

[First Reprint]

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:

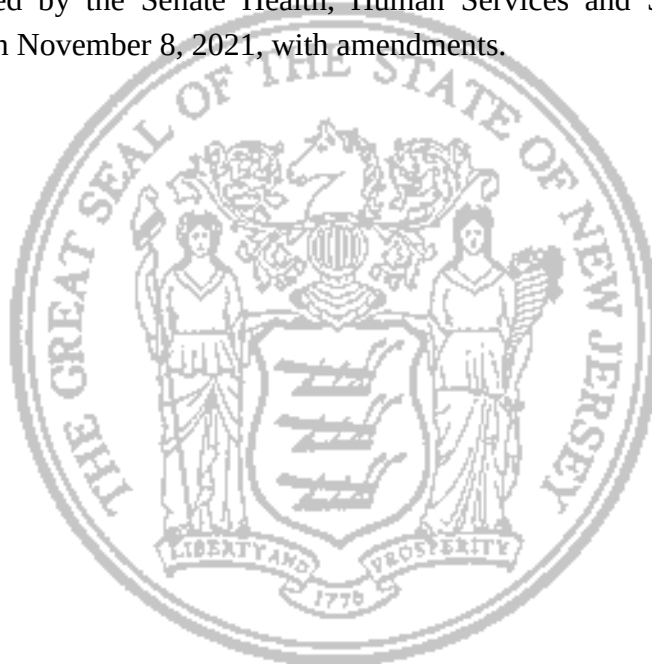
**Senators Greenstein, Turner, Brown, Pou, Ruiz, Gopal, A.M.Bucco,
Addiego, Lagana, Gill, Codey, Sacco, Cruz-Perez and Bateman**

SYNOPSIS

Establishes Prescription Drug Affordability Board; appropriates \$1 million.

CURRENT VERSION OF TEXT

As reported by the Senate Health, Human Services and Senior Citizens Committee on November 8, 2021, with amendments.



(Sponsorship Updated As Of: 12/2/2021)

1 AN ACT concerning pharmaceuticals ¹**[and]** ¹ supplementing Title
 2 24 of the Revised Statutes ¹, and making an appropriation¹ .

3
 4 **BE IT ENACTED** by the Senate and General Assembly of the State
 5 of New Jersey:

6
 7 1. As used in this act:

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

10 “Board” means the Prescription Drug Affordability Board
 11 established pursuant to section 2 of this act.

12 “Brand name drug” means a drug that is produced or distributed in
 13 accordance with an original new drug application approved under 21
 14 U.S.C. s.355(c). “Brand name drug” shall not include an authorized
 15 generic drug as defined in 42 C.F.R. s.447.502.

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

18 “Council” means the Prescription Drug Affordability Stakeholder
 19 Council established pursuant to section 3 of this act.

20 “Generic drug” means: a retail drug that is marketed or distributed
 21 in accordance with an abbreviated new drug application that is
 22 approved under 21 U.S.C. s.355(j); an authorized generic as defined in
 23 42 C.F.R. s.447.502; or a drug that entered the market before 1962 that
 24 was not originally marketed under a new drug application.

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

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

29 ¹“Logistics provider” means an entity that receives a prescription
 30 drug product from the original or contract manufacturer, warehouses
 31 and delivers the prescription drug product at the direction of the
 32 manufacturer, and does not purchase, sell, trade, or take title to the
 33 prescription drug product.¹

34 “Manufacturer” means an entity that: engages in the manufacture
 35 of a prescription drug product or enters into a lease with another
 36 manufacturer to market and distribute a prescription drug product
 37 under the entity’s own name; and sets or changes the wholesale
 38 acquisition cost of the prescription drug product that it manufactures or
 39 markets.

40 “Prescription drug product” means a brand name drug, a generic
 41 drug, a biological product, or an interchangeable product.

42 ¹“Wholesale distributor” means a business registering under
 43 P.L.1961, c.52 (C.24:6B-1 et seq.) that is engaged in the wholesale
 44 distribution of a prescription drug product. “Wholesale distributor”
 45 shall not include a common carrier, or an employee thereof, whose

EXPLANATION – Matter enclosed in bold-faced brackets **[thus]** in the above bill is
 not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Senate SHH committee amendments adopted November 8, 2021.

