

[First Reprint]

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)

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District 6 (Burlington and Camden)

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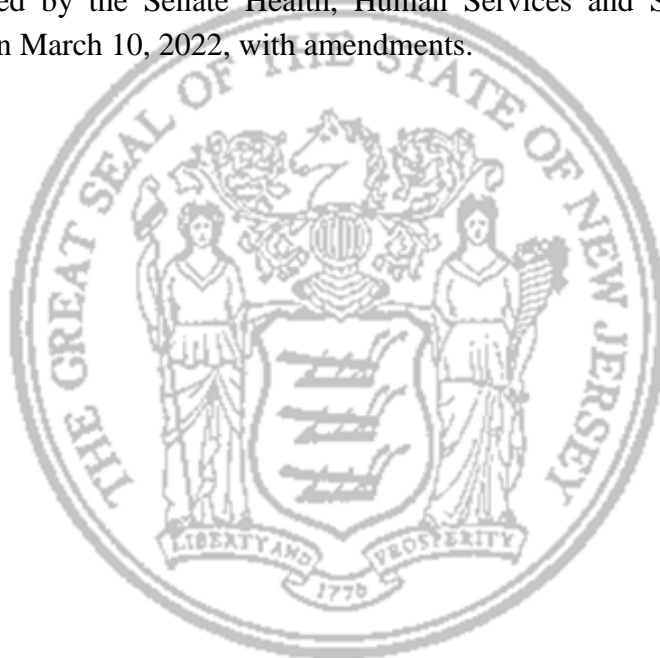
**Senators Greenstein, Turner, Pou, Ruiz, Gopal, A.M.Bucco, Lagana, Gill,
Codey, Sacco, Cruz-Perez, Cunningham, Cryan, Stack and Madden**

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 March 10, 2022, with amendments.



(Sponsorship Updated As Of: 3/24/2022)

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

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 “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.

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 “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”

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 March 10, 2022.

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

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

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

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

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

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

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

32 (3) No public member ¹or alternate public member¹ of the board
33 may be an employee of, a board member of, or a consultant to, a
34 manufacturer, pharmacy benefits manager, pharmacy services
35 administrative organization, pharmacy, ¹pharmacist,¹ health
36 benefits plan carrier, or wholesale distributor or related trade
37 association. ¹【No alternate public member of the board may be an
38 employee of, a board member of, or a consultant to, a health
39 benefits plan carrier or a wholesale distributor or related trade
40 association.】¹

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

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

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

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

22 f. The board shall meet in open session at least once every six
23 weeks, provided that the chair shall have the authority to postpone
24 or cancel any required meeting. ¹Subject to the requirements of
25 paragraph (2) of this subsection, all meetings of the board shall be
26 subject to the requirements of the “Senator Byron M. Baer Open
27 Public Meetings Act,” P.L.1975, c.231 (C.10:4-6 et seq.).¹ Three
28 members shall constitute a quorum for the purposes of conducting
29 official board business.

