HB3493

LRB10110677RAB55787b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB3493

Introduced 2/15/2019, by Rep. Will Guzzardi

SYNOPSIS AS INTRODUCED:

New Act
30 ILCS 105/5.891 new

Creates the Prescription Drug Affordability Act. Defines terms. Creates the Prescription Drug Affordability Board and includes provisions regarding: purpose; members; alternate members; conflict of interest; terms; additional staff; salary; compensation and reimbursement; and meetings. Creates the Prescription Drug Affordability Stakeholder Council and includes provisions regarding: purpose; members; knowledge requirements; terms; and compensation. Provides the manner in which a conflict of interest shall be disclosed. Provides that gifts or donations of services or property that indicate a potential conflict of interest may not be accepted by any member of the Board, Board staff, or third-party contractor. Includes provisions on applicability. Provides that the Board shall identify specified prescription drug products and determine whether each prescription drug product should be subject to a cost review. Provides that if the Board finds that spending on a prescription drug product creates affordability challenges, the Board shall establish an upper payment limit that applies to all purchases and payor reimbursements. Includes provisions regarding remedies and an appeal process. Creates the Prescription Drug Affordability Fund. Provides that the Board shall submit a report to the General Assembly including specified information. Includes a provision on term expiration for Board and Council members. Provides that the Board shall conduct a study of the operation of the generic drug market that includes specified information on or before June 1, 2020. Makes conforming changes in the State Finance Act. Effective immediately.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health care.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Prescription Drug Affordability Act.

Section 5. Definitions. In this Act:

"Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. 447.502.

"Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. 262(k)(3).

"Board" means the Prescription Drug Affordability Board.

"Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. 355(c). "Brand name drug" does not include an authorized generic drug as defined by 42 CFR 447.502.

"Council" means the Prescription Drug Affordability Stakeholder Council.

"Generic drug" means:

(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 CFR 447.502; or

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

"Manufacturer" means an entity that:

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

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

(3) sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

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

Section 10. Prescription Drug Affordability Board.

(a) The Prescription Drug Affordability Board is created.

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

(c) The Board shall consist of the following members who have expertise in health care economics or clinical medicine:

(1) one member appointed by the Governor;

(2) one member appointed by the President of the Senate;

(3) one member appointed by the Speaker of the House of Representatives;

(4) one member appointed by the Attorney General; and

(5) one member appointed jointly by the President of the Senate and the Speaker of the House of Representatives, who shall serve as chair of the Board.

(d) The Board shall have the following alternate members who have expertise in health care economics or clinical medicine and who are designated by the Board chair to participate in deliberations of the Board when a member is recused:

(1) one alternate member appointed by the Governor;

(2) one alternate member appointed by the President of the Senate; and

(3) one alternate member appointed by the Speaker of the House of Representatives.

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

(f) 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) 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 the State.

(h) The term of a member is 5 years.

(i) The terms of the members are staggered as required by the terms provided for members beginning October 1, 2019.

(j) The chair shall hire an executive director, general counsel, and staff for the Board.

(k) Staff of the Board shall receive a salary as provided in the budget of the Board.

(l) A member of the Board:

(1) may receive compensation as a member of the Board; and

(2) is entitled to reimbursement for expenses.

(m) Except as provided in paragraphs (1) and (2) of this subsection, the Board shall meet in open session at least every 6 weeks to review prescription drug product information.

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

(2) Notwithstanding the Open Meetings Act, the Board may meet in closed session to discuss proprietary data and information, but a decision of the Board shall be made in open session.

(3) Public notice of each Board meeting shall be

provided at least 2 weeks in advance of the meeting.

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

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

(6) The Board shall provide the public with the opportunity to provide written comments on pending decisions of the Board.

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

(8) To the extent feasible and 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; and

(ii) accessing other available pricing information.

(9) The following actions by the Board shall be made in open session:

(i) deliberations on whether to subject a prescription drug product to a cost review under subsection (a) of Section 30; and

(ii) any vote on whether to impose an upper payment limit on purchases and payor reimbursements of

prescription drug products in this State.

(10) A majority of the members of the Board constitutes a quorum.

(11) A member of the board shall recuse themselves from decisions related to a prescription drug product if the member, or immediate family 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 any 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.

