SENATE, No. 329

STATE OF NEW JERSEY

220th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2022 SESSION

Sponsored by:
Senator TROY SINGLETON
District 7 (Burlington)
Senator JAMES BEACH
District 6 (Burlington and Camden)

Co-Sponsored by:
Senators Greenstein, Turner, Pou, Ruiz, Gopal, A.M.Bucco, Lagana, Gill, Codey, Sacco, Cruz-Perez, Cunningham, Cryan, Schepisi and Stack

SYNOPSIS

Establishes Prescription Drug Affordability Board; appropriates $1 million.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

(Sponsorship Updated As Of: 3/7/2022)

AN ACT concerning pharmaceuticals, supplementing Title 24 of the Revised Statutes, and making an appropriation.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Biological product" means the same as that term is defined in section 1 of P.L.2015, c.130 (C.24:6K-1).

"Board" means the Prescription Drug Affordability Board established pursuant to section 2 of this act.

"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. s.355(c). "Brand name drug" shall not include an authorized generic drug as defined in 42 C.F.R. s.447.502.

"Carrier" means the same as that term is defined in section 2 of P.L.1997, c.192 (C.26:2S-2).

"Council" means the Prescription Drug Affordability Stakeholder Council established pursuant to section 3 of this act.

"Generic drug" means: a retail drug that is marketed or distributed in accordance with an abbreviated new drug application that is approved under 21 U.S.C. s.355(j); an authorized generic as defined in 42 C.F.R. s.447.502; or a drug that entered the market before 1962 that was not originally marketed under a new drug application.

"Health benefits plan" means the same as that term is defined in section 2 of P.L.1997, c.192 (C.26:2S-2).

"Interchangeable" means the same as that term is defined in section 1 of P.L.2015, c.130 (C.24:6K-1).

"Logistics provider" means an entity that receives a prescription drug product from the original or contract manufacturer, warehouses and delivers the prescription drug product at the direction of the manufacturer, and does not purchase, sell, trade, or take title to the prescription drug product.

"Manufacturer" means an entity that: engages in the manufacture of a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and sets or changes the wholesale acquisition cost of the prescription drug product that it manufactures or markets.

"Prescription drug product" means a brand name drug, a generic drug, a biological product, or an interchangeable product.

"Wholesale distributor" means a business registering under P.L.1961, c.52 (C.24:6B-1 et seq.) that is engaged in the wholesale distribution of a prescription drug product. "Wholesale distributor" shall not include a common carrier, or an employee thereof, whose possession of a prescription drug product is in the usual course of the common carrier's or employee's business or employment, and shall not include a logistics provider or an employee thereof.

2. a. The Prescription Drug Affordability Board is established in, but not of, the Department of Law and Public Safety. Notwithstanding the foregoing, the board shall be independent of any supervision or control by the department or by any agency, board, office, or individual within the department.

b. It shall be the duty of the board to protect New Jersey residents, State and local governments, health benefits plans, health care providers, licensed pharmacies, and other stakeholders within the State health care system from the high costs of prescription drug products.

c. (1) The board shall comprise five public members and three alternate public members, who shall participate in board deliberations in any case in which a public member is recused.

(a) The five public members of the board shall be appointed as follows: one member by the Governor; one member by the President of the Senate; one member by the Speaker of the General Assembly; one member by the Attorney General; and one member jointly by the President of the Senate and the Speaker of the General Assembly, which member shall serve as chair of the board.

(b) The three alternate public members of the board shall be appointed as follows: one member by the Governor; one member by the President of the Senate; and one member by the Speaker of the General Assembly.

(2) Each public member and alternate public member of the board shall have expertise in health care economics or clinical medicine.

(3) No public member of the board may be an employee of, a board member of, or a consultant to, a manufacturer, pharmacy benefits manager, health benefits plan carrier, or wholesale distributor or related trade association. No alternate public member of the board may be an employee of, a board member of, or a consultant to, a health benefits plan carrier or a wholesale distributor or related trade association.

(4) An individual appointed to the board as a public member or an alternate public member shall disclose, at the time of appointment, 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 the individual's decision in matters related to the board or the conduct of the board's activities.