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

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

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

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

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

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

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

- 1 (4) The board shall provide an opportunity for public comment
2 at each open meeting of the board.
- 3 (5) The board shall provide the public with the opportunity to
4 provide written comments on pending decisions of the board.
- 5 (6) The board may allow expert testimony at board meetings,
6 including when the board meets in closed session.
- 7 (7) To the extent practicable, the board shall access pricing
8 information for prescription drug products by:
- 9 (a) entering into a memorandum of understanding with another
10 state to which manufacturers already report pricing information;
11 and
- 12 (b) accessing other available pricing information.
- 13 (8) (a) Public members of the board shall recuse themselves
14 from decisions related to a prescription drug product if the member,
15 or an immediate family member of the member, has received or
16 could receive any of the following:
- 17 (i) a direct financial benefit of any amount deriving from the
18 result or finding of a study or determination by or for the board; or
- 19 (ii) a financial benefit from any person that owns, manufactures,
20 or provides prescription drug products, services, or items to be
21 studied by the board that, in the aggregate, exceeds \$500 per year.
- 22 (b) For the purposes of subparagraph (a) of this paragraph, a
23 financial benefit includes honoraria, fees, stock, the value of the
24 member's or immediate family member's stock holdings, and any
25 direct financial benefit deriving from the finding of a review
26 conducted under this act.
- 27 (c) An alternate public member shall serve in the place of a
28 recused public member, provided the alternate public member or an
29 immediate family member of the alternate public member has not
30 received, and could not receive, any financial benefit for which
31 recusal is required pursuant to subparagraph (a) of this paragraph.
- 32 g. In addition to the other powers set forth in this act, the board
33 may:
- 34 (1) conduct hearings concerning possible violations of this act
35 and determine appropriate penalties or other remedies to be
36 assessed against individuals in violation of the requirements of this
37 act;
- 38 (2) refer non-compliance matters to the Attorney General, who
39 may pursue appropriate legal remedies; and
- 40 (3) enter into a contract with a qualified, independent third party
41 for any service necessary to carry out the powers and duties of the
42 board. Unless permission is granted by the board, a third party
43 hired by the board pursuant to this paragraph shall not release,
44 publish, or otherwise use any information to which the third party
45 has access under its contract.
- 46 h. Public members, alternate public members, staff, and third
47 party contractors of the board shall not accept any gift or donation

1 of services or property that indicates a potential conflict of interest
2 or has the appearance of biasing the work of the board.

3 ¹i. A member of the board shall not be liable in an action for
4 damages to any person for any action taken or recommendation
5 made by the member within the scope of the member's functions as
6 a member, if the action or recommendation was taken or made
7 without malice. The members of the board shall be indemnified and
8 their defense of any action provided for in the same manner and to
9 the same extent as employees of the State under the "New Jersey
10 Tort Claims Act," P.L.1972, c.45 (C.59:1-1 et seq.) on account of
11 acts or omissions in the scope of their service.¹

12

13 3. a. The Prescription Drug Affordability Stakeholder Council
14 is established in ¹**[**, but not of,**]¹ the Prescription Drug
15 Affordability Board.**

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

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

21 (1) The Speaker of the General Assembly shall appoint nine
22 members, including: (a) one representative of generic drug
23 corporations; (b) one representative of nonprofit health benefits
24 plan carriers; (c) one representative of a Statewide health care
25 advocacy coalition; (d) one representative of a Statewide advocacy
26 organization for seniors; (e) one representative of a Statewide
27 organization for diverse communities; (f) one representative of a
28 labor union; (g) one health services researcher specializing in
29 prescription drugs; ¹**[and]**¹ (h) ¹**[two public members]** one
30 representative of a Medicaid managed care organization; and (i) one
31 public member¹ ;

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

40 (3) The Governor shall appoint nine members, including: (a)
41 one representative of brand name drug corporations; (b) one
42 representative of generic drug corporations; (c) one representative
43 of biotechnology companies; (d) one representative of for profit
44 health benefits plan carriers; (e) one representative of employers; (f)
45 one representative of pharmacy benefits managers; (g) one
46 representative of pharmacists; (h) one pharmacologist; and (i) one
47 ¹**[public member]** representative of wholesale distributors¹ .

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

- 3 (a) the pharmaceutical business model;
- 4 (b) supply chain business models;
- 5 (c) the practice of medicine and clinical training;
- 6 (d) consumer and patient perspectives;
- 7 (e) health care cost trends and drivers;
- 8 (f) clinical and health services research; and
- 9 (g) the State's health care marketplace.

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

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

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

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

27

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

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

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

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

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

1 5. a. The Prescription Drug Affordability Board shall conduct
2 a study of the entire pharmaceutical distribution and payment
3 system in the State and any policy options that are being used in
4 other states and countries to lower the list price of pharmaceutical
5 drug products, including, but not limited to: establishing upper
6 payment limits; ¹~~using a reverse auction marketplace~~ revising the
7 number of permitted cost sharing tiers and the limitations on cost
8 sharing amounts; enhancing distribution of specialty drugs;
9 developing, or adopting measures to facilitate the development of,
10 new supply pipelines; adopting measures to facilitate the
11 availability of new interchangeable biological products; adopting
12 measures to promote the administration of pharmaceutical drug
13 products in the most cost-effective settings¹ ; using a closed
14 formulary; authorizing importation of prescription drugs from other
15 countries; and implementing a bulk purchasing process. The study
16 required pursuant to this subsection shall be completed no later than
17 18 months after the effective date of this act.

