502 (relating to definitions).

"Fund." The Prescription Drug Affordability Fund established under section 9.

"Generic drug." The term includes the following:

(1) a retail drug that is marketed or distributed in accordance with an abbreviated new drug application, approved under 21 U.S.C. § 355(j);

(2) an authorized generic drug as defined by 42 C.F.R. 447.502; or

(3) a drug that entered the market before 1962 that was not originally marketed under a new drug application.

"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.

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

"Prescription drug product." A brand name drug, a generic drug, a biologic or a biosimilar.

"Stakeholder council." The Prescription Drug Affordability Stakeholder Council established under section 8.

Section 3. Prescription Drug Affordability Board.

(a) Establishment.--There is established a Prescription Drug Affordability Board for the purposes under subsection (b).

(b) Purpose.--The purpose of the board is to protect residents of this Commonwealth, local governments, commercial health plans, health care providers, pharmacies licensed in this Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products.

(c) Membership.--The board shall be composed of five individuals, appointed by the Governor and confirmed by the Senate, who shall have expertise in health care economics or clinical medicine.

(d) Alternate members.--Three alternate members, who shall have expertise in health care economics or clinical medicine, shall be appointed by the Governor and confirmed by the Senate. Each alternate member shall participate in deliberations of the board when a member is recused.

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

(f) Conflict of interest.--Any 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, shall be considered and disclosed when appointing

members and alternate members to the board.

(g) Board diversity.--To the extent practicable and consistent with Federal and State law, the membership of the board shall reflect the racial, ethnic and gender diversity of this Commonwealth.

(h) Term of office.--Members of the board shall serve as follows:

(1) The term of a member or an alternate member shall be five years.

(2) The terms of the members and alternate members shall be staggered as provided under subsection (i).

(i) Expiration of terms.--The terms of the initial members and alternate members of board shall expire as follows:

(1) One member and one alternate member three years after appointment.

(2) Two members and one alternate member four years after appointment.

(3) Two members, including the chair of the board, and one alternate member five years after appointment.

(j) Board staff.--The board shall be staffed as follows:

(1) The chair shall hire an executive director.

(2) The executive director shall hire a general counsel and staff for the board.

(3) Staff of the board shall receive a salary as determined by the board.

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

(1) May receive compensation as a member of the board.

(2) Shall be entitled to reimbursement for actual and necessary expenses incurred in the performance of their duties.

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

(m) Meetings.--The board shall meet as follows:

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

(ii) The chair may cancel or postpone a meeting if there are no prescription drug products to review.

(iii) The following actions by the board shall be made in open session:

(A) Deliberations on whether to subject a prescription drug product to a cost review under section 5(f).

(B) A vote on whether to impose an upper payment limit on purchases and payor reimbursements of prescription drug products in this Commonwealth.

(C) A decision by the board.

(iv) Notwithstanding 65 Pa.C.S. Ch.7 (relating to open meetings), 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 in advance of the meeting.

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

(4) The board shall provide an opportunity for public comment at each open meeting of the board.

(5) The board shall provide the public with the opportunity to provide written comments on pending decisions

of the board.

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

(7) To the extent practicable, the board shall access pricing information for prescription drug products by:

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

(ii) Accessing other available pricing information.

Section 4. Conflict of interest.

(a) General rule.--The following shall apply to conflicts of interest:

(1) A member of the board shall recuse themselves from decisions related to a prescription drug product if the member, or an immediate family member of the member, has received or could receive any of the following:

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

(ii) a financial benefit from a person who 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.

(2) For the purposes of paragraph (1), a 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 finding of a review conducted under this act.

(b) Disclosure requirements.--A conflict of interest shall be disclosed:

(1) By the board when hiring board staff.

(2) By the appointing authority when appointing members and alternate members to the board and members to the stakeholder council.

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

(4) In advance of the first open meeting after the conflict is identified or within five days after the conflict is identified.

(c) Posting requirement.--A conflict of interest disclosed under subsection (b) shall be posted on the publicly accessible Internet website of the board unless the chair of the board recuses the member who has the conflict of interest from any final decision resulting from a review of a prescription drug product. A posting under this subsection shall include the type, nature and magnitude of the interests of the member involved.

(d) Gifts and donations.--Members and alternate members of the board, board staff and third-party contractors may not accept any 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.

Section 5. Powers and duties of the board.

(a) General rule.--The board may:

(1) Promulgate regulations for the implementation of this act.

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

(b) Third party contracts.--Unless permission is granted by

the board, a third party hired by the board under subsection (a)(2) may not release, publish or otherwise use any information to which the third party has access under its contract.

(c) Identification of prescription drug products.--The board shall identify prescription drug products that are:

(1) Brand name drugs or biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have:

(i) a launch wholesale acquisition cost of $30,000 or more per year or course of treatment; or

(ii) a wholesale acquisition cost increase of $3,000 or more in any 12-month period or course of treatment if less than 12 months.

(2) Biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched.