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

d. Public members and alternate public members of the board shall serve for a term of five years, except that, of the public members first appointed, one shall serve a term of three years, two shall serve a term of four years, and two shall serve a term of five years. Public members and alternate public members shall be eligible for reappointment to the board. Vacancies in the membership shall be filled in the same manner as provided for the original appointment, and members shall serve until a successor has been appointed.

e. The chair of the board shall hire an executive director, general counsel, and staff. Every five years, the chair shall develop a five-year budget and staffing plan and submit it to the board for approval. The executive director, general counsel, and staff of the board shall receive a salary as provided in the budget of the board. Public and alternate public members of the board shall be entitled to such compensation as may be approved under the State budget, and shall be entitled to reimbursement for expenses reasonably incurred in the performance of their official duties.

f. The board shall meet in open session at least once every six weeks, provided that the chair shall have the authority to postpone or cancel any required meeting. Three members shall constitute a quorum for the purposes of conducting official board business.

(1) The following board actions shall be undertaken in open session:

(a) the study required under section 5 of this act;

(b) deliberations as to whether to subject a prescription drug product to a cost review pursuant to section 7 of this act;

(c) any vote on whether to establish an upper payment limit on purchases and payor reimbursements of prescription drug products in the State or to authorize and develop requirements for the importation of prescription drug products from other countries; and

(d) any enforcement, regulatory, or other decision by the board.

(2) The board may meet in closed session to discuss trade secrets or confidential and proprietary data and information, as described in section 8 of this act.

(3) The board shall provide public notice of each board meeting at least two weeks in advance of the meeting. Materials for each board meeting shall be made available to the public at least seven calendar days 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:

(a) entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and

(b) accessing other available pricing information.

(8) (a) Public members 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 any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the board that, in the aggregate, exceeds $500 per year.

(b) For the purposes of subparagraph (a) of this paragraph, 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.

(c) An alternate public member shall serve in the place of a recused public member, provided the alternate public member or an immediate family member of the alternate public member has not received, and could not receive, any financial benefit for which recusal is required pursuant to subparagraph (a) of this paragraph.

g. In addition to the other powers set forth in this act, the board may:

(1) conduct hearings concerning possible violations of this act and determine appropriate penalties or other remedies to be assessed against individuals in violation of the requirements of this act;

(2) refer non-compliance matters to the Attorney General, who may pursue appropriate legal remedies; and

(3) enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board. Unless permission is granted by the board, a third party hired by the board pursuant to this paragraph shall not release, publish, or otherwise use any information to which the third party has access under its contract.

h. Public members, alternate public members, staff, and third party contractors of the board shall 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.

3. a. The Prescription Drug Affordability Stakeholder Council is established in, but not of, the Prescription Drug Affordability Board.

b. It shall be the duty of the council to provide stakeholder input to assist the board in making decisions as required under this act.

c. The council shall comprise 27 members, to be appointed as follows:

(1) The Speaker of the General Assembly shall appoint nine members, including: (a) one representative of generic drug corporations; (b) one representative of nonprofit health benefits plan carriers; (c) one representative of a Statewide health care advocacy coalition; (d) one representative of a Statewide advocacy organization for seniors; (e) one representative of a Statewide organization for diverse communities; (f) one representative of a labor union; (g) one health services researcher specializing in prescription drugs; and (h) two public members;

(2) The President of the Senate shall appoint nine members, including: (a) one representative of brand name drug corporations; (b) one representative of physicians; (c) one representative of nurses; (d) one representative of hospitals; (e) one representative of dentists; (f) one representative of health benefits plan carriers; (g) one representative of the Office of Budget and Management in the Department of the Treasury; (h) one clinical researcher; and (i) one public member; and

(3) The Governor shall appoint nine members, including: (a) one representative of brand name drug corporations; (b) one representative of generic drug corporations; (c) one representative of biotechnology companies; (d) one representative of for profit health benefits plan carriers; (e) one representative of employers; (f) one representative of pharmacy benefits managers; (g) one representative of pharmacists; (h) one pharmacologist; and (i) one public member.

d. (1) The membership of the council shall collectively have knowledge of:

(a) the pharmaceutical business model;

(b) supply chain business models;

(c) the practice of medicine and clinical training;

(d) consumer and patient perspectives;

(e) health care cost trends and drivers;

(f) clinical and health services research; and

(g) the State's health care marketplace.

