

[Second Reprint]

SENATE, No. 1615

STATE OF NEW JERSEY

220th LEGISLATURE

INTRODUCED FEBRUARY 14, 2022

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Wimberly, Mukherji, Assemblywomen Jasey, Murphy and Pintor Marin

SYNOPSIS

Establishes certain data reporting requirements for prescription drug supply chain; establishes Drug Affordability Council; appropriates \$1,500,000.

CURRENT VERSION OF TEXT

As amended by the Senate on June 26, 2023.

(Sponsorship Updated As Of: 6/30/2023)

1 AN ACT concerning prescription drug prices, supplementing Title
2 45 of the 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 P.L. , c. (C.) (pending before the
8 Legislature as this bill):

9 “Biosimilar” means a drug that is produced or distributed
10 pursuant to a biologics license application approved under 42
11 U.S.C. s.262(k)(3).

12 “Brand name drug” means a prescription drug approved under 21
13 USC s.355(b) or 42 USC s.262.

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

16 “Division” means the Division of Consumer Affairs in the
17 Department of Law and Public Safety.

18 “Drug group” means a group of drugs defined by the division for
19 the purpose of facilitating revenue and cost reporting by
20 manufacturers, carriers, pharmacy benefits managers, and
21 wholesalers under sections 2 through ¹5] 6¹ of P.L. , c. (C.)
22 (pending before the Legislature as this bill).

23 ¹“Logistics provider” means an entity that receives a prescription
24 drug product from the original or contract manufacturer,
25 warehouses and delivers the prescription drug product at the
26 direction of the manufacturer, and does not purchase, sell, trade, or
27 take title to the prescription drug product.¹

28 “Manufacturer” means a business registering under P.L.1961,
29 c.52 (C.24:6B-1 et seq.) ¹that is either engaged in the production,
30 preparation, propagation, compounding, conversion, or processing
31 of drug products or is engaged in the packaging, repackaging,
32 labeling, relabeling, or distribution of drug products] as a drug
33 manufacturing business as defined in section 13 of P.L.1961, c.52
34 (C.24:6B-12)¹.

35 “Market introduction” means the month and year in which a
36 manufacturer acquired or first marketed a drug for sale in New
37 Jersey.

38 ¹“Medicare Part D specialty threshold” means the specialty tier
39 cost threshold established by the Centers for Medicare and
40 Medicaid Services.

41 “New drug” means a prescription drug that has received initial
42 approval under an original new drug application under 21 U.S.C.
43 s.355(b), under an abbreviated new drug application under 21

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 SBA committee amendments adopted May 11, 2023.

²Senate floor amendments adopted June 26, 2023.

1 U.S.C. s.355(j), or under a biologics license application under 42
2 U.S.C. s.262. In cases where multiple products are included on an
3 application, each product shall be considered a new prescription
4 drug.¹

5 “Pharmacy benefits manager” means a corporation, business, or
6 other entity, or unit within a corporation, business, or other entity
7 that, pursuant to a contract or under an employment relationship
8 with a carrier, a self-insurance plan or other third-party payer, either
9 directly or through an intermediary, administers prescription drug
10 benefits on behalf of a ¹**【purchaser】** carrier, self-funded plan, or
11 other third-party payer.

12 “Pharmacy services administrative organization” means an entity
13 operating within the State that contracts with independent
14 pharmacies to conduct business on their behalf with third-party
15 payers.

16 “Pricing unit” means the smallest dispensable amount of a
17 prescription drug that could be dispensed¹.

18 “Reporting entity” means any manufacturer, carrier, pharmacy
19 benefits manager, wholesaler, ¹pharmacy services administrative
20 organization,¹ or any other entity required to report to the division
21 under P.L. , c. (C.) (pending before the Legislature as this
22 bill).

