

[First Reprint]

**SENATE, No. 1615**

**STATE OF NEW JERSEY**  
**220th LEGISLATURE**

INTRODUCED FEBRUARY 14, 2022

**Sponsored by:**

**Senator TROY SINGLETON**

**District 7 (Burlington)**

**Senator JOSEPH F. VITALE**

**District 19 (Middlesex)**

**Senator NELLIE POU**

**District 35 (Bergen and Passaic)**

**Co-Sponsored by:**

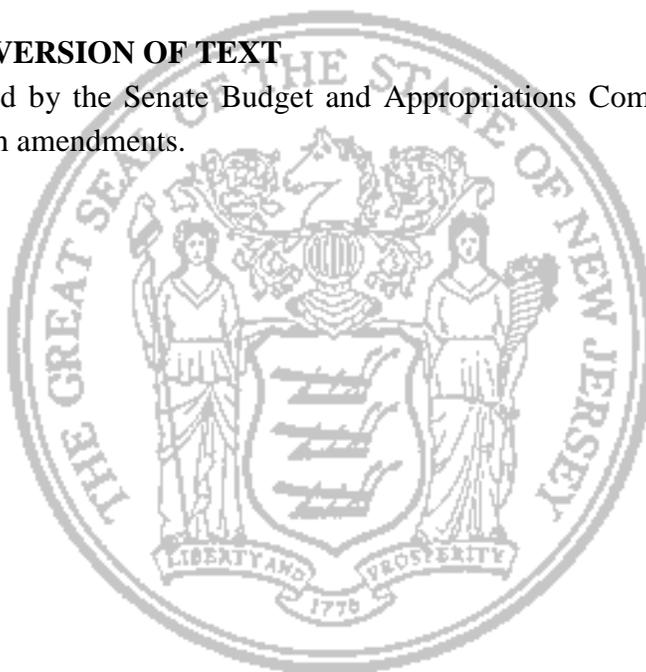
**Senators Greenstein, Gill, Ruiz, Gopal, Burgess, Turner and Diegnan**

**SYNOPSIS**

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

**CURRENT VERSION OF TEXT**

As reported by the Senate Budget and Appropriations Committee on May 11, 2023, with amendments.



**(Sponsorship Updated As Of: 6/5/2023)**

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 Legislature  
8 as this bill):

9 “Biosimilar” means a drug that is produced or distributed pursuant  
10 to a biologics license application approved under 42 U.S.C.  
11 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 wholesalers  
21 under sections 2 through <sup>1</sup>**[5]** <sup>1</sup>6 of P.L. , c. (C. ) (pending before  
22 the Legislature as this bill).

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

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

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

36 <sup>1</sup>“Medicare Part D specialty threshold” means the specialty tier  
37 cost threshold established by the Centers for Medicare and Medicaid  
38 Services.

39 “New drug” means a prescription drug that has received initial  
40 approval under an original new drug application under 21 U.S.C.  
41 s.355(b), under an abbreviated new drug application under 21 U.S.C.  
42 s.355(j), or under a biologics license application under 42 U.S.C.  
43 s.262. In cases where multiple products are included on an application,

**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:

<sup>1</sup>Senate SBA committee amendments adopted May 11, 2023.

1 each product shall be considered a new prescription drug.<sup>1</sup>

2 “Pharmacy benefits manager” means a corporation, business, or  
3 other entity, or unit within a corporation, business, or other entity that,  
4 pursuant to a contract or under an employment relationship with a  
5 carrier, a self-insurance plan or other third-party payer, either directly  
6 or through an intermediary, administers prescription drug benefits on  
7 behalf of a <sup>1</sup>**[purchaser]** carrier, self-funded plan, or other third-party  
8 payer.

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

12 “Pricing unit” means the smallest dispensable amount of a  
13 prescription drug that could be dispensed<sup>1</sup>.

14 “Reporting entity” means any manufacturer, carrier, pharmacy  
15 benefits manager, wholesaler, <sup>1</sup>pharmacy services administrative  
16 organization,<sup>1</sup> or any other entity required to report to the division  
17 under P.L. , c. (C. ) (pending before the Legislature as this  
18 bill).