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

(3) The chair of the Prescription Drug Affordability Board shall select, from among the membership of the council, two members who shall serve as co-chairs of the council.

e. Each member of the council shall serve a term of three years, except that, of the members first appointed, nine shall serve for a term of one year, nine shall serve for a term of two years, and nine shall serve for a term of three years. Members shall be eligible for reappointment to the council. Vacancies in the membership shall be filled in the same manner as provided for the original appointment, and members shall serve until a successor has been appointed.

f. Members of the council shall serve without compensation, but may be reimbursed for expenses reasonably incurred in the performance of their official duties.

4. a. Conflicts of interest involving the Prescription Drug Affordability Board shall be disclosed to the public on the board's Internet website as follows:

(1) conflicts of interest involving staff of the Prescription Drug Affordability Board shall be disclosed at the time the staff member is hired or at such time as an existing staff member identifies or acquires a new conflict of interest;

(2) conflicts of interest involving the public members and alternate public members of the board shall be disclosed by the appointing authority at the time of appointment or at such time as an existing member identifies or acquires a new conflict of interest; and

(3) conflicts of interest requiring recusal of a public member of the board from a final decision resulting from a review of a prescription drug product shall be disclosed in advance of the first public meeting after the conflict is identified, or within five days after the conflict is identified, whichever occurs first.

b. Disclosure of a conflict of interest pursuant to this section shall include the type, nature, and magnitude of the interests of the individual involved.

5. a. The Prescription Drug Affordability Board shall conduct a study of the entire pharmaceutical distribution and payment system in the State and any policy options that are being used in other states and countries to lower the list price of pharmaceutical drug products, including, but not limited to: establishing upper payment limits; using a reverse auction marketplace; using a closed formulary; authorizing importation of prescription drugs from other countries; and implementing a bulk purchasing process. The study required pursuant to this subsection shall be completed no later than 18 months after the effective date of this act.

b. No later than six months after the effective date of this act, the board shall conduct a study of the operation of the generic drug market in the United States, which study shall include a review of practitioner-administered drugs and consideration of:

(1) the prices of generic drugs on a year-to-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 annual State spending under the State Health Benefits Program, the School Employees Health Benefits Program, the Medicaid and NJ FamilyCare programs, the Senior Gold program, and the Pharmaceutical Assistance to the Aged and Disabled program; and

(6) any other issues the board deems relevant.

c. No later than six months after the effective date of this act, the board shall conduct a study of pharmacy benefit managers, with a focus on practices used by pharmacy benefit managers that may impact the cost of pharmaceutical drug products in New Jersey, as well as methods to regulate or otherwise restrict practices demonstrated to impact pharmaceutical drug product costs, including:

(1) requiring pharmacy benefits managers to disclose to the board the sources and formulas used by pharmacy benefit managers to determine multiple source generic drug pricing and brand-name drug pricing, which sources and formulas are set forth in contracts between a

pharmacy benefits manager and a pharmacy services administrative organization, or between a pharmacy benefits manager and a contracted pharmacy, pursuant to section 2 of P.L.2015, c.179 (C.17B:27F-2), and reviewing those sources and formulas;

(2) reviewing whether health benefits plans and pharmacy benefit managers apply all manufacturer and pharmacy discounts, rebates, concessions, and fees at the point of sale or otherwise use the savings to reduce premiums to reduce the cost of pharmaceutical drug products for covered persons;

(3) prohibiting pharmacy benefit managers from establishing high prices for payers and low reimbursement rates for pharmacies; and

(4) reviewing the effects of manufacturer couponing on premium costs as well as copay accumulator adjustments and copayment maximizers for such coupons, and ensuring that the value of manufacturer payments are counted against the patient's deductible and limits on out-of-pocket payments.

6. a. No later than 18 months after the effective date of this act, the Prescription Drug Affordability Board shall:

(1) collect and review publicly-available information regarding prescription drug product manufacturers, health benefits plan carriers, wholesale distributors, and pharmacy benefits managers; and

(2) identify states that require reporting on the cost of prescription drug products and initiate the process of entering into memoranda of understanding with those states to aid in the collection of transparency data for prescription drug products.

b. Based on the information and data collected pursuant to subsection a. of this section, the board shall, in consultation with the Prescription Drug Affordability Stakeholder Council:

(1) establish methods for collecting additional data necessary to carry out its duties under this act; and

(2) identify circumstances under which the cost of a prescription drug product may create or has created affordability challenges for the State health care system and for New Jersey patients.

c. The board shall use the information and data collected pursuant to subsection a. of this section to identify prescription drug products that are:

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

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

(b) a wholesale acquisition cost increase of $3,000 or more in any 12-month period, or over any course of treatment that is less than 12 months in duration;

(2) interchangeable biological products that have a launch wholesale acquisition cost that is not at least 15 percent lower than

the referenced brand name biological product at the time the interchangeable product is launched;

(3) generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost:

(a) of $100 or more for:

(i) 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;

(ii) 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

(iii) one unit of the drug, if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and

(b) that increased by 200 percent 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; and

(4) in consultation with the council, other prescription drug products that the board determines may create affordability issues for the State health care system and New Jersey patients.