23 “Wholesale acquisition cost (WAC)” means ¹, with respect to a
24 prescription drug,¹ the manufacturer’s list price ¹for the drug¹ to
25 wholesalers or direct purchasers in New Jersey ¹**【on December 31**
26 **of the reference year, as reported in wholesale price guides or other**
27 **publications of drug or biological pricing data. WAC shall not**
28 **include prompt pay or other discounts, rebates, or reductions in**
29 **price. The current or proposed WAC is the amount that prompts**
30 **reporting under this act. If reported by drug group, it is the average**
31 **WAC weighted by the relevant number of WAC units dispensed in**
32 **the State】**, as defined in 42 U.S.C. s.1395w-3a(c)(6)(B), excluding
33 any discounts, rebates, or reductions in price, for the most recent
34 month for which the information is available, as reported in
35 wholesale price guides or other publications of prescription drug
36 pricing¹.

37 ¹**【“WAC unit” means the lowest identifiable quantity of the drug**
38 **or biological that is dispensed, in the State exclusive of any diluent**
39 **without reference to volume measures pertaining to liquids. If**
40 **reporting by drug group as indicated by the division, it is the total**
41 **number of WAC units dispensed in this State in the drug group.】**¹

42 “Wholesaler” means a business registering under P.L.1961, c.52
43 (C.24:6B-1 et seq.) ¹**【that is engaged in the sale of prescription**
44 **drugs to persons other than a consumer or patient】** as a wholesale
45 drug business as defined in section 13 of ²**【that act】** P.L.1961, c.52
46 (C.24:6B-12)² . “Wholesaler” shall not include a common carrier,

1 or an employee thereof, whose possession of a prescription drug
2 product is in the usual course of the common carrier's or
3 employee's business or employment, and shall not include a
4 logistics provider or an employee thereof¹.

5
6 2. a. A manufacturer shall notify the division if it is increasing
7 the WAC of a brand-name drug by more than 10 percent per ¹**["WAC]**
8 pricing¹ unit during any 12-month period, or if it is increasing the
9 WAC of a generic drug priced at ¹greater than¹ \$10 ¹**["or more]** but
10 less than \$100¹ per ¹**["WAC]** pricing¹ unit by more than ¹**["10]** 40¹
11 percent during any 12-month period ¹, or if it is increasing the WAC of
12 a generic drug priced at \$100 or more per pricing unit by more than 10
13 percent during any 12-month period¹. The notice shall be provided in
14 writing ¹**["at least 60 days prior to the planned]** within 10 days
15 following the¹ effective date of the increase ¹and the division shall
16 notify consumers of the increase on its Internet website¹.

17 b. A manufacturer shall notify the division if it ¹**["intends to**
18 **introduce]** introduces¹: (1) a new drug in the State that has a WAC
19 ¹**["of \$670 per WAC unit or more]** that exceeds the Medicare Part D
20 specialty threshold¹; or (2) a biosimilar in the State that has a WAC
21 that is not at least 15 percent less than the WAC of the referenced
22 brand biologic at the time the biosimilar is launched. The notice shall
23 be provided in writing ¹**["at least 60 days prior to]** within 10 days
24 following¹ market introduction ¹and the division shall notify
25 consumers of the price on its Internet website¹.

26 c. A manufacturer that notifies the division pursuant to subsection
27 a. of this section shall report to the division the following minimum
28 data, and any other data that may be specified by the division, ¹**["at**
29 **least 30]** within 20¹ days ¹**["before]** following¹ the price increase:

30 (1) the national drug code, proprietary drug name, non-proprietary
31 drug name, and ¹**["WAC]** pricing¹ unit of the brand-name drug or
32 generic drug, as applicable;

33 (2) sales volume in the State in the previous calendar year and
34 projected sales volume in the State for the current calendar year for the
35 drug or drug group as specified by the division;

36 (3) the wholesale price and related information for the drug or drug
37 group as specified by the division, which may include but shall not be
38 limited to the year of market introduction, WAC at market
39 introduction, WAC in the previous calendar year, and current WAC;