A financial benefit as described in this paragraph 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 subtitled.

Section 15. Prescription Drug Affordability Stakeholder Council.

(a) The Prescription Drug Affordability Stakeholder Council is created.

(b) The purpose of the Council is to provide stakeholder input to assist the Board in making decisions as required under

this Act.

(c) The Council shall consist of 21 members appointed in accordance with this subsection.

(1) The Speaker of the House of Representatives shall appoint:

(i) one representative of a statewide health care advocacy coalition;

(ii) one representative of a statewide advocacy organization for seniors;

(iii) one representative of a statewide organization for diverse communities;

(iv) one representative of a labor union;

(v) two health services researchers specializing in prescription drugs; and

(vi) one public member at the discretion of the Speaker of the House of Representatives.

(2) The President of the Senate shall appoint:

(i) one representative of doctors;

(ii) one representative of nurses;

(iii) one representative of hospitals;

(iv) one representative of health insurers;

(v) one representative of the Governor's Office of Management and Budget;

(vi) one clinical researcher; and

(vii) one public member at the discretion of the President of the Senate.

(3) The Governor shall appoint:

(i) one representative of brand name drug corporations;

(ii) one representative of generic drug corporations;

(iii) one representative of employers;

(iv) one representative of pharmacy benefit managers;

(v) one representative of pharmacists;

(vi) one pharmacologist; and

(vii) one public member at the discretion of the Governor.

(d) The members of the Council shall have knowledge of 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 costs trends and drivers;

(6) clinical and health services research; or

(7) the State's health care marketplace.

(e) To the extent practicable and consistent with federal and State law, the membership of the Council shall reflect the racial, ethnic, and gender diversity of this State.

(f) From among the membership of the Council, the Board chair shall appoint 2 members to be co-chairs of the Council.

(g) The term of a member is 3 years.

(h) The initial members of the Council shall serve staggered terms as required by the terms provided for members beginning October 1, 2019.

(i) A member of the Council may not receive compensation as a member of the Council, but is entitled to reimbursement for expenses.

Section 20. Conflict of interest.

(a) A conflict of interest shall be disclosed in the following manner:

(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 Council; and

(3) by the Board, describing any recusal by a member of the Board in any final decision resulting from a review of a prescription drug product.

(b) A conflict of interest shall be disclosed:

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

(2) within 5 days after the conflict is identified.

(c) A conflict of interest disclosed under subsection (a) shall be posted on the website of the Board unless the chair of the Board recuses the member from any final decision resulting from a review of a prescription drug product.

(d) A post under subsection (c) shall include the type, nature, and magnitude of the interests of the member involved.

Section 25. Gifts and donations. A member of the Board, Board staff, and third-party contractor may not accept any gift or donation of services or property that indicate a potential conflict of interest or have the appearance of biasing the work of the Board.

Section 30. Application; cost review.

(a) This Section does not apply to a prescription drug product used in an in-patient setting if the drug is regulated by the Department of Financial and Professional Regulation.

(b) Nothing in this Section may be construed to prevent a manufacturer from marketing a prescription drug product approved by the Federal Food and Drug Administration while the product is under review by the Board.

(c) Nothing in this Act may be construed to effect:

(1) an entity's eligibility for the federal Drug Pricing Program under Section 340B of the federal Public Health Service Act; or

(2) the discounts that are available to an entity that is eligible for the federal Drug Pricing Discount Program under Section 340B of the federal Public Health Service Act.

(d) The Board shall identify the following prescription

drug products and determine whether each identified prescription drug product should be subject to a cost review as described in subsection (g):

(1) brand-name drugs and 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 for a 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 biosimilar is 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 30 consecutive days based on the recommended dosage approved for labeling by the Federal Drug Administration;

(B) a supply lasting a patient for fewer than 30 days based on the recommended dosage approved for labeling by the Federal Drug Administration;

or

(C) one unit of the drug if the labeling approved by the Federal Drug Administration does not recommend a finite dosage; and

(ii) that increased by 200% or more during the 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 preceding 12-months; and

(4) in consultation with the Council, prescription drug products that may create affordability challenges for the State healthcare system, including patients.