(3) Generic drugs that, as adjusted annually for inflation in accordance with the consumer price index, have a wholesale acquisition cost:

(i) Of $100 or more for:

(A) a 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration;

(B) a supply lasting a patient for fewer than 30 days based on the recommended dosage approved for labeling by the United States Food and Drug Administration; or

(C) one unit of the drug if the labeling

approved by the United States Food and Drug Administration does not recommend a finite dosage.

(ii) That increased by 200% or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding 12 months.

(4) Other prescription drug products that may create affordability burdens for the health care system and patients in this Commonwealth, in consultation with the stakeholder council.

(d) Cost review.--After identifying prescription drug products as provided under subsection (c), the board shall determine whether to conduct a cost review as described under subsection (f) for each identified prescription drug product by:

(1) Seeking stakeholder council input about the prescription drug product.

(2) Considering the average patient cost share of the prescription drug product.

(e) Request of information.--Information for a cost review may be obtained and utilized as follows:

(1) To the extent there is no publicly available information to conduct a cost review as described under subsection (f), the board shall request the information from the manufacturer of the prescription drug product.

(2) The information to conduct a cost review may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management,

net average price in this Commonwealth, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug product.

(3) Failure of a manufacturer to provide the board with the information requested under this subsection shall not affect the authority of the board to conduct a review as described under subsection (f) or establish an upper payment limit as authorized under subsection (g).

(f) Conduct of cost review.--A cost review under this section shall be conducted as follows:

(1) If the board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability burdens for the state health care system or high out-of-pocket costs for patients.

(2) To the extent practicable, in determining whether a prescription drug product identified under subsection (c) has led or will lead to an affordability burden, the board shall consider the following factors:

(i) The wholesale acquisition cost for the prescription drug product sold in this Commonwealth.

(ii) The average monetary price concession, discount or rebate the manufacturer provides to health plans in this Commonwealth or is expected to provide to health plans in this Commonwealth as reported by manufacturers and health plans, expressed as a percent of the wholesale acquisition cost for the prescription drug product under review.

(iii) The total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefits manager operating in this Commonwealth for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percent of the wholesale acquisition costs for the prescription drug product under review.

(iv) The price at which therapeutic alternatives have been sold in this Commonwealth.

(v) The average monetary concession, discount or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in this Commonwealth for therapeutic alternatives.

(vi) The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications or accepted medical practice.

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

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

(ix) The relative financial impacts to health, medical or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives.

(x) The average patient copay or other cost-sharing for the prescription drug product in this Commonwealth.

(xi) Any other factors as determined by the board in regulations adopted by the board.

(3) If the board is unable to determine whether a prescription drug product will produce or has produced challenges to the affordability of the drug for the health care system in this Commonwealth, using the factors listed under paragraph (2), the board may consider the following factors:

(i) The manufacturer's research and development costs, as indicated on the manufacturer's Federal tax filing or information filed with the Federal Securities and Exchange Commission for the most recent tax year in proportion to the manufacturer's sales in this Commonwealth.

(ii) The portion of direct-to-consumer marketing costs eligible for favorable Federal tax treatment in the most recent tax year that are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in-State sales to total manufacturer sales in the United States for the product under review.

(iii) Gross and net manufacturer revenues for the most recent tax year.

(iv) Any additional factors proposed by the manufacturer that the board considers relevant.

(v) Any additional factors as established by the board in regulations.

(g) Upper payment limit.--The board may impose an upper payment limit as follows:

(1) If the board finds that the spending on a

prescription drug product reviewed under this section has led or will lead to an affordability burden, the board shall recommend or establish an upper payment limit of this subsection after considering:

(i) The cost of administering the drug.

(ii) The cost of delivering the drug to consumers.

(iii) Other relevant administrative costs related to the drug.

(2) The upper payment limit shall apply to all purchases and payor reimbursements of the prescription drug product dispensed or administered to individuals in this Commonwealth in person, by mail or by other means.

(h) Refusal to sell.--If a manufacturer refuses to sell a prescription drug product subject to a cost review under section 5(f) in this Commonwealth or an upper payment limit established by the board, the board may work with the Federal Government to import the prescription drug product that the manufacturer refuses to sell in this Commonwealth.

(i) Public information.--Any information submitted to the board under this section shall be subject to public inspection as provided by law.

(j) Construction.--This section may not be construed to prevent a manufacturer from marketing a prescription drug product approved by the United States Food and Drug Administration while the product is under review by the board.

(k) Report.--On or before December 31 of each year, the board shall submit a report to the chair and minority chair of the Health and Human Services Committee of the Senate and the chair and minority chair of the Health Committee of the House of Representatives that includes:

(1) Price trends for prescription drug products.

(2) The number of prescription drug products that were subject to board review, including the results of the review, and the number and disposition of appeals and judicial reviews of board decisions.

(3) Any recommendations the board may have on further legislation needed to make prescription drug products more affordable in this Commonwealth.