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

32 <sup>1</sup>**[“WAC unit” means the lowest identifiable quantity of the drug**  
33 **or biological that is dispensed, in the State exclusive of any diluent**  
34 **without reference to volume measures pertaining to liquids. If**  
35 **reporting by drug group as indicated by the division, it is the total**  
36 **number of WAC units dispensed in this State in the drug group.]**<sup>1</sup>

37 “Wholesaler” means a business registering under P.L.1961, c.52  
38 (C.24:6B-1 et seq.) <sup>1</sup>**[that is engaged in the sale of prescription drugs**  
39 **to persons other than a consumer or patient]** as a wholesale drug  
40 business as defined pursuant to section 13 of that act. “Wholesaler”  
41 shall not include a common carrier, or an employee thereof, whose  
42 possession of a prescription drug product is in the usual course of the  
43 common carrier’s or employee’s business or employment, and shall  
44 not include a logistics provider or an employee thereof<sup>1</sup>.

1           2. a. A manufacturer shall notify the division if it is increasing  
2 the WAC of a brand-name drug by more than 10 percent per <sup>1</sup>~~WAC~~  
3 pricing<sup>1</sup> unit during any 12-month period, or if it is increasing the  
4 WAC of a generic drug priced at <sup>1</sup>greater than<sup>1</sup> \$10 <sup>1</sup>~~or more~~ but  
5 less than \$100<sup>1</sup> per <sup>1</sup>~~WAC~~ pricing<sup>1</sup> unit by more than <sup>1</sup>~~10~~ 40<sup>1</sup>  
6 percent during any 12-month period <sup>1</sup>, or if it is increasing the WAC of  
7 a generic drug priced at \$100 or more per pricing unit by more than 10  
8 percent during any 12-month period<sup>1</sup>. The notice shall be provided in  
9 writing <sup>1</sup>~~at least 60 days prior to the planned~~ within 10 days  
10 following the<sup>1</sup> effective date of the increase <sup>1</sup>and the division shall  
11 notify consumers of the increase on its Internet website<sup>1</sup>.

12           b. A manufacturer shall notify the division if it <sup>1</sup>~~intends to~~  
13 introduce<sup>1</sup> introduces<sup>1</sup>: (1) a new drug in the State that has a WAC  
14 <sup>1</sup>~~of \$670 per WAC unit or more~~ that exceeds the Medicare Part D  
15 specialty threshold<sup>1</sup>; or (2) a biosimilar in the State that has a WAC  
16 that is not at least 15 percent less than the WAC of the referenced  
17 brand biologic at the time the biosimilar is launched. The notice shall  
18 be provided in writing <sup>1</sup>~~at least 60 days prior to~~ within 10 days  
19 following<sup>1</sup> market introduction <sup>1</sup>and the division shall notify  
20 consumers of the price on its Internet website<sup>1</sup>.

21           c. A manufacturer that notifies the division pursuant to subsection  
22 a. of this section shall report to the division the following minimum  
23 data, and any other data that may be specified by the division, <sup>1</sup>~~at~~  
24 least 30 within 20<sup>1</sup> days <sup>1</sup>~~before~~ following<sup>1</sup> the price increase:

25           (1) the national drug code, proprietary drug name, non-proprietary  
26 drug name, and <sup>1</sup>~~WAC~~ pricing<sup>1</sup> unit of the brand-name drug or  
27 generic drug, as applicable;

28           (2) sales volume in the State in the previous calendar year and  
29 projected sales volume in the State for the current calendar year for the  
30 drug or drug group as specified by the division;

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

35           (4) revenue from the sale of the drug or drug group in the State in  
36 the previous calendar year and projected revenue from the sale of the  
37 drug or drug group in the current calendar year, expressed in U.S.  
38 dollars per <sup>1</sup>~~WAC~~ pricing<sup>1</sup> unit;