18 b. No later than six months after the effective date of this act,
19 the board shall conduct a study of the operation of the generic
20 ¹~~drug market~~ , brand name, and specialty drug markets¹ in the
21 United States, which study shall include a review of practitioner-
22 administered drugs and consideration of:

23 (1) the prices of generic ¹, brand name, and specialty¹ drugs on
24 a year-to-year basis;

25 (2) the degree to which generic ¹, brand name, and specialty¹
26 drug prices affect yearly insurance premium changes;

27 (3) annual changes in insurance cost-sharing for generic ¹, brand
28 name, and specialty¹ drugs;

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

30 (5) the degree to which generic ¹, brand name, and specialty¹
31 drug prices affect annual State spending under the State Health
32 Benefits Program, the School Employees' Health Benefits Program,
33 the Medicaid and NJ FamilyCare programs, the Senior Gold
34 program, and the Pharmaceutical Assistance to the Aged and
35 Disabled program; and

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

37 c. No later than six months after the effective date of this act,
38 the board shall conduct a study of pharmacy benefit managers ¹and
39 pharmacy services administrative organizations¹ , with a focus on
40 practices used by pharmacy benefit managers ¹and pharmacy
41 services administrative organizations¹ that may impact the cost of
42 pharmaceutical drug products in New Jersey, as well as methods to
43 regulate or otherwise restrict practices demonstrated to impact
44 pharmaceutical drug product costs, including:

45 (1) requiring pharmacy benefits managers to disclose to the
46 board the sources and formulas used by pharmacy benefit managers

1 to determine multiple source generic drug pricing and brand-name
2 drug pricing, which sources and formulas are set forth in contracts
3 between a pharmacy benefits manager and a pharmacy services
4 administrative organization, or between a pharmacy benefits
5 manager and a contracted pharmacy, pursuant to section 2 of
6 P.L.2015, c.179 (C.17B:27F-2), and reviewing those sources and
7 formulas;

8 (2) ¹requiring pharmacy services administrative organizations to
9 disclose to the board the sources and formulas used by pharmacy
10 services administrative organizations to determine multiple source
11 generic drug pricing and brand-name drug pricing, which sources
12 and formulas are set forth in contracts between a pharmacy services
13 administrative organization and a pharmacy benefits manager, or
14 between a pharmacy services administrative organization and a
15 contracted pharmacy, and reviewing those sources and formulas;

16 (3)¹ reviewing whether health benefits plans and pharmacy
17 benefit managers ¹and pharmacy services administrative
18 organizations¹ apply all manufacturer and pharmacy discounts,
19 rebates, concessions, and fees at the point of sale or otherwise use
20 the savings to reduce premiums to reduce the cost of pharmaceutical
21 drug products for covered persons ¹, consistent with applicable
22 State and federal laws¹ ;

23 ¹[(3) prohibiting pharmacy benefit managers from establishing
24 high prices for payers and low reimbursement rates for pharmacies;
25 and]¹

26 (4) ¹taking appropriate measures to eliminate, restrict, or revise
27 practices that are designed to increase or sustain disproportionate
28 profit margins within discrete points in the pharmaceutical supply
29 chain without promoting improvements in the quality of care
30 provided to, or reducing the costs of pharmaceutical drug products
31 for, covered individuals; and

32 (5)¹ reviewing the effects of manufacturer couponing on
33 premium costs as well as copay accumulator adjustments and
34 copayment maximizers for such coupons, and ensuring that the
35 value of manufacturer payments are counted against the patient's
36 deductible and limits on out-of-pocket payments.