7. a. After identifying prescription drug products pursuant to subsection c. of section 6 of this act, the Prescription Drug Affordability Board shall determine whether to conduct a cost review for each identified prescription drug product by seeking input from the Prescription Drug Affordability Stakeholder Council about the product and considering the average cost share of the product.

b. (1) 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 the State, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the prescription drug product.

(2) To the extent that there is no publicly-available information to conduct a cost review pursuant to this section, the board shall request the information from the manufacturer of the prescription drug product and, as appropriate, a wholesale distributor, pharmacy benefits manager, or health benefits plan carrier with relevant information on how the cost of the prescription drug product in the State was established. The failure of a manufacturer, wholesale distributor, pharmacy benefits manager, or health benefits plan carrier to provide the board with information requested under this paragraph shall not affect the ability of the board to conduct a review pursuant to subsection c. of this section.

c. (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 in a manner 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 challenges for the State health care system or high out-of-pocket costs for New Jersey patients.

(2) To the extent possible, in determining whether a prescription drug product identified pursuant to subsection c. of section 6 of this act has led or will lead to an affordability challenge, the board shall consider the following factors:

(a) the wholesale acquisition cost and any other relevant prescription drug cost index for the prescription drug product sold in the State;

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

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

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

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

(f) the costs to health benefits plans based on patient access consistent with United States Food and Drug Administration label indications;

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

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

(i) the relative financial effects on health, medical, and social service costs as can be quantified and compared to the baseline effects of existing therapeutic alternatives;

(j) the average patient copay or other cost-sharing for the prescription drug product in the State; and

(k) any additional factors established by the board by regulation.

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

(a) 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 the State;

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

(c) gross and net manufacturer, pharmacy benefits manager, and wholesale distributor revenues for the prescription drug product under review for the most recent tax year;

(d) any additional factors proposed by the manufacturer and appropriate health benefits plan carriers, wholesale distributors, and pharmacy benefits managers that the board considers relevant; and

(e) any additional factors that the board establishes by regulation.

d. The board's process and criteria for identifying prescription drugs pursuant to subsection c. of section 6 of this act, and for determining whether to conduct a cost review of the prescription drug pursuant to this section, shall be established by the board by rules and regulations adopted pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), which rules and regulations shall constitute the comprehensive operating plan governing the board, and may include such other requirements as shall be necessary to implement the provisions of this act.

8. All information and data obtained by the Prescription Drug Affordability Board pursuant to this act shall be made publicly available unless the board determines the information or data to be a trade secret or confidential or proprietary information. Information and data determined to be a trade secret or confidential or proprietary information shall not be a government record pursuant to P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.). Only board members and board staff shall have access to information and data the board determines to be a trade secret or confidential or proprietary information pursuant to this section.

9. a. If, pursuant to the study conducted under section 5 of this act, the Prescription Drug Affordability Board determines that it is in the best interests of the State to establish a process for establishing upper payment limits for, or allowing importation from other countries of, prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Prescription Drug Affordability Stakeholder Council, shall draft a plan of action for implementing the recommended action. The board, in its discretion, may recommend both establishing upper payments limits and allowing importation from other countries for a given prescription drug product.

(1) If the board determines it is in the best interests of the State to establish upper payment limits, the board's plan of action shall include

the criteria the board will use to establish upper payment limits, which criteria shall include consideration of:

(a) the cost of administering the prescription drug product;

(b) the cost of delivering the prescription drug product to consumers; and

(c) other relevant administrative costs related to the prescription drug product.

