SENATE, No. 1066

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

Sponsored by:
Senator TROY SINGLETON
District 7 (Burlington)
Senator LORETTA WEINBERG
District 37 (Bergen)

Co-Sponsored by:
Senators Greenstein, Turner, Brown, Pou, Ruiz, Gopal, A.M.Bucco, Addiego, Lagana, Gill and Codey

SYNOPSIS

Establishes Prescription Drug Affordability Board.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 11/8/2021)

AN ACT concerning pharmaceuticals and supplementing Title 24 of the Revised Statutes.

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).

"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.

2. a. The Prescription Drug Affordability Board is established in, but not of, the Division of Consumer Affairs in the Department of Law and Public Safety.

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 or alternate 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.

(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 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) adopt rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to implement the provisions of this act; and

(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. 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; 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.

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.

8. All information and data obtained by the Prescription Drug Affordability Board pursuant to this act that is not otherwise publicly available shall be deemed to be a trade secret and confidential and proprietary information, and shall not be deemed to be a public 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 deemed to be a trade secret and confidential and proprietary information pursuant to this section.

9. a. No later than 18 months after the effective date of this act, the Prescription Drug Affordability Board shall identify a funding source for the board. If appropriate, the board may submit to the Legislature its recommendations for legislation or other action the board determines to be necessary to establish a funding source for the board. In identifying an appropriate funding source, the board shall consider:

(1) assessing and collecting a fee on manufacturers, pharmacy benefits managers, health benefits plan carriers, and other entities;

(2) using rebates received by State and local government entities from manufacturers; and

(3) any other method the board determines to be an appropriate source of funding.

b. The board shall be established using general funds, which funds shall be repaid to the State with funds from the funding source identified and established pursuant to subsection a. of this section.

10. 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. (1) 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 Legislature shall have 45 days to approve the plan by adopting a concurrent resolution, provided that, if either House of the Legislature does not convene a voting session during that 45-day period, that House shall have until the second voting session scheduled for the House after the expiration of the 45-day period to adopt a concurrent resolution approving the plan. If the Legislature does not approve the plan, the board shall submit the plan to the Governor and the Attorney General for approval pursuant to paragraph (2) of this subsection.

(2) The Governor and the Attorney General shall have 45 days to approve a plan of action submitted to them pursuant to paragraph (1) of this subsection. If the Governor and the Attorney General do not both approve the plan within 45 days, the plan shall be deemed rejected.

(3) 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 by the Legislature pursuant to paragraph (1) of this subsection or by the Governor and the Attorney General pursuant to paragraph (2) of this subsection.

11. 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.

12. A person aggrieved by a decision of the Prescription Drug Affordability Board may appeal the decision to the board within 30 days after the issuance of the decision. The board shall hear the appeal and make a final decision no later than 60 days after the appeal is requested. A final decision of the board may be appealed to the Appellate Division of the Superior Court.

13. 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 18 months after the effective date of this act, and annually thereafter, 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 price 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 price 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.

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 Division of Consumer Affairs in the Department of Law and Public Safety.

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 may adopt rules and regulations to implement the provisions of the bill, and may 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 of the Board

may appeal the decision within 30 days after the decision is issued. The Board will hear the appeal and make a final decision no later than 60 days after the appeal is requested. A final decision of the Board may be appealed to the Appellate Division of the Superior Court.

The Board will be initially established using general funds; however, no later than 18 months after the effective date of the bill, the Board is to identify an independent funding source and, if appropriate, submit to the Legislature its recommendations concerning legislation or other action necessary to establish a funding source. In identifying an independent funding source, the Board may consider assessing fees on various pharmaceutical industry entities, using rebates received by State and local government entities from manufacturers, or using other appropriate methods. The Board is to repay the General Fund for the costs of its establishment from the independent funding source.

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; 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. This study is 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, 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.

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. Subject to certain considerations, the Legislature will have 45 days to approve the plan by adopting a concurrent resolution; if the

Legislature does not approve the plan, the Board will then submit the plan to the Governor and the Attorney General for approval. If the plan is not approved by both the Governor and the Attorney General within 45 days, the plan will be deemed rejected. 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 either by the Legislature or by both the Governor and the Attorney General.

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 price 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.