1 possession of a prescription drug product is in the usual course of the
2 common carrier's or employee's business or employment, and shall
3 not include a logistics provider or an employee thereof.¹

4
5 2. a. The Prescription Drug Affordability Board is established in,
6 but not of, ¹~~the Division of Consumer Affairs in~~¹ the Department of
7 Law and Public Safety. ¹Notwithstanding the foregoing, the board
8 shall be independent of any supervision or control by the department
9 or by any agency, board, office, or individual within the department.¹

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

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

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

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

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

30 (3) No public member ¹~~or alternate public member~~¹ of the board
31 may be an employee of, a board member of, or a consultant to, a
32 manufacturer, pharmacy benefits manager, health benefits plan carrier,
33 or wholesale distributor or related trade association. ¹No alternate
34 public member of the board may be an employee of, a board member
35 of, or a consultant to, a health benefits plan carrier or a wholesale
36 distributor or related trade association.¹

37 (4) An individual appointed to the board as a public member or an
38 alternate public member shall disclose, at the time of appointment, any
39 conflict of interest, including whether the individual has an
40 association, including a financial or personal association, that has the
41 potential to bias or has the appearance of biasing the individual's
42 decision in matters related to the board or the conduct of the board's
43 activities.

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

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

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

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

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

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

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

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

31 (d) any ¹enforcement, regulatory, or other¹ decision by the board.

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

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

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

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

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

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

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

1 (b) accessing other available pricing information.

2 (8) (a) Public members of the board shall recuse themselves from
3 decisions related to a prescription drug product if the member, or an
4 immediate family member of the member, has received or could
5 receive any of the following:

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

8 (ii) a financial benefit from any person that owns, manufactures, or
9 provides prescription drug products, services, or items to be studied by
10 the board that, in the aggregate, exceeds \$500 per year.

11 (b) For the purposes of subparagraph (a) of this paragraph, a
12 financial benefit includes honoraria, fees, stock, the value of the
13 member's or immediate family member's stock holdings, and any
14 direct financial benefit deriving from the finding of a review
15 conducted under this act.

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

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

23 (1) ¹~~adopt rules and regulations, pursuant to the "Administrative~~
24 ~~Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to implement~~
25 ~~the provisions]~~ conduct hearings concerning possible violations of this
26 act and determine appropriate penalties or other remedies to be
27 assessed against individuals in violation of the requirements¹ of this
28 act; ¹~~and]~~¹

29 (2) ¹refer non-compliance matters to the Attorney General, who
30 may pursue appropriate legal remedies; and

31 (3)¹ enter into a contract with a qualified, independent third party
32 for any service necessary to carry out the powers and duties of the
33 board. Unless permission is granted by the board, a third party hired
34 by the board pursuant to this paragraph shall not release, publish, or
35 otherwise use any information to which the third party has access
36 under its contract.

37 h. Public members, alternate public members, staff, and third
38 party contractors of the board shall not accept any gift or donation of
39 services or property that indicates a potential conflict of interest or has
40 the appearance of biasing the work of the board.

41

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

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

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

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

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

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

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

- 30 (a) the pharmaceutical business model;
- 31 (b) supply chain business models;
- 32 (c) the practice of medicine and clinical training;
- 33 (d) consumer and patient perspectives;
- 34 (e) health care cost trends and drivers;
- 35 (f) clinical and health services research; and
- 36 (g) the State's health care marketplace.

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

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

43 e. Each member of the council shall serve a term of three
44 years, except that, of the members first appointed, nine shall serve
45 for a term of one year, nine shall serve for a term of two years, and
46 nine shall serve for a term of three years. Members shall be eligible
47 for reappointment to the council. Vacancies in the membership
48 shall be filled in the same manner as provided for the original

1 appointment, and members shall serve until a successor has been
2 appointed.

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

6

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

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

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

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

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

27

28 5. a. The Prescription Drug Affordability Board shall conduct a
29 study of the entire pharmaceutical distribution and payment system in
30 the State and any policy options that are being used in other states and
31 countries to lower the list price of pharmaceutical drug products,
32 including, but not limited to: establishing upper payment limits; using
33 a reverse auction marketplace; 'using a closed formulary;'¹ authorizing
34 importation of prescription drugs from other countries; and
35 implementing a bulk purchasing process. The study required pursuant
36 to this subsection shall be completed no later than 18 months after the
37 effective date of this act.

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

42 (1) the prices of generic drugs on a year-to-year basis;

43 (2) the degree to which generic drug prices affect yearly insurance
44 premium changes;

45 (3) annual changes in insurance cost-sharing for generic drugs;

46 (4) the potential for, and history of, drug shortages;

47 (5) the degree to which generic drug prices affect annual State
48 spending under the State Health Benefits Program, the School

1 Employees Health Benefits Program, the Medicaid and NJ FamilyCare
2 programs, the Senior Gold program, and the Pharmaceutical
3 Assistance to the Aged and Disabled program; and

4 (6) any other issues the board deems relevant.