(2) If the board determines it is in the best interests of the State to establish a process for importing prescription drugs from other countries, the board's plan of action shall include the criteria the board will use to establish the process, which criteria shall include consideration of:

(a) the administrative costs of establishing a system to import prescription drugs;

(b) whether to allow direct importation by New Jersey consumers or to limit importation to pharmacies or to authorized State entities;

(c) the costs of developing mechanisms to ensure the safety and security of a prescription drug importation system, including mechanisms to verify the quality, source, and integrity of imported prescription drug products;

(d) whether the added costs of implementing a prescription drug product importation system will negate the anticipated savings of allowing prescription drug importation; and

(e) other relevant administrative costs.

b. The process for establishing upper payment limits shall:

(1) prohibit the application of an upper payment limit for a prescription drug that is included in the prescription drug shortage list promulgated by the United States Food and Drug Administration; and

(2) require the board to monitor the availability of any prescription drug product for which it establishes an upper payment limit and, if there becomes a shortage of the prescription drug product in the State, reconsider or suspend the upper payment limit.

c. No later than 24 months after the effective date of this act, the board shall submit a plan of action drafted pursuant to subsection a. of this section to the Legislature for approval. The plan shall be deemed rejected unless legislation implementing the plan is adopted within 90 days after the date the plan is submitted to Legislature for approval. Legislation approving a plan submitted by the board may include modifications to the plan as submitted for approval, and in no case shall a plan be deemed rejected solely because the legislation implementing the plan makes technical or substantive changes to the plan submitted by the board. The board shall have no authority to establish upper payment limits for prescription drug products pursuant to section 11 of this act, or authorize the importation of prescription drug products from other countries, unless the board's plan of action has been approved through the adoption of implementing legislation as provided in this subsection.

10. a. Subject to the requirements of subsection c. of section 10 of this act, commencing 30 months after the effective date of this act, the Prescription Drug Affordability Board may establish upper payment limits for prescription drug products that are:

(1) purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government;

(2) paid for through a health benefit plan on behalf of a unit of State or local government; or

(3) purchased or paid for by the State Medicaid or NJ FamilyCare programs.

b. The upper payment limits established pursuant to subsection a. of this section shall be established for prescription drug products that have led or will lead to an affordability challenge, and shall be established in accordance with the criteria established by the board by regulation.

c. The board shall monitor the availability of any prescription drug for which it establishes an upper payment limit and, if there becomes a shortage of the prescription drug product in the State, determine whether to suspend or alter the upper payment limit for that prescription drug product.

d. An upper payment limit established pursuant to subsection a. of this section shall not apply to any prescription drug product included in the prescription drug shortage list maintained by the United States Food and Drug Administration.

11. a. A person aggrieved by a decision or order of the Prescription Drug Affordability Board may seek a rehearing of the decision to the board within 30 days after the issuance of the decision or order, or the decision or order shall become final.

b. The board shall conduct a new hearing on a decision or order for which a rehearing is requested pursuant to subsection a. of this section, and make a final decision or issue a final order no later than 60 days after the rehearing is requested.

c. A final decision or order of the board may be appealed to the Appellate Division of the Superior Court no later than 45 days after issuance of the decision. The court shall have the power to grant such relief as it deems just and proper, and to make or enter an order enforcing, modifying, or setting aside, in whole or in part, the board's decision or order. The findings of fact on which a decision or order of the board is based shall be conclusive if supported by substantial evidence on the record considered as a whole.

d. Filing an appeal to the Appellate Division of the Superior Court pursuant to subsection c. of this section shall not stay enforcement of a final decision or order of the board unless a stay is issued by the court upon application in accordance with the Rules of Court or by the board upon terms and conditions as it deems proper.

12. The Prescription Drug Affordability Board shall submit the following reports to the Governor and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the Legislature:

a. No later than March 31 of each year, the board shall submit a report concerning:

(1) price trends for prescription drug products;

(2) the number of prescription drug products that were subject to board review and the results of the review; and

(3) recommendations for legislation or other action as may be necessary to make prescription drug products more affordable in the State.

b. No later than 18 months after the effective date of this act, the board shall submit a report concerning the board's recommendations with regard to each policy option reviewed under the study completed pursuant to subsection a. of section 5 of this act and its recommendations for legislative, executive, and administrative action as may be appropriate.

c. No later than 36 months after the effective date of this act, the board shall submit a report concerning:

(1) the legality, obstacles, and benefits of establishing upper payment limits on all purchases and payor reimbursements of prescription drug products in the State;

(2) recommendations as to whether the authority of the board should be expanded legislatively to allow the board to establish upper payment limits on all purchases and payor reimbursements of prescription drug products in the State; and

(3) recommendations concerning the importation of prescription drug products from other countries, including recommendations for legislation as may be necessary to authorize the practice and ensure the safety, security, quality, and integrity of imported prescription drug products.