40 (4) revenue from the sale of the drug or drug group in the State in
41 the previous calendar year and projected revenue from the sale of the
42 drug or drug group in the current calendar year, expressed in U.S.
43 dollars per ¹**["WAC]** pricing¹ unit;

44 (5) manufacturer cost associated with sales of the drug or drug
45 group in the State as specified by the division in the previous calendar
46 year and projected for the current calendar year;

1 (6) current calendar-year projections or incurred cost year to date,
2 as the division may indicate, related directly or allocated specifically
3 to sales of this drug or drug group in the State; and

4 (7) the reason or reasons that the manufacturer increased the WAC
5 of the drug or drug group compared with last year.

6 d. A manufacturer that notifies the division pursuant to subsection
7 b. of this section shall report to division the following minimum data,
8 and any other data that may be specified by the division, ¹~~at least 60~~
9 within 20¹ days ¹~~before~~ following¹ the date of market introduction:

10 (1) the national drug code, proprietary drug name, non-proprietary
11 drug name, and ¹~~WAC~~ pricing¹ unit of the new drug;

12 (2) projected patient volume in the current year for the drug and
13 drug group in the State;

14 (3) projected revenue for the drug and drug group in the current
15 year in the State; and

16 (4) WAC at market introduction.

17 e. ¹If a manufacturer certifies to the division that it does not have
18 access to the State-specific data required to be reported pursuant to this
19 section and has no way of obtaining the data, the division may permit
20 the manufacturer to report the data on a national level upon proof
21 satisfactory to the division that State-specific data is unavailable to the
22 manufacturer. In the event State-specific data is unavailable to the
23 manufacturer, the division shall attempt to obtain the data from other
24 reporting entities subject to the provisions of P.L. , c. (C.)
25 (pending before the Legislature as this bill) for any drug or drug group
26 reported on by a manufacturer pursuant to subsections a. and b. of this
27 section.

28 f.¹ Disclosure of all information reported under this section shall
29 be subject to protections defined in section ¹~~8~~ 9¹ of P.L. , c.
30 (C.) (pending before the Legislature as this bill).

31
32 3. a. A pharmacy ¹~~benefit~~ benefits¹ manager shall, to the extent
33 allowed by law, report ¹~~annually~~¹ to the division the following
34 minimum data, and other data that may be specified by the division ¹~~,~~
35 within 60 days after receiving notification by the division indicating¹.
36 The division shall annually notify pharmacy benefits managers of¹ the
37 specific drugs or drug groups for which reporting is required ¹and a
38 pharmacy benefits manager shall have 60 days following such
39 notification to report to the division the following¹:

40 (1) minimum and maximum WAC for each indicated drug and
41 drug group for which the pharmacy ¹~~benefit~~ benefits¹ manager has
42 negotiated directly with the manufacturer in the last calendar year,
43 related to prescriptions under an insurance policy issued in the State;

44 (2) volume in ¹~~WAC~~ pricing¹ units of each indicated drug and
45 drug group that the pharmacy ¹~~benefit~~ benefits¹ manager negotiated

1 directly with the manufacturer in the last calendar year, for business in
2 the State, in total and for each payer type as relevant;

3 (3) total rebates, discounts, and price concessions received or
4 negotiated directly with the manufacturer for each drug and drug group
5 as indicated by the division in the last calendar year, for business in the
6 State, in total and for each payer type as relevant;

7 (4) total discounts, dispensing fees, and other fees negotiated last
8 year with pharmacies, prescription drug networks, or pharmacy
9 services administrative organizations for each drug and drug group as
10 indicated by the division in the last calendar year, for business in the
11 State, in total and for each payer type as relevant; and

12 (5) total net income received in the last calendar year for each drug
13 and drug group as indicated by ¹the¹ division, for business in the State,
14 in total and for each payer type as relevant.