5 ¹c. No later than six months after the effective date of this act, the
6 board shall conduct a study of pharmacy benefit managers, with a
7 focus on practices used by pharmacy benefit managers that may
8 impact the cost of pharmaceutical drug products in New Jersey, as well
9 as methods to regulate or otherwise restrict practices demonstrated to
10 impact pharmaceutical drug product costs, including:

11 (1) requiring pharmacy benefits managers to disclose to the board
12 the sources and formulas used by pharmacy benefit managers to
13 determine multiple source generic drug pricing and brand-name drug
14 pricing, which sources and formulas are set forth in contracts between
15 a pharmacy benefits manager and a pharmacy services administrative
16 organization, or between a pharmacy benefits manager and a
17 contracted pharmacy, pursuant to section 2 of P.L.2015, c.179
18 (C.17B:27F-2), and reviewing those sources and formulas;

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

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

26 (4) reviewing the effects of manufacturer couponing on premium
27 costs as well as copay accumulator adjustments and copayment
28 maximizers for such coupons, and ensuring that the value of
29 manufacturer payments are counted against the patient's deductible
30 and limits on out-of-pocket payments.¹

31
32 6. a. No later than 18 months after the effective date of this
33 act, the Prescription Drug Affordability Board shall:

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

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

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

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

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

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

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

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

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

15 (2) interchangeable biological products that have a launch
16 wholesale acquisition cost that is not at least 15 percent lower than
17 the referenced brand name biological product at the time the
18 interchangeable product is launched;

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

22 (a) of \$100 or more for:

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

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

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

32 (b) that increased by 200 percent or more during the
33 immediately preceding 12-month period, as determined by the
34 difference between the resulting wholesale acquisition cost and the
35 average of the wholesale acquisition cost reported over the
36 immediately preceding 12 months; and

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

40

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

47 b. (1) The information to conduct a cost review may include any
48 document and research related to the manufacturer's selection of the

1 introductory price or price increase of the prescription drug product,
2 including life cycle management, net average price in the State, market
3 competition and context, projected revenue, and the estimated value or
4 cost-effectiveness of the prescription drug product.

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

16 c. (1) If the board conducts a review of the cost of a prescription
17 drug product, the review shall determine whether use of the
18 prescription drug product in a manner that is fully consistent with the
19 labeling approved by the United States Food and Drug Administration
20 or standard medical practice has led or will lead to affordability
21 challenges for the State health care system or high out-of-pocket costs
22 for New Jersey patients.

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

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

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

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

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

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

46 (f) the costs to health benefits plans based on patient access
47 consistent with United States Food and Drug Administration label
48 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.

¹d. 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.¹

8. All information and data obtained by the Prescription Drug Affordability Board pursuant to this act ¹~~that is not otherwise~~ shall be made¹ publicly available ¹~~shall be deemed~~ unless the board determines the information or data¹ to be a trade secret ¹~~and~~ or¹ confidential ¹~~and~~ or¹ proprietary information ¹~~, and shall not be deemed to~~ . Information and data determined to be a trade secret or

1 confidential or proprietary information shall not¹ be a ¹~~['public]~~
2 ~~government~~¹ record pursuant to P.L.1963, c.73 (C.47:1A-1 et seq.) or
3 P.L.2001, c.404 (C.47:1A-5 et al.). Only board members and board
4 staff shall have access to information and data ¹~~['deemed]~~ the board
5 determines¹ to be a trade secret ¹~~['and]~~ or¹ confidential ¹~~['and]~~ or¹
6 proprietary information pursuant to this section.
7

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

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

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

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

21 b. The board shall be established using general funds, which
22 funds shall be repaid to the State with funds from the funding
23 source identified and established pursuant to subsection a. of this
24 section.¹
25

26 ¹~~['10.]~~ 9.¹ a. If, pursuant to the study conducted under section 5
27 of this act, the Prescription Drug Affordability Board determines that it
28 is in the best interests of the State to establish a process for
29 establishing upper payment limits for, or allowing importation from
30 other countries of, prescription drug products that it determines have
31 led or will lead to an affordability challenge, the board, in conjunction
32 with the Prescription Drug Affordability Stakeholder Council, shall
33 draft a plan of action for implementing the recommended action. The
34 board, in its discretion, may recommend both establishing upper
35 payments limits and allowing importation from other countries for a
36 given prescription drug product.

37 (1) If the board determines it is in the best interests of the State to
38 establish upper payment limits, the board's plan of action shall include
39 the criteria the board will use to establish upper payment limits, which
40 criteria shall include consideration of:

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

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

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

46 (2) If the board determines it is in the best interests of the State to
47 establish a process for importing prescription drugs from other

1 countries, the board's plan of action shall include the criteria the board
2 will use to establish the process, which criteria shall include
3 consideration of:

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

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

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

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

15 (e) other relevant administrative costs.