37
38 6. a. No later than 18 months after the effective date of this
39 act, the Prescription Drug Affordability Board shall:

40 (1) collect and review publicly-available information regarding
41 prescription drug product manufacturers, health benefits plan
42 carriers, wholesale distributors, ¹[(and)]¹ pharmacy benefits
43 managers ¹, and pharmacy services administrative organizations¹ ;
44 and

45 (2) identify states that require reporting on the cost of
46 prescription drug products and initiate the process of entering into

1 memoranda of understanding with those states to aid in the
2 collection of transparency data for prescription drug products.

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

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

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

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

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

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

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

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

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

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

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

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

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

39 (b) that increased by 200 percent or more during the
40 immediately preceding 12-month period, as determined by the
41 difference between the resulting wholesale acquisition cost and the
42 average of the wholesale acquisition cost reported over the
43 immediately preceding 12 months; and

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

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

8 b. (1) The information to conduct a cost review may include
9 any document and research related to the manufacturer's selection
10 of the introductory price or price increase of the prescription drug
11 product, including life cycle management, net average price in the
12 State, market competition and context, projected revenue, and the
13 estimated value or cost-effectiveness of the prescription drug
14 product.

15 (2) To the extent that there is no publicly-available information
16 to conduct a cost review pursuant to this section, the board shall
17 request the information from the manufacturer of the prescription
18 drug product and, as appropriate, a wholesale distributor, pharmacy
19 benefits manager, ¹pharmacy services administrative organization,¹
20 or health benefits plan carrier with relevant information on how the
21 cost of the prescription drug product in the State was established.
22 The failure of a manufacturer, wholesale distributor, pharmacy
23 benefits manager, ¹pharmacy services administrative organization,¹
24 or health benefits plan carrier to provide the board with information
25 requested under this paragraph shall not affect the ability of the
26 board to conduct a review pursuant to subsection c. of this section.

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

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

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

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

46 (c) the total amount of the price concession, discount, or rebate
47 the manufacturer provides to each pharmacy benefits manager ¹and

- 1 pharmacy services administrative organization¹ operating in the
2 State for the prescription drug product under review, as reported by
3 manufacturers ¹**[and]** ¹ pharmacy benefits managers ¹, and
4 pharmacy services administrative organizations¹, expressed as a
5 percent of the wholesale acquisition costs;
- 6 (d) the price at which therapeutic alternatives have been sold in
7 the State;
- 8 (e) the average monetary concession, discount, or rebate the
9 manufacturer provides or is expected to provide to health benefits
10 plan payors ¹**[and]** ¹ pharmacy benefits managers ¹, and pharmacy
11 services administrative organizations¹ in the State for therapeutic
12 alternatives;
- 13 (f) the costs to health benefits plans based on patient access
14 consistent with United States Food and Drug Administration label
15 indications;
- 16 (g) the effects on patient access resulting from the cost of the
17 prescription drug product relative to insurance benefit design;
- 18 (h) the current or expected dollar value of the drug-specific
19 patient access programs that are supported by the manufacturer;
- 20 (i) the relative financial effects on health, medical, and social
21 service costs as can be quantified and compared to the baseline
22 effects of existing therapeutic alternatives;
- 23 (j) the average patient copay or other cost-sharing for the
24 prescription drug product in the State; and
- 25 (k) any additional factors established by the board by regulation.
- 26 (3) If the board is unable to determine, using the factors listed in
27 paragraph (2) of this subsection, whether a prescription drug
28 product will produce or has produced challenges to the affordability
29 of the product to the State health care system, the board may
30 consider the following factors:
- 31 (a) the manufacturer's research and development costs, as
32 indicated on the manufacturer's federal tax filing or information
33 filed with the federal Securities and Exchange Commission for the
34 most recent tax year, in proportion to the manufacturer's sales in the
35 State;
- 36 (b) the portion of direct-to-consumer marketing costs specific to
37 the prescription drug product under review that are eligible for
38 favorable federal tax treatment in the most recent tax year,
39 multiplied by the ratio of total manufacturer in-State sales to total
40 manufacturer sales in the United States for the product;
- 41 (c) gross and net manufacturer, pharmacy benefits manager,
42 pharmacy services administrative organization,¹ and wholesale
43 distributor revenues for the prescription drug product under review
44 for the most recent tax year;
- 45 (d) any additional factors proposed by the manufacturer and
46 appropriate health benefits plan carriers, wholesale distributors,