15 b. Disclosure of all information reported under this section shall
16 be subject to protections defined in section ¹[8] ⁹ of P.L. , c.
17 (C.) (pending before the Legislature as this bill).

18
19 4. a. A wholesaler shall report ¹[annually]¹ to the division the
20 following minimum data, and other data that may be specified by the
21 division ¹[, within 60 days after receiving notification by the division
22 indicating]. The division shall annually notify wholesalers of¹ the
23 specific drugs or drug groups for which reporting is required ¹and a
24 wholesaler shall have 60 days following such notification to report to
25 the division the following¹:

26 (1) minimum and maximum WAC for each indicated drug and
27 drug group for which the wholesaler has negotiated directly with the
28 manufacturer in the last calendar year, related to prescriptions under an
29 insurance policy issued in the State;

30 (2) volume in ¹[WAC] pricing¹ units of each indicated drug and
31 drug group that the wholesaler negotiated directly with the
32 manufacturer in the last calendar year, for business in the State, in total
33 and for each payer type as relevant;

34 (3) total rebates, discounts, and price concessions negotiated
35 directly with the manufacturer for each drug and drug group as
36 indicated by the division in the last calendar year, for business in the
37 State, in total and for each payer type as relevant;

38 (4) total discounts, dispensing fees, and other fees negotiated last
39 year with pharmacies, prescription drug networks, or pharmacy
40 services administrative organizations for each drug and drug group as
41 indicated by the division in the last calendar year, for business in the
42 State, in total and for each payer type as relevant; and

43 (5) total net income received in the last calendar year for each drug
44 and drug group as indicated by the division, for business in the State,
45 in total and for each payer type as relevant.

b. Disclosure of all information reported under this section shall be subject to protections defined in section ~~18~~ 9 of P.L. , c. (C.) (pending before the Legislature as this bill).

5. a. A carrier designated by the division as a reporting entity shall report annually to the division, to the extent allowed by law, the spending on prescription drugs before enrollee cost sharing ¹and enrollee cost sharing¹, in total and per prescription drug user, in total and for each of the top 25 prescription drugs and drug groups as defined by the division in the following ~~four~~¹ categories:

(1) the greatest total spending before enrollee cost sharing in the last calendar year;

(2) the greatest total spending per user of any drug in the drug group before enrollee cost sharing in the last calendar year;

(3) the highest year-over-year increase in total spending before enrollee cost sharing; ~~and~~¹

(4) the highest year-over-year increase in total spending per user of any drug in the drug group before enrollee cost sharing¹;

(5) total enrollee cost sharing in the last calendar year; and

(6) the highest year-over-year increase in enrollee cost sharing per user of any drug in the drug group¹.

b. For each drug and drug group as defined by the division, the carrier shall report to the division the following minimum data, and other data that may be specified by the division, within 60 days of the close of each calendar year:

(1) total issuer spending before enrollee cost sharing in the last calendar year;

(2) margins and fees for each drug listed in subsection a. of this section paid directly to pharmacy benefits managers or pharmacy services administrative organizations in the last calendar year; and

(3) other retail discounts, price concessions, and fees for each drug listed in subsection a. of this section paid in the last calendar year.

¹6. a. A pharmacy services administrative organization shall, to the extent allowed by law, report annually to the division:

(1) the negotiated reimbursement rate that the pharmacy services administrative organization is to pay pharmacies for brand, generic, and specialty drugs for each pharmacy benefits manager pharmacy network;

(2) the negotiated reimbursement rate that the pharmacy benefits manager is to pay the pharmacy services administrative organization for brand, generic, and specialty drugs for each pharmacy benefits manager's pharmacy network; and

(3) the schedule of fees charged by the organization to pharmacies.

b. Disclosure of all information reported under this section shall be subject to protections defined in section 9 of P.L. , c. (C.) (pending before the Legislature as this bill).¹

1 ¹**[6.] 7.** a. The reporting entity shall certify required reporting
2 under sections 2 through ¹**[5] 6** of P.L. , c. (C.) (pending
3 before the Legislature as this bill) as accurate under the penalty of
4 perjury.