16 b. The process for establishing upper payment limits shall:

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

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

24 c. **'[(1)]'** No later than 24 months after the effective date of this
25 act, the board shall submit a plan of action drafted pursuant to
26 subsection a. of this section to the Legislature for approval. The
27 **'[Legislature shall have 45] plan shall be deemed rejected unless**
28 **legislation implementing the plan is adopted within 90'** days **'[to**
29 approve the plan by adopting a concurrent resolution, provided that, if
30 either House of the Legislature does not convene a voting session
31 during that 45-day period, that House shall have until the second
32 voting session scheduled for the House after the expiration of the 45-
33 day period to adopt a concurrent resolution approving the plan. If the
34 Legislature does not approve the plan, the board shall submit the plan
35 to the Governor and the Attorney General for approval pursuant to
36 paragraph (2) of this subsection.

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

42 (3) **after the date the plan is submitted to Legislature for approval.**
43 **Legislation approving a plan submitted by the board may include**
44 **modifications to the plan as submitted for approval, and in no case**
45 **shall a plan be deemed rejected solely because the legislation**
46 **implementing the plan makes technical or substantive changes to the**
47 **plan submitted by the board.'**¹ The board shall have no authority to

1 establish upper payment limits for prescription drug products pursuant
2 to section 11 of this act, or authorize the importation of prescription
3 drug products from other countries, unless the board's plan of action
4 has been approved ¹by the Legislature pursuant to paragraph (1) of
5 through the adoption of implementing legislation as provided in¹ this
6 subsection ¹or by the Governor and the Attorney General pursuant to
7 paragraph (2) of this subsection¹ .

8
9 ¹~~11.~~ 10.¹ a. Subject to the requirements of subsection c. of
10 section 10 of this act, commencing 30 months after the effective
11 date of this act, the Prescription Drug Affordability Board may
12 establish upper payment limits for prescription drug products that
13 are:

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

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

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

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

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

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

34
35 ¹~~12.~~ 11. a.¹ A person aggrieved by a decision ¹or order¹ of the
36 Prescription Drug Affordability Board may ¹appeal¹ seek a rehearing
37 of¹ the decision to the board within 30 days after the issuance of the
38 decision ¹or order, or the decision or order shall become final¹ .

39 ¹b.¹ The board shall ¹hear the appeal¹ conduct a new hearing on
40 a decision or order for which a rehearing is requested pursuant to
41 subsection a. of this section,¹ and make a final decision ¹or issue a
42 final order¹ no later than 60 days after the ¹appeal¹ rehearing¹ is
43 requested.

44 ¹c.¹ A final decision ¹or order¹ of the board may be appealed to
45 the Appellate Division of the Superior Court ¹no later than 45 days¹
46 after issuance of the decision. The court shall have the power to grant
47 such relief as it deems just and proper, and to make or enter an order

1 enforcing, modifying, or setting aside, in whole or in part, the board's
2 decision or order. The findings of fact on which a decision or order of
3 the board is based shall be conclusive if supported by substantial
4 evidence on the record considered as a whole.

5 d. Filing an appeal to the Appellate Division of the Superior
6 Court pursuant to subsection c. of this section shall not stay
7 enforcement of a final decision or order of the board unless a stay is
8 issued by the court upon application in accordance with the Rules of
9 Court or by the board upon terms and conditions as it deems proper¹ .

10
11 ¹**13.** 12.¹ The Prescription Drug Affordability Board shall
12 submit the following reports to the Governor and, pursuant to section 2
13 of P.L.1991, c.164 (C.52:14-19.1), to the Legislature:

14 a. No later than ¹**18** months after the effective date of this act,
15 and annually thereafter **March 31 of each year**¹ , the board shall
16 submit a report concerning:

17 (1) price trends for prescription drug products;

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

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

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

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

31 (1) the legality, obstacles, and benefits of establishing upper
32 ¹**price** payment¹ limits on all purchases and payor reimbursements
33 of prescription drug products in the State;

34 (2) recommendations as to whether the authority of the board
35 should be expanded legislatively to allow the board to establish upper
36 ¹**price** payment¹ limits on all purchases and payor reimbursements
37 of prescription drug products in the State; and

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

43
44 ¹**13.** a. There is appropriated from the General Fund to the
45 Prescription Drug Affordability Board established pursuant to this act
46 the sum of \$1,000,000 million for the purposes of effectuating the
47 provisions of this act.

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

5

6 14. This act shall take effect immediately.