1 ¹~~and~~ ¹ pharmacy benefits managers ¹, and pharmacy services
2 administrative organizations¹ that the board considers relevant; and

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

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

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

26 ¹b. Any person who knowingly divulges, discloses, or uses
27 records or files containing information or data determined to be a
28 trade secret or confidential or proprietary information pursuant to
29 subsection a. of this section shall be guilty of a crime of the fourth
30 degree. Any person who knowingly examines records or files
31 containing information or data determined to be a trade secret or
32 confidential or proprietary information pursuant to subsection a. of
33 this section for any reason other than a reason necessitated by the
34 performance of official duties shall be guilty of a disorderly persons
35 offense.

36 c. Whenever records and files are used in connection with the
37 prosecution of a person for knowingly divulging, disclosing, or
38 using records or files containing information or data determined to
39 be a trade secret or confidential or proprietary information pursuant
40 to subsection a. of this section, or for examining records and files
41 containing information or data determined to be a trade secret or
42 confidential or proprietary information pursuant to subsection a. of
43 this section for any reason other than a reason necessitated by the
44 performance of official duties, the defendant shall be given access
45 to those records and files. The court shall review the records and
46 files in camera, and that portion of the court record containing the
47 records and files shall be sealed by the court.¹

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

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

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

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

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

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

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

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

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

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

37 (e) other relevant administrative costs.

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

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

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

46 c. No later than 24 months after the effective date of this act, the
47 board shall submit a plan of action drafted pursuant to subsection a. of

1 this section to the Legislature for approval. The plan shall be deemed
2 rejected unless legislation implementing the plan is adopted within 90
3 days after the date the plan is submitted to Legislature for approval.
4 Legislation approving a plan submitted by the board may include
5 modifications to the plan as submitted for approval, and in no case
6 shall a plan be deemed rejected solely because the legislation
7 implementing the plan makes technical or substantive changes to the
8 plan submitted by the board. The board shall have no authority to
9 establish upper payment limits for prescription drug products pursuant
10 to section 10 of this act, or authorize the importation of prescription
11 drug products from other countries, unless the board's plan of action
12 has been approved through the adoption of implementing legislation as
13 provided in this subsection.
14

15 10. a. Subject to the requirements of subsection c. of section 9
16 of this act, commencing 30 months after the effective date of this
17 act, the Prescription Drug Affordability Board may establish upper
18 payment limits for prescription drug products that are:

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

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

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

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

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

35 d. An upper payment limit established pursuant to subsection a.
36 of this section shall not apply to any prescription drug product
37 included in the prescription drug shortage list maintained by the
38 United States Food and Drug Administration.
39

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

44 b. The board shall conduct a new hearing on a decision or order
45 for which a rehearing is requested pursuant to subsection a. of this
46 section, and make a final decision or issue a final order no later than
47 60 days after the rehearing is requested.

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

9 d. Filing an appeal to the Appellate Division of the Superior
10 Court pursuant to subsection c. of this section shall not stay
11 enforcement of a final decision or order of the board unless a stay is
12 issued by the court upon application in accordance with the Rules of
13 Court or by the board upon terms and conditions as it deems proper.
14

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

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

20 (1) price trends for prescription drug products;

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

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

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

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

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

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

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

S329 [1R] SINGLETON, BEACH

17

- 1 13. a. There is appropriated from the General Fund to the
2 Prescription Drug Affordability Board established pursuant to this act
3 the sum of \$1,000,000 for the purposes of effectuating the provisions
4 of this act.
- 5 b. The Legislature shall annually appropriate from the General
6 Fund to the Prescription Drug Affordability Board established
7 pursuant to this act the sum of \$1,000,000 for the purposes of
8 effectuating the provisions of this act.
- 9
- 10 14. This act shall take effect immediately.