5 b. Failure of a reporting entity to comply with any section of
6 P.L. , c. (C.) (pending before the Legislature as this bill) may
7 result in a civil penalty as determined by the Director of the Division
8 of Consumer Affairs. Civil penalties under P.L. , c. (C.)
9 (pending before the Legislature as this bill) may be imposed in the
10 amount of ¹**[\$20,000] \$10,000** for the first day that the reporting
11 entity is found to have violated any section of P.L. , c. (C.)
12 (pending before the Legislature as this bill), and for subsequent days of
13 non-compliance, an amount ¹**[of]** starting at ¹**[\$21,000] \$11,000**¹
14 and increasing by \$1,000 for each additional day of non-compliance,
15 not to exceed \$100,000 per day.

16 c. The division may audit the data submitted to the division by a
17 reporting entity pursuant to sections 2 through ¹**[5] 6** of P.L. , c.
18 (C.) (pending before the Legislature as this bill), in a form and
19 manner specified by the division. The reporting entity shall pay all
20 costs associated with the audit.

21 d. The division may require a reporting entity to submit a
22 corrective action plan, in a form and manner specified by the division,
23 to correct deficiencies in reporting pursuant to sections 2 through ¹**[5]**
24 **6** of P.L. , c. (C.) (pending before the Legislature as this
25 bill).

26 e. ¹**[The]** In addition to the annual public hearing required under
27 subsection a. of section 9 of P.L. , c. (C.) (pending before the
28 Legislature as this bill), the¹ division may call one or more
29 ¹additional public hearings and may subpoena any reporting entity
30 pursuant to sections 2 through ¹**[5] 6** of P.L. , c. (C.)
31 (pending before the Legislature as this bill).

32

33 ¹**[7.] 8.** a. Each reporting entity shall register with the division
34 in a form and manner specified by the division no later than January
35 31 of each calendar year.

36 b. (1) ²**[Each]** With exception to pharmacy services
37 administrative organizations, each² reporting entity shall pay an
38 annual assessment set by the division to support the operational
39 costs of the division's activities as required by P.L. ,
40 c. (C.) (pending before the Legislature as this bill) ¹,
41 including funding necessary to support the Drug Affordability
42 Council¹. Operational costs shall include staff salaries,
43 administrative expenses, data system expenses, and consulting fees
44 of the division to effectuate the provisions of
45 P.L. , c. (C.) (pending before the Legislature as this
46 bill). The Director of the Division of Consumer Affairs shall certify

1 actual and prospective costs of the division's activities under
2 P.L. , c. (C.) (pending before the Legislature as this bill),
3 which costs shall be the basis for the establishment of the annual
4 assessment. ¹The division shall not vary the amount of annual
5 assessment based on whether a reporting entity is a carrier,
6 pharmacy benefits manager, wholesaler, manufacturer, ²[pharmacy
7 services administrative organizations,] ² or other entity. If the total
8 amount of the assessment that the division collects in a calendar
9 year exceeds the operational costs certified by the division pursuant
10 to this subsection, the division shall issue a notice of such surplus
11 and remit the surplus funds in a timely, fair, and equitable manner
12 across all reporting entities that paid the assessment. Penalties
13 collected pursuant to section 7 of P.L. , c. (C.) shall not be
14 refunded pursuant to this subsection. ¹

15 (2) ²A pharmacy services administrative organization shall be
16 subject to an annual assessment, to be determined by the Director of
17 the Division of Consumer Affairs, which is separate from the
18 annual assessment required pursuant to paragraph (1) of this
19 subsection.