13. a. There is appropriated from the General Fund to the Prescription Drug Affordability Board established pursuant to this act the sum of $1,000,000 million for the purposes of effectuating the provisions of this act.

b. The Legislature shall annually appropriate from the General Fund to the Prescription Drug Affordability Board established pursuant to this act the sum of $1,000,000 for the purposes of effectuating the provisions of this act.

14. This act shall take effect immediately.

STATEMENT

This bill establishes the Prescription Drug Affordability Board (Board), which will be charged with protecting New Jersey residents,

State and local governments, health benefits plans, health care providers, licensed pharmacies, and other stakeholders within the State health care system from the high costs of prescription drug products, including brand name and generic drugs, biological products, and interchangeable biological products. The Board will be established in, but not of, the Department of Law and Public Safety, and will be independent of any supervision or control by the department or any agency within the department.

The Board will comprise five public members and three alternate public members, who will participate in Board deliberations in any case in which a public member is recused. All Board members will be required to have expertise in health care economics or clinical medicine. The Governor, the President of the Senate, the Speaker of the General Assembly, and the Attorney General will each appoint one public member, and the President of the Senate and the Speaker of the General Assembly will jointly appoint the fifth member, who will serve as chair of the Board. The Governor, the President of the Senate, and the Speaker of the General Assembly will each appoint one alternate public member. To the extent practicable and consistent with State and federal law, the membership of the Board is to reflect the racial, ethnic, and gender diversity of the State.

Board members will serve for a term of five years, with staggered appointment for the public members first appointed. Board members will be eligible for reappointment, and vacancies in the membership are to be filled in the same manner as provided for the original appointment.

The chair of the Board is to hire an executive director, general counsel, and staff, and develop a five-year budget and staffing plan that will be subject to approval by the Board as a whole. The executive director, general counsel, and board staff will receive a salary as provided in the Board's budget. Board members will be entitled to such compensation as may be approved under the State budget, and will be entitled to reimbursement for expenses reasonably incurred in the performance of their official duties.

The Board will meet in open session at least once every six weeks, except that the chair will have the authority to postpone or cancel any required meeting. Three Board members will constitute a quorum for the purposes of conducting official Board business. Generally, Board deliberations and proceedings are to take place in open session; however the Board may meet in closed session to discuss trade secrets or confidential and proprietary data and information, which is defined in the bill to include any information that is not otherwise available from public sources. To the extent practicable, the Board is to access pricing information for prescription drug products by entering into memoranda of understanding with other states to which manufacturers already report pricing information, but it may seek out other available sources of pricing information.

The Board is to provide public notice of each Board meeting at least two weeks in advance of the meeting, and make materials for each

meeting available to the public at least seven calendar days in advance of the meeting. The Board is to provide an opportunity for public comment at each open meeting and provide the public with the opportunity to submit written comments on pending decisions.

Board members will be prohibited from employment with, serving on the board of, or consulting for, pharmaceutical manufacturers, pharmacy benefits managers, health benefits plan carriers, or wholesale distributors or related trade associations. Individuals appointed to the Board will be required to disclose, at the time of appointment, any conflict of interest, including whether the individual has any association that has the potential to bias or create the appearance of biasing the individual's decisions in Board matters. Public Board members are to 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 a financial benefit deriving from the work of the Board or a benefit from a manufacturer that, in the aggregate, exceeds $500 per year. Board members, staff, and third party contractors will be prohibited from accepting 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. The bill requires conflicts of interest involving Board staff, Board members, and mandatory recusals of Board members to be disclosed to the public on the board's Internet website, including information on the type, nature, and magnitude of the interests of the individual involved.

The Board will be required to conduct hearings on possible violations of the provisions of the bill and determine appropriate penalties or other remedies to be assessed for substantiated violations, and refer non-compliance matters to the Attorney General for further legal action. The Board will be permitted to enter into contracts with qualified, independent third parties for any service necessary to carry out its powers and duties. A person aggrieved by a decision or order of the Board will have 30 days to seek a rehearing of the decision or order; thereafter, the decision or order becomes final. When so requested, the Board will conduct a new hearing on the decision or order and make a final decision or issue a final order no later than 60 days after the rehearing is requested. A final decision of the Board may be appealed to the Appellate Division of the Superior Court no later than 45 days after issuance of the decision. The Board's findings of fact will be deemed conclusive on appeal if supported by substantial evidence on the record. An appeal to the Appellate Division will not automatically stay enforcement of the final order or decision; however, the court will have the authority to issue a stay as it deems proper.