(e) After identifying a prescription drug product as required by subsection (d), the Board shall determine whether to conduct a cost review as described in subsection (d) for each identified prescription drug product by:

(1) seeking Council input about the prescription drug product; and

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

(f) To the extent there is no publicly available information to conduct a cost review as described in subsection (d), the Board shall request the information from the manufacturer of the prescription drug product. 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 State, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the prescription drug product. The failure of a manufacturer to provide the Board with the information requested under this subsection does not affect the authority of the Board to conduct a review as described in subsection (g) or establish an upper payment limit as authorized under subsection (h).

(g) If the Board conducts a review of the cost of a prescription drug product, the review shall determine if utilization of the prescription drug product, that is fully consistent with the labeling approved by the Federal Food and Drug Administration or standard medical practice, has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients. To the extent feasible, the Board shall consider the following factors in determining whether a prescription drug product identified under subsection (d) has or will lead to an affordability challenge for the State health care system, including patients:

(1) the wholesale acquisition cost for the prescription drug product sold in this State;

(2) the average monetary price concession, discount, or rebate the manufacturer provides to health plans in this State or is expected to provide to health plans in this State as reported by manufacturers and health plans,

expressed as a percent of the wholesale acquisition cost for the prescription drug product under review;

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

(4) the price at which therapeutic alternatives have been sold in this State;

(5) the average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefit managers in this State for therapeutic alternatives;

(6) the costs to health plans based on patient access consistent with Federal Food and Drug Administration labeled indications;

(7) the impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

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

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

(10) the average patient co-pay or other cost-sharing for the prescription drug product in this State; and

(11) any other factors as determined by the Board.

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 State health care system, using the factors listed in this subsection, 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 State;

(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 ration 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; and

(v) any additional factors as established by the Board.

(h) If the Board finds that the spending on a prescription drug product reviewed under this Section creates affordability

challenges for the State health care system, including patients, the Board shall establish an upper payment limit that applies to all purchases and payor reimbursements of the prescription drug product in this State.

(i) Any information submitted to the Board related to a cost review conducted in accordance with subsection (g) shall be subject to public inspection.

Section 35. Remedies. The Attorney General may pursue any available remedy under State law when enforcing this Act.

Section 40. Appeal of Board decisions.

(a) A person aggrieved by a decision of the Board may request an appeal of the decision within 30 days after the finding of the Board.

(b) The Board shall hear the appeal and make a final decision within 60 days of the hearing.

(c) Any person aggrieved by a final decision of the Board may petition for judicial review.

Section 45. Prescription Drug Affordability Board Fund.

(a) In this Section, "fund" means the Prescription Drug Affordability Board Fund.

(b) The Prescription Drug Affordability Board Fund is created. 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.

(c) Subject to subsection (g), the Board shall be funded by an assessment on all manufacturers. The Board shall determine the amount of the assessment required under this subsection based on each manufacturer's relative share of gross revenue from drug sales.

(d) The Board shall pay all moneys collected from the assessment into the fund.

(e) Any investment earnings shall be retained to the credit of the fund.

(f) This Section may not be construed to prohibit the fund from receiving moneys from any other source.

(g) The Board shall be established using general funds, which shall be repaid to the State with the assessments required under subsection (c).

Section 50. Report. The Board shall submit to the General Assembly a report 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; and

(3) any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in this State.

Section 55. Term expiration. The terms of:

(1) the initial members of the Board as established by Section 10 of this Act, shall expire as follows:

(i) one member in 2022,

(ii) two members in 2023; and

(iii) two members, including the chair of the Board, in 2024; and

(2) the initial members of the Council as established by Section 15 of this Act shall expire as follows:

(i) seven members in 2022;

(ii) seven members in 2023; and

(iii) seven members in 2024.

Section 60. Study. On or before June 1, 2020, 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 drugs 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 State Medicaid spending; and

(vi) any other relevant study questions; and

(2) report to the General Assembly on its findings.

Section 97. Severability. If any provision of this Act or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of this Act that can be given effect without the invalid provision or application, and for this purpose the provisions of this Act are declared severable.

Section 900. The State Finance Act is amended by adding Section 5.891 as follows:

(30 ILCS 105/5.891 new)

Sec. 5.891. The Prescription Drug Affordability Board Fund.

Section 999. Effective date. This Act takes effect upon becoming law.