20 (3) ²Requests for payment of the final assessments shall be sent
21 by the division to all reporting entities under P.L. , c. (C.)
22 (pending before the Legislature as this bill). ¹[All assessments shall
23 be due to the division within 30 days of receipt of the request for
24 payment] The division shall allow reporting entities to make partial
25 payments when paying the assessment required under this
26 subsection, with the final payment, as well as any amounts
27 remaining uncollected from the assessment of the previous fiscal
28 year, to be made no later than December 31 of a given reporting
29 year ¹.

30
31 ¹[8.] 9. ¹ a. The division shall annually prepare and make
32 available on its website a report on emerging trends in prescription
33 drug prices, and conduct an annual public hearing based on the
34 report findings. The report shall include, but may not be limited to,
35 analysis of manufacturer prices and price increases as reported
36 under P.L. , c. (C.) (pending before the Legislature as this
37 bill), and analysis of information as reported by carriers, pharmacy
38 ¹[benefit] benefits ¹ managers, and wholesalers under P.L. , c.
39 (C.) (pending before the Legislature as this bill), so as to
40 make clear the major components of prescription drug pricing along
41 the supply chain, and the impacts on insurance premiums and
42 consumer cost sharing. The data in the report ¹[may not reveal
43 information specific to any individual reporting entity] shall not
44 include any information that the division determines to be
45 confidential pursuant to this section ¹.

1 b. ²(1)² Except as provided in subsection a. of this section, the
2 division shall keep confidential all information submitted by an
3 individual reporting entity, and protect it from public disclosure.
4 The division ¹“~~may~~ shall” share such information with the ¹Drug
5 Affordability Council and the¹ Department of Banking and
6 Insurance which shall keep confidential any information shared by
7 the division under P.L. , c. (C.) (pending before the
8 Legislature as this bill) and protect it from public disclosure.
9 ¹Information that is otherwise publicly available shall not be
10 deemed confidential solely because it was submitted to the division
11 pursuant to P.L. , c. (C.) (pending before the Legislature as
12 this bill). The confidentiality protections of this section shall be
13 imposed on any downstream third party that may receive or
14 otherwise have access to this information.

15 ²(2) A person who is authorized to access information submitted
16 by an individual reporting entity to the division who willfully
17 discloses such information to any person or entity who is not
18 authorized to access the information shall be subject to a civil
19 penalty in an amount not to exceed \$2,500.

20 A civil penalty imposed under this subsection shall be collected
21 by the director pursuant to the “Penalty Enforcement Law of 1999,”
22 P.L.1999, c.274 (C.2A:58-10 et seq.).²

23 c. Any records, documents, or data provided pursuant to
24 P.L. , c. (C.) (pending before the Legislature as this bill)
25 shall not be considered a government record under P.L.1963, c.73
26 (C.47:1A-1 et seq.) or the common law concerning access to
27 government records.

28 d. The division shall make available on its Internet website a
29 method for consumers to submit a complaint to the division
30 regarding the failure of a reporting entity to provide to the division
31 any information required by section 2 through 6 of
32 P.L. , c. (C.) (pending before the Legislature as this bill).¹
33

34 ¹10. a. The Drug Affordability Council is established in, but not
35 of, the Department of Law and Public Safety. The purpose of the
36 council is to formulate legislative and regulatory policy
37 recommendations that will protect New Jersey residents, State and
38 local governments, health benefits plans, health care providers,
39 licensed pharmacies, and other stakeholders within the State health
40 care system from the high costs of prescription drug products.

41 b. The council shall be comprised of five public members and
42 three alternate public members, who shall participate in council
43 deliberations in any case in which a public member is recused or if
44 there is a vacancy on the council. Public members and alternative
45 public members shall be appointed within 180 days following the
46 effective date of P.L. , c. (C.) (pending before the
47 Legislature as this bill).

1 (1) (a) The five public members of the council shall be
2 appointed as follows: three members shall be appointed by the
3 Governor; one member shall be appointed by the Governor upon
4 recommendation of the President of the Senate; and one member
5 shall be appointed by the Governor upon recommendation of the
6 Speaker of the General Assembly.