(l) Study.--On or before June 1, 2021, the board shall:

(1) Conduct a study of the operation of the generic drug market in the United States that includes a review of physician-administered prescription drug products and considers:

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

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

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

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

(v) The degree to which generic drug prices affect yearly Medicaid spending in this Commonwealth.

(vi) Any other relevant study questions.

(2) Report its findings to the General Assembly.

Section 6. Appeals.

(a) General rule.--A person aggrieved by a decision of the board may file an appeal of the decision within 30 days after the board renders the decision.

(b) Final decision.--The board shall hear the appeal and

make a final decision within 60 days after the appeal is filed.

(c) Judicial review.--Any person aggrieved by a final decision of the board may petition for judicial review as provided under 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial review of Commonwealth agency action).

Section 7. Employee Retirement Income Security Act of 1974 Plans and Medicare Drug Plans.

Employee Retirement Income Security Act of 1974 plans and Medicare Part D plans are not bound by decisions of the board and can choose to reimburse more than the upper payment limit. Health care providers who dispense and administer drugs in this Commonwealth to individuals in this Commonwealth shall bill all payers no more than the upper payment limit to the patient without regard to whether or not an Employee Retirement Income Security Act plan or Medicare Part D plan chooses to reimburse the health care provider above the upper payment limit.

Section 8. Prescription Drug Affordability Stakeholder Council.

(a) Establishment.--The Prescription Drug Affordability Stakeholder Council is established for the purpose under subsection (b).

(b) Purpose.--The purpose of the stakeholder council is to provide stakeholder input to assist the board in making decisions as required under this act.

(c) Membership.--The stakeholder council shall consist of the following members appointed by the Governor from lists of qualified individuals submitted by the President pro tempore of the Senate, in consultation with the Majority Leader and Minority Leader of the Senate, and the Speaker of the House of Representatives, in consultation with the Majority Leader and

Minority Leader of the House of Representatives:

(1) One representative from the Department of Human Services.

(2) One representative from the Department of Health.

(3) One representative from the Insurance Department.

(4) One representative of brand name drug corporations.

(5) One representative of generic drug corporations.

(6) One representative of employers.

(7) One representative of pharmacy benefits managers.

(8) One representative of pharmacists.

(9) One pharmacologist.

(10) One representative of doctors.

(11) One representative of nurses.

(12) One representative of hospitals.

(13) One representative of health insurers.

(14) One representative of the Office of Budget.

(15) One clinical researcher.

(16) One representative of a Statewide consumer health care advocacy coalition.

(17) One representative of a Statewide advocacy organization for seniors.

(18) One representative of a Statewide organization for diverse communities.

(19) One representative of a labor union.

(20) Two health services researchers specializing in prescription drugs.

(21) Five consumer representatives.

(d) Expertise of members.--A member of the stakeholder council shall have knowledge in one or more of the following:

(1) the pharmaceutical business model;

(2) supply chain business models;

(3) the practice of medicine or clinical training;

(4) consumer or patient perspectives;

(5) health care cost trends and drivers;

(6) clinical and health services research; or

(7) the Commonwealth's health care marketplace.

(e) Diversity.--To the extent practicable and consistent with Federal and State law, the membership of the stakeholder council shall reflect the racial, ethnic, and gender diversity of this Commonwealth.

(f) Co-chairs.--From among the membership of the stakeholder council, the chair of the board shall appoint two members to be co-chairs of the stakeholder council.

(g) Terms.--A member of the stakeholder council shall serve a term of three years. The initial members of the stakeholder council shall serve staggered terms as determined by the board.

(h) Compensation and reimbursement.--A member of the stakeholder council:

(1) May not receive compensation as a member.

(2) Shall be entitled to reimbursement for actual and necessary expenses incurred in the performance of their duties.

Section 9. Prescription Drug Affordability Fund.

(a) Establishment.--The Prescription Drug Affordability Fund is established as a special fund in the State Treasury. Money in the fund shall be appropriated to the board on a continuing basis to carry out the purposes of this act, including any costs expended by any State agency to implement this act. To the extent money is appropriated to the board from the General Fund, that money shall be repaid to the General Fund with the fee

imposed under subsection (c).

(b) Investment of fund.--Money in the fund shall be invested and reinvested in the same manner as other funds in the custody of the State Treasurer in the manner provided by law. Any investment earnings shall be retained to the credit of the fund. This subsection shall not be construed to prohibit the fund from receiving additional money from any other source.

(c) Fee.--The board shall assess a fee on each manufacturer on the manufacturer's relative share of gross revenue from drug sales in this Commonwealth which shall be deposited into the fund. A manufacturer assessed under this section shall annually pay the fee to the board.

Section 10. Enforcement.

The Office of Attorney General shall enforce the provisions of this act.

Section 11. Severability.

The provisions of this act are severable. If a provision of this act or the provision's application to a person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application.

Section 12. Effective date.

This act shall take effect in 180 days.