The Board will be initially established using $1 million appropriated under the bill for this purpose. Thereafter, the Legislature is directed to annually appropriate $1 million to support the Board's operations.

The bill additionally establishes the Prescription Drug Affordability Stakeholder Council (Council), which will provide stakeholder input to assist the Board in making decisions. The Council will comprise 27

members, with nine members each to be appointed by the Speaker of the General Assembly, the Senate President, and the Governor. Council members will represent various stakeholders throughout the pharmaceutical and healthcare system, and are to collectively have knowledge of the pharmaceutical business model, supply chain business models, the practice of medicine and clinical training, consumer and patient perspectives, health care cost trends and drivers, clinical and health services research, and the State health care marketplace. To the extent practicable and consistent with State and federal law, the membership of the Council is to reflect the racial, ethnic, and gender diversity of the State. The chair of the Prescription Drug Affordability Board will select two Council members to serve as co-chairs of the Council. Members of the council will serve a term of three years, with staggered appointments for the members first appointed. Council members will be eligible for reappointment to the Council; vacancies in the membership are to be filled in the same manner as provided for the original appointment; and members will serve until a successor has been appointed. Council members will serve without compensation but may be reimbursed for expenses reasonably incurred in the performance of their official duties.

The bill requires the Prescription Drug Affordability Board to conduct a study of the entire pharmaceutical distribution and payment system in the State, as well as policy options being used in other states and countries to lower the list price of pharmaceutical drug products, including, but not limited to: establishing upper payment limits; using a reverse auction marketplace; using a closed formulary; allowing importation of pharmaceutical drug products from other countries; and implementing a bulk purchasing process. This study is to be completed no later than 18 months after the effective date of the bill.

The Board will also conduct a study of the operation of the generic drug market in the United States that includes a review of practitioner-administered drugs and that considers: the prices of generic drugs on a year-to-year basis; the degree to which generic drug prices affect yearly insurance premium changes; annual changes in insurance cost-sharing for generic drugs; the potential for, and history of, drug shortages; the degree to which generic drug prices affect annual State spending under the State Health Benefits Program, the School Employees Health Benefits Program, the Medicaid and NJ FamilyCare programs, the Senior Gold program, and the Pharmaceutical Assistance to the Aged and Disabled program; and any other issues the Board deems relevant.

The Board will further be required to conduct a study of pharmacy benefit managers, with a focus on practices used by pharmacy benefit managers that may impact the cost of pharmaceutical drug products in New Jersey, as well as methods to regulate or otherwise restrict practices demonstrated to impact pharmaceutical drug product costs, including: (1) requiring disclosure of the sources and formulas used by pharmacy benefit managers to determine multiple source generic drug pricing and brand-name drug pricing; (2) reviewing whether health

benefits plans and pharmacy benefit managers apply all manufacturer and pharmacy discounts, rebates, concessions, and fees at the point of sale or use the savings to reduce premiums to reduce the cost of pharmaceutical drug products for covered persons; (3) prohibiting pharmacy benefit managers from establishing high prices for payers and low reimbursement rates for pharmacies; and (4) reviewing the effects of manufacturer couponing on premium costs as well as copay accumulator adjustments and copayment maximizers for such coupons, and ensuring that the value of manufacturer payments are counted against the patient's deductible and limits on out-of-pocket payments.

The studies of the generic drug market and pharmacy benefit managers are to be conducted within six months of the effective date of the bill.

The Board is also required, in consultation with the Council, to collect and review publicly-available information regarding prescription drug product manufacturers, health benefits plan carriers, wholesale distributors, and pharmacy benefits managers; identify states that require reporting on the cost of prescription drug products; and initiate the process of entering into memoranda of understanding with those states to aid in the collection of transparency data for prescription drug products. The Board is to establish methods for collecting additional data necessary to carry out its duties, and identify circumstances under which the cost of a prescription drug product may create or has created affordability challenges for the State health care system and New Jersey patients.