7 (b) The three alternate members of the Council shall be
8 appointed as follows: one member shall be appointed by the
9 Governor; one member shall be appointed by the Governor upon
10 recommendation of the President of the Senate; and one member
11 shall be appointed by the Governor upon recommendation of the
12 Speaker of the General Assembly.

13 (2) Each public member of the council shall have expertise in
14 health care economics, health care policy, or clinical medicine. The
15 membership of the council shall collectively have knowledge of:

- 16 (a) the pharmaceutical business model;
- 17 (b) supply chain business models;
- 18 (c) the practice of medicine and clinical training;
- 19 (d) consumer and patient perspectives;
- 20 (e) health care cost trends and drivers;
- 21 (f) clinical and health services research; and
- 22 (g) the State's health care marketplace.

23 (3) No public member of the council may be an employee or
24 board member of, or a consultant to, a manufacturer, pharmacy
25 benefits manager, pharmacy services administrative organization,
26 pharmacy, pharmacist, health benefits plan carrier, or wholesale
27 distributor or related trade association.

28 (4) An individual appointed to the council as a public member
29 shall disclose, at the time of appointment, any conflict of interest,
30 including whether the individual has an association, including a
31 financial or personal association, that has the potential to bias or has
32 the appearance of biasing the individual's decision in matters
33 related to the council or the conduct of the council's activities.

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

37 (6) The council shall appoint a chair from among its members.

38 c. Public members and alternative members of the council shall
39 serve for a term of five years, except that, of the public members
40 first appointed, one shall serve a term of three years, two shall serve
41 a term of four years, and two shall serve a term of five
42 years. Public members and alternative members shall be eligible
43 for reappointment to the council. Vacancies in the membership
44 shall be filled in the same manner as provided for the original
45 appointment, and members shall serve until a successor has been
46 appointed.

47 d. (1) The council shall meet in open session, except the
48 council shall meet in closed session to discuss any information

1 confidential pursuant to section 9 of P.L. , c. (C.) (pending
2 before the Legislature as this bill). The chair shall have the
3 authority to postpone or cancel any required meeting. All meetings
4 of the council shall be subject to the requirements of the “Senator
5 Byron M. Baer Open Public Meetings Act,” P.L.1975, c.231
6 (C.10:4-6 et seq.). Three members shall constitute a quorum for the
7 purposes of conducting official council business. The division shall
8 post on its Internet website information concerning public meetings
9 of the council and reports issued by the council. Posts on the
10 division’s Internet website shall be subject to the confidentiality
11 requirements set forth in section 9 of P.L. , c. (C.)
12 (pending before the Legislature as this bill) and subsection h. of this
13 section.

14 (2) The council shall provide an opportunity for public comment
15 at each open meeting of the council.

16 (3) The council shall provide the public with the opportunity to
17 provide written comments.

18 (4) The council may allow expert testimony at council meetings.

19 e. Public members of the council shall not accept any gift or
20 donation of services or property that indicates a potential conflict of
21 interest or has the appearance of biasing the work of the council.

22 f. The council may call to its assistance and avail itself of the
23 services of employees of the division as may be required and made
24 available for the purposes of this section. Members of the council
25 shall serve without compensation but may be reimbursed for
26 expenses reasonably incurred in the performance of their official
27 duties. The council may call to its assistance and avail itself of the
28 services of any State, county, or municipal department, board,
29 commission, or agency, as it may require, and as may be available
30 to it for its purposes. The council may consult with any government
31 entity, association, organization, or individual having knowledge or
32 experience relevant to its work.

33 g. The council shall be constituted and hold its first meeting
34 within 30 days following appointment of all public members and
35 alternative public members pursuant to subsection b. of this section.