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

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

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

- 1 d. A manufacturer that notifies the division pursuant to subsection  
2 b. of this section shall report to division the following minimum data,  
3 and any other data that may be specified by the division, <sup>1</sup>["at least 60"]  
4 within 20<sup>1</sup> days <sup>1</sup>["before"] following<sup>1</sup> the date of market introduction:  
5 (1) the national drug code, proprietary drug name, non-proprietary  
6 drug name, and <sup>1</sup>["WAC"] pricing<sup>1</sup> unit of the new drug;  
7 (2) projected patient volume in the current year for the drug and  
8 drug group in the State;  
9 (3) projected revenue for the drug and drug group in the current  
10 year in the State; and  
11 (4) WAC at market introduction.
- 12 e. <sup>1</sup>If a manufacturer certifies to the division that it does not have  
13 access to the State-specific data required to be reported pursuant to this  
14 section and has no way of obtaining the data, the division may permit  
15 the manufacturer to report the data on a national level upon proof  
16 satisfactory to the division that State-specific data is unavailable to the  
17 manufacturer. In the event State-specific data is unavailable to the  
18 manufacturer, the division shall attempt to obtain the data from other  
19 reporting entities subject to the provisions of P.L. , c. (C. )  
20 (pending before the Legislature as this bill) for any drug or drug group  
21 reported on by a manufacturer pursuant to subsections a. and b. of this  
22 section.
- 23 f.<sup>1</sup> Disclosure of all information reported under this section shall  
24 be subject to protections defined in section <sup>1</sup>["8"] <sup>1</sup>9<sup>1</sup> of P.L. , c.  
25 (C. ) (pending before the Legislature as this bill).
- 26
- 27 3. a. A pharmacy <sup>1</sup>["benefit"] benefits<sup>1</sup> manager shall, to the extent  
28 allowed by law, report <sup>1</sup>["annually"]<sup>1</sup> to the division the following  
29 minimum data, and other data that may be specified by the division <sup>1</sup>["  
30 within 60 days after receiving notification by the division indicating"].  
31 The division shall annually notify pharmacy benefits managers of<sup>1</sup> the  
32 specific drugs or drug groups for which reporting is required <sup>1</sup>and a  
33 pharmacy benefits manager shall have 60 days following such  
34 notification to report to the division the following<sup>1</sup>:  
35 (1) minimum and maximum WAC for each indicated drug and  
36 drug group for which the pharmacy <sup>1</sup>["benefit"] benefits<sup>1</sup> manager has  
37 negotiated directly with the manufacturer in the last calendar year,  
38 related to prescriptions under an insurance policy issued in the State;  
39 (2) volume in <sup>1</sup>["WAC"] pricing<sup>1</sup> units of each indicated drug and  
40 drug group that the pharmacy <sup>1</sup>["benefit"] benefits<sup>1</sup> manager negotiated  
41 directly with the manufacturer in the last calendar year, for business in  
42 the State, in total and for each payer type as relevant;  
43 (3) total rebates, discounts, and price concessions received or  
44 negotiated directly with the manufacturer for each drug and drug group  
45 as indicated by the division in the last calendar year, for business in the  
46 State, in total and for each payer type as relevant;

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

6 (5) total net income received in the last calendar year for each drug  
7 and drug group as indicated by <sup>1</sup>the<sup>1</sup> division, for business in the State,  
8 in total and for each payer type as relevant.

9 b. Disclosure of all information reported under this section shall  
10 be subject to protections defined in section <sup>1</sup>[8] <sup>1</sup>9<sup>1</sup> of P.L. , c.  
11 (C. ) (pending before the Legislature as this bill).

12  
13 4. a. A wholesaler shall report <sup>1</sup>[annually]<sup>1</sup> to the division the  
14 following minimum data, and other data that may be specified by the  
15 division <sup>1</sup>[, within 60 days after receiving notification by the division  
16 indicating]. The division shall annually notify wholesalers of<sup>1</sup> the  
17 specific drugs or drug groups for which reporting is required <sup>1</sup>and a  
18 wholesaler shall have 60 days following such notification to report to  
19 the division the following<sup>1</sup>:

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

24 (2) volume in <sup>1</sup>[WAC] pricing<sup>1</sup> units of each indicated drug and  
25 drug group that the wholesaler negotiated directly with the  
26 manufacturer in the last calendar year, for business in the State, in total  
27 and for each payer type as relevant;

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

32 (4) total discounts, dispensing fees, and other fees negotiated last  
33 year with pharmacies, prescription drug networks, or pharmacy  
34 services administrative organizations for each drug and drug group as  
35 indicated by the division in the last calendar year, for business in the  
36 State, in total and for each payer type as relevant; and

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

40 b. Disclosure of all information reported under this section shall  
41 be subject to protections defined in section <sup>1</sup>[8] <sup>1</sup>9<sup>1</sup> of P.L. ,  
42 c. (C. ) (pending before the Legislature as this bill).

43  
44 5. a. A carrier designated by the division as a reporting entity  
45 shall report annually to the division, to the extent allowed by law, the  
46 spending on prescription drugs before enrollee cost sharing <sup>1</sup>and  
47 enrollee cost sharing<sup>1</sup>, in total and per prescription drug user, in total

1 and for each of the top 25 prescription drugs and drug groups as  
2 defined by the division in the following <sup>1</sup>~~four~~<sup>1</sup> categories:

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

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

7 (3) the highest year-over-year increase in total spending before  
8 enrollee cost sharing; <sup>1</sup>~~and~~<sup>1</sup>

9 (4) the highest year-over-year increase in total spending per user of  
10 any drug in the drug group before enrollee cost sharing<sup>1</sup>;

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

12 (6) the highest year-over-year increase in enrollee cost sharing per  
13 user of any drug in the drug group<sup>1</sup>.

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

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

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

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

25

26 <sup>1</sup>6. a. A pharmacy services administrative organization shall, to the  
27 extent allowed by law, report annually to the division:

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

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

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

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

40

41 <sup>1</sup>~~6.] 7.~~<sup>1</sup> a. The reporting entity shall certify required reporting  
42 under sections 2 through <sup>1</sup>~~5] 6~~<sup>1</sup> of P.L. , c. (C. ) (pending  
43 before the Legislature as this bill) as accurate under the penalty of  
44 perjury.

45 b. Failure of a reporting entity to comply with any section of  
46 P.L. , c. (C. ) (pending before the Legislature as this bill) may  
47 result in a civil penalty as determined by the Director of the Division

1 of Consumer Affairs. Civil penalties under P.L. , c. (C. )  
2 (pending before the Legislature as this bill) may be imposed in the  
3 amount of <sup>1</sup>[\$20,000] \$10,000<sup>1</sup> for the first day that the reporting  
4 entity is found to have violated any section of P.L. , c. (C. )  
5 (pending before the Legislature as this bill), and for subsequent days of  
6 non-compliance, an amount <sup>1</sup>[of] starting at <sup>1</sup>[\$21,000] \$11,000<sup>1</sup>  
7 and increasing by \$1,000 for each additional day of non-compliance,  
8 not to exceed \$100,000 per day.

9 c. The division may audit the data submitted to the division by a  
10 reporting entity pursuant to sections 2 through <sup>1</sup>[5] 6<sup>1</sup> of P.L. , c.  
11 (C. ) (pending before the Legislature as this bill), in a form and  
12 manner specified by the division. The reporting entity shall pay all  
13 costs associated with the audit.

14 d. The division may require a reporting entity to submit a  
15 corrective action plan, in a form and manner specified by the division,  
16 to correct deficiencies in reporting pursuant to sections 2 through <sup>1</sup>[5]  
17 6<sup>1</sup> of P.L. , c. (C. ) (pending before the Legislature as this  
18 bill).

19 e. <sup>1</sup>[The] In addition to the annual public hearing required under  
20 subsection a. of section 9 of P.L. , c. (C. ) (pending before the  
21 Legislature as this bill), the<sup>1</sup> division may call one or more  
22 <sup>1</sup>additional<sup>1</sup> public hearings and may subpoena any reporting entity  
23 pursuant to sections 2 through <sup>1</sup>[5] 6<sup>1</sup> of P.L. , c. (C. )  
24 (pending before the Legislature as this bill).

25

26 <sup>1</sup>[7.] 8.<sup>1</sup> a. Each reporting entity shall register with the division in  
27 a form and manner specified by the division no later than January 31  
28 of each calendar year.

29 b. (1) Each reporting entity shall pay an annual assessment set by  
30 the division to support the operational costs of the division's activities  
31 as required by P.L. , c. (C. ) (pending before the Legislature  
32 as this bill) <sup>1</sup>, including funding necessary to support the Drug  
33 Affordability Council<sup>1</sup>. Operational costs shall include staff salaries,  
34 administrative expenses, data system expenses, and consulting fees of  
35 the division to effectuate the provisions of  
36 P.L. , c. (C. ) (pending before the Legislature as this  
37 bill). The Director of the Division of Consumer Affairs shall certify  
38 actual and prospective costs of the division's activities under  
39 P.L. , c. (C. ) (pending before the Legislature as this bill),  
40 which costs shall be the basis for the establishment of the annual  
41 assessment. <sup>1</sup>The division shall not vary the amount of annual  
42 assessment based on whether a reporting entity is a carrier, pharmacy  
43 benefits manager, wholesaler, manufacturer, pharmacy services  
44 administrative organizations, or other entity. If the total amount of the  
45 assessment that the division collects in a calendar year exceeds the  
46 operational costs certified by the division pursuant to this subsection,  
47 the division shall issue a notice of such surplus and remit the surplus

1 funds in a timely, fair, and equitable manner across all reporting  
2 entities that paid the assessment. Penalties collected pursuant to  
3 section 7 of P.L. , c. (C. ) shall not be refunded pursuant to this  
4 subsection.<sup>1</sup>

5 (2) Requests for payment of the final assessments shall be sent by  
6 the division to all reporting entities under P.L. , c. (C. )  
7 (pending before the Legislature as this bill). <sup>1</sup>**【All assessments shall be**  
8 **due to the division within 30 days of receipt of the request for**  
9 **payment】** The division shall allow reporting entities to make partial  
10 payments when paying the assessment required under this subsection,  
11 with the final payment, as well as any amounts remaining uncollected  
12 from the assessment of the previous fiscal year, to be made no later  
13 than December 31 of a given reporting year<sup>1</sup>.

14  
15 <sup>1</sup>**【8.】** <sup>1</sup>9. a. The division shall annually prepare and make available  
16 on its website a report on emerging trends in prescription drug prices,  
17 and conduct an annual public hearing based on the report findings. The  
18 report shall include, but may not be limited to, analysis of  
19 manufacturer prices and price increases as reported under P.L. , c.  
20 (C. ) (pending before the Legislature as this bill), and analysis of  
21 information as reported by carriers, pharmacy <sup>1</sup>**【benefit】** benefits<sup>1</sup>  
22 managers, and wholesalers under P.L. , c. (C. ) (pending  
23 before the Legislature as this bill), so as to make clear the major  
24 components of prescription drug pricing along the supply chain, and  
25 the impacts on insurance premiums and consumer cost sharing. The  
26 data in the report <sup>1</sup>**【may not reveal information specific to any**  
27 individual reporting entity】 shall not include any information that the  
28 division determines to be confidential pursuant to this section<sup>1</sup>.

29 b. Except as provided in subsection a. of this section, the division  
30 shall keep confidential all information submitted by an individual  
31 reporting entity, and protect it from public disclosure. The division  
32 <sup>1</sup>**【may】** shall<sup>1</sup> share such information with the <sup>1</sup>Drug Affordability  
33 Council and the<sup>1</sup> Department of Banking and Insurance which shall  
34 keep confidential any information shared by the division under P.L. ,  
35 c. (C. ) (pending before the Legislature as this bill) and  
36 protect it from public disclosure. <sup>1</sup>Information that is otherwise  
37 publicly available shall not be deemed confidential solely because it  
38 was submitted to the division pursuant to P.L. , c. (C. )  
39 (pending before the Legislature as this bill). The confidentiality  
40 protections of this section shall be imposed on any downstream third  
41 party that may receive or otherwise have access to this information.

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

46 d. The division shall make available on its Internet website a  
47 method for consumers to submit a complaint to the division regarding

1 the failure of a reporting entity to provide to the division any  
2 information required by section 2 through 6 of P.L. , c. (C. )  
3 (pending before the Legislature as this bill).<sup>1</sup>  
4

5 <sup>1</sup>10. a. The Drug Affordability Council is established in, but not  
6 of, the Department of Law and Public Safety. The purpose of the  
7 council is to formulate legislative and regulatory policy  
8 recommendations that will protect New Jersey residents, State and  
9 local governments, health benefits plans, health care providers,  
10 licensed pharmacies, and other stakeholders within the State health  
11 care system from the high costs of prescription drug products.

12 b. The council shall be comprised of five public members and  
13 three alternate public members, who shall participate in council  
14 deliberations in any case in which a public member is recused or if  
15 there is a vacancy on the council. Public members and alternative  
16 public members shall be appointed within 180 days following the  
17 effective date of P.L. , c. (C. ) (pending before the  
18 Legislature as this bill).

19 (1) (a) The five public members of the council shall be  
20 appointed as follows: three members shall be appointed by the  
21 Governor; one member shall be appointed by the Governor upon  
22 recommendation of the President of the Senate; and one member  
23 shall be appointed by the Governor upon recommendation of the  
24 Speaker of the General Assembly.

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

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

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

41 (3) No public member of the council may be an employee or  
42 board member of, or a consultant to, a manufacturer, pharmacy  
43 benefits manager, pharmacy services administrative organization,  
44 pharmacy, pharmacist, health benefits plan carrier, or wholesale  
45 distributor or related trade association.

46 (4) An individual appointed to the council as a public member  
47 shall disclose, at the time of appointment, any conflict of interest,  
48 including whether the individual has an association, including a

1 financial or personal association, that has the potential to bias or has  
2 the appearance of biasing the individual's decision in matters  
3 related to the council or the conduct of the council's activities.

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

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

8 c. Public members and alternative members of the council shall  
9 serve for a term of five years, except that, of the public members  
10 first appointed, one shall serve a term of three years, two shall serve  
11 a term of four years, and two shall serve a term of five  
12 years. Public members and alternative members shall be eligible  
13 for reappointment to the council. Vacancies in the membership  
14 shall be filled in the same manner as provided for the original  
15 appointment, and members shall serve until a successor has been  
16 appointed.

17 d. (1) The council shall meet in open session, except the  
18 council shall meet in closed session to discuss any information  
19 confidential pursuant to section 9 of P.L. , c. (C. ) (pending  
20 before the Legislature as this bill). The chair shall have the  
21 authority to postpone or cancel any required meeting. All meetings  
22 of the council shall be subject to the requirements of the "Senator  
23 Byron M. Baer Open Public Meetings Act," P.L.1975, c.231  
24 (C.10:4-6 et seq.). Three members shall constitute a quorum for the  
25 purposes of conducting official council business. The division shall  
26 post on its Internet website information concerning public meetings  
27 of the council and reports issued by the council. Posts on the  
28 division's Internet website shall be subject to the confidentiality  
29 requirements set forth in section 9 of P.L. , c. (C. )  
30 (pending before the Legislature as this bill) and subsection h. of this  
31 section.

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

34 (3) The council shall provide the public with the opportunity to  
35 provide written comments.

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

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

40 f. The council may call to its assistance and avail itself of the  
41 services of employees of the division as may be required and made  
42 available for the purposes of this section. Members of the council  
43 shall serve without compensation but may be reimbursed for  
44 expenses reasonably incurred in the performance of their official  
45 duties. The council may call to its assistance and avail itself of the  
46 services of any State, county, or municipal department, board,  
47 commission, or agency, as it may require, and as may be available  
48 to it for its purposes. The council may consult with any government

1 entity, association, organization, or individual having knowledge or  
2 experience relevant to its work.

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

6 h. In addition to reviewing the reports issued and data collected  
7 by the division pursuant to P.L. , c. (C. ) (pending before  
8 the Legislature as this bill), the council may collect and review any  
9 available information regarding prescription drug product  
10 manufacturers, health benefits plan carriers, wholesale distributors,  
11 pharmacy benefits managers, and pharmacy services administrative  
12 organizations, and any other transparency data for prescription drug  
13 products which the council may access and may find useful for its  
14 work. Information obtained by the council shall be made public,  
15 excluding identifying information about a patient or information  
16 that is a trade secret; provided, however, information obtained by  
17 the council from the division that was provided by reporting entities  
18 pursuant to P.L. , c. (C. ) (pending before the Legislature as  
19 this bill) shall be deemed confidential in accordance with section 9  
20 of P.L. , c. (C. ) (pending before the Legislature as this  
21 bill), except that information that is otherwise publicly available  
22 shall not be deemed confidential solely because it was submitted to  
23 the division pursuant to P.L. , c. (C. ) (pending before the  
24 Legislature as this bill). The council shall impose the  
25 confidentiality protections of this subsection on any downstream  
26 third party that may receive or otherwise have access to this  
27 information.

28 i. The council shall review the reports issued and data  
29 collected by the division pursuant to P.L. , c. (C. ) (pending  
30 before the Legislature as this bill) and the information gathered  
31 under subsection h. of this section, and following such review,  
32 submit annually recommendations for legislative, regulatory or  
33 other action to the Governor and, pursuant to section 2 of P.L.1991,  
34 c.164 (C.52:14-19.1), to the Legislature that seek to advance the  
35 goal of more affordable and accessible prescription drugs for New  
36 Jersey residents, including recommendations designed to lower the  
37 cost of prescription drug products that the council determines have  
38 led or will lead to an affordability challenge for the State health  
39 care system and for New Jersey patients and recommendations  
40 concerning the types of data to be reported pursuant to P.L. , c.  
41 (C. ) (pending before the Legislature as this bill). In  
42 developing and providing recommendations, the council shall  
43 consider and address in its reports the impact that any  
44 recommendation could have on research and development, access to  
45 care, or any other direct or indirect economic or social costs that the  
46 council deems relevant. Reports issued by the council shall be  
47 subject to the confidentiality requirements set forth in section 9 of

1 P.L. , c. (C. ) (pending before the Legislature as this bill) and  
2 subsection h. of this section.<sup>1</sup>

3

4 <sup>1</sup>**[9.] 11.**<sup>1</sup> If any provision of this act, P.L. , c. (C. )  
5 (pending before the Legislature as this bill) or the application  
6 thereof to any person or circumstance is held invalid, the invalidity  
7 shall not affect other provisions or applications of the sections  
8 which can be given effect without the invalid provision or  
9 application, and to this end the provisions of this act are severable.

10

11 <sup>1</sup>**[10] 12.**<sup>1</sup> Notwithstanding the provisions of the  
12 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et  
13 seq.), to the contrary, the Director of the Division of Consumer  
14 Affairs may adopt, immediately upon filing with the Office of  
15 Administrative Law, regulations that the director deems necessary  
16 to implement the provisions of P.L. , c. (C. ) (pending  
17 before the Legislature as this bill, which regulations shall be  
18 effective for a period not to exceed <sup>1</sup>**[180] 545**<sup>1</sup> days from the date  
19 of the filing. The director shall thereafter amend, adopt, or readopt  
20 the regulations in accordance with the requirements of P.L.1968,  
21 c.410 (C.52:14B-1 et seq.).

22

23 <sup>1</sup>**[11.] 13.**<sup>1</sup> There is appropriated from the General Fund to the  
24 Division of Consumer Affairs in the Department of Law and Public  
25 Safety <sup>1</sup>**[\$900,000] \$1,500,000**<sup>1</sup> to implement the provisions of this  
26 act.

27

28 <sup>1</sup>**[12.] 14.**<sup>1</sup> This act shall take effect immediately but sections 1