The Board is to use the information and data collected under the bill to identify prescription drug products that have a significantly high wholesale acquisition cost or that have a wholesale acquisition cost that has increased by a significant percentage over a 12-month period, interchangeable biological products that have a launch wholesale cost that is not at least 15 percent lower than the referenced brand name biological product, generic drugs with a high wholesale acquisition cost or a wholesale acquisition cost that has significantly increased over the preceding 12 month period, as well as other prescription drug products that the Board determines may create affordability issues. After identifying prescription drug products, the Board will be required to determine whether to conduct a cost review for each identified prescription drug product by seeking input from the Council about the product and considering the average cost share of the product. The information to conduct a cost review may include any document or research related to the manufacturer's selection of the introductory price or price increase of the product, as well as additional information provided by various stakeholders upon request of the Board if other public information is not available.

A review of the cost of a prescription drug product is to determine whether use of the prescription drug product in a manner that is fully consistent with the labeling approved by the United States Food and Drug Administration (FDA) or standard medical practice has led or will

lead to affordability challenges. In determining whether a prescription drug product has led or will lead to an affordability challenge, the board is to consider: the wholesale acquisition cost and any other relevant prescription drug cost index for the product; the average monetary price concession, discount, or rebate provided by the manufacturer and the total amount of the price concession, discount, or rebate; the price at which therapeutic alternatives have been sold in the State; the average monetary concession, discount, or rebate provided by the manufacturer for therapeutic alternatives; the cost of the product to health benefits plans; the effects on patient access resulting from the cost of the product relative to insurance benefit design; the current or expected dollar value of the drug-specific patient access programs that are supported by the manufacturer; the relative financial effects on health, medical, and social service costs; the average patient copay or other cost-sharing for the product; and any additional factors the Board establishes by regulation.

If the Board is unable to determine whether a prescription drug product will produce or has produced affordability challenges, the Board may additionally consider: the manufacturer's research and development costs in proportion to the manufacturer's sales in the State; the portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment; gross and net revenues for the product; any additional factors proposed by the various stakeholders that the Board considers relevant; and any additional factors the Board establishes by regulation.

The Board's criteria for identifying prescription drugs and determining whether to conduct a cost review are to be established by regulation, which, along with any other requirements the Board establishes by regulation, will constitute the comprehensive operating plan governing the Board.

If the Board determines that it is in the best interests of the State to develop a process to establish upper payment limits for, or allow importation from other countries of, prescription drug products that it determines have led or will lead to an affordability challenge, the Board, in conjunction with the Council, will be required to draft a plan of action for implementing the process that includes the criteria the Board will use to establish upper payment limits or consideration of certain cost and logistical factors that may affect importations from other countries. The board may recommend both establishing upper payment limits and allowing importation of pharmaceutical products from other countries.

The process for establishing upper payment limits will be required to prohibit the application of an upper payment limit for a drug that is included in the FDA's prescription drug shortage list, and will require the Board to monitor the availability of any prescription drug product for which it establishes an upper payment limit and reconsider or suspend the upper payment limit if there are availability issues. Upper payment limits will apply to prescription drug products purchased by or

on behalf of State and local government entities, programs, and organizations.

The Board's action plan is to be submitted to the Legislature for approval no later than 24 months after the effective date of the bill. The plan will be deemed rejected unless legislation implementing the plan is adopted within 90 days after the date the plan is submitted to the Legislature. Legislation approving a plan may include modifications to the plan that was submitted by the Board, and in no case may a plan be deemed rejected solely because the implementing legislation includes technical or substantive differences from the plan that was submitted for approval. The Board will have no authority to establish upper payment limits for, or importations from other countries of, prescription drug products unless the action plan has been approved through the adoption of implementing legislation.

The bill requires the Board to submit various reports to the Governor and to the Legislature, including reports concerning price trends for prescription drug products; the number of products that were subject to board review and the results of the review; and recommendations for legislation or other action as may be needed to make prescription drug products more affordable in the State. Separate reports will include the Board's recommendations with regard to various policy options to address prescription drug product affordability; the legality, obstacles, and benefits of establishing upper payment limits, as well as recommendations as to whether the authority of the Board should be expanded; and recommendations concerning the importation of prescription drug products from other countries, including recommendations for legislation as may be necessary to authorize the practice and ensure the safety, security, quality, and integrity of imported prescription drug products.

All information and data obtained by the Board will be made publicly available unless the Board determines the information or data to be a trade secret, confidential, or proprietary. Information or data deemed to be a trade secret, confidential, or proprietary will be exempt from the State's open public records laws.