36 h. In addition to reviewing the reports issued and data collected
37 by the division pursuant to P.L. , c. (C.) (pending before
38 the Legislature as this bill), the council may collect and review any
39 available information regarding prescription drug product
40 manufacturers, health benefits plan carriers, wholesale distributors,
41 pharmacy benefits managers, and pharmacy services administrative
42 organizations, and any other transparency data for prescription drug
43 products which the council may access and may find useful for its
44 work. Information obtained by the council shall be made public,
45 excluding identifying information about a patient or information
46 that is a trade secret; provided, however, information obtained by
47 the council from the division that was provided by reporting entities
48 pursuant to P.L. , c. (C.) (pending before the Legislature as

1 this bill) shall be deemed confidential in accordance with section 9
2 of P.L. , c. (C.) (pending before the Legislature as this
3 bill), except that information that is otherwise publicly available
4 shall not be deemed confidential solely because it was submitted to
5 the division pursuant to P.L. , c. (C.) (pending before the
6 Legislature as this bill). The council shall impose the
7 confidentiality protections of this subsection on any downstream
8 third party that may receive or otherwise have access to this
9 information.

10 i. The council shall review the reports issued and data
11 collected by the division pursuant to P.L. , c. (C.) (pending
12 before the Legislature as this bill) and the information gathered
13 under subsection h. of this section, and following such review,
14 submit annually recommendations for legislative, regulatory or
15 other action to the Governor and, pursuant to section 2 of P.L.1991,
16 c.164 (C.52:14-19.1), to the Legislature that seek to advance the
17 goal of more affordable and accessible prescription drugs for New
18 Jersey residents, including recommendations designed to lower the
19 cost of prescription drug products that the council determines have
20 led or will lead to an affordability challenge for the State health
21 care system and for New Jersey patients and recommendations
22 concerning the types of data to be reported pursuant to P.L. , c.
23 (C.) (pending before the Legislature as this bill). In
24 developing and providing recommendations, the council shall
25 consider and address in its reports the impact that any
26 recommendation could have on research and development, access to
27 care, or any other direct or indirect economic or social costs that the
28 council deems relevant. Reports issued by the council shall be
29 subject to the confidentiality requirements set forth in section 9 of
30 P.L. , c. (C.) (pending before the Legislature as this bill) and
31 subsection h. of this section.¹

32
33 ¹[9.] 11.¹ If any provision of this act, P.L. , c. (C.)
34 (pending before the Legislature as this bill) or the application
35 thereof to any person or circumstance is held invalid, the invalidity
36 shall not affect other provisions or applications of the sections
37 which can be given effect without the invalid provision or
38 application, and to this end the provisions of this act are severable.

39
40 ¹[10] 12.¹ Notwithstanding the provisions of the
41 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
42 seq.), to the contrary, the Director of the Division of Consumer
43 Affairs may adopt, immediately upon filing with the Office of
44 Administrative Law, regulations that the director deems necessary
45 to implement the provisions of P.L. , c. (C.) (pending
46 before the Legislature as this bill, which regulations shall be
47 effective for a period not to exceed ¹[180] 545¹ days from the date
48 of the filing. The director shall thereafter amend, adopt, or readopt

1 the regulations in accordance with the requirements of P.L.1968,
2 c.410 (C.52:14B-1 et seq.).

3

4 ¹~~11.~~ 13.¹ There is appropriated from the General Fund to the
5 Division of Consumer Affairs in the Department of Law and Public
6 Safety ¹~~900,000~~ 1,500,000¹ to implement the provisions of this
7 act.

8

9 ¹~~12.~~ 14.¹ This act shall take effect immediately but sections 1
10 through 9 of this act shall remain inoperable until the first day of
11 the thirteenth month next following the date of enactment. The New
12 Jersey Division of Consumer Affairs may take such anticipatory
13 rulemaking and other administrative action in advance of the
14 operative date of this act as shall be necessary for the
15 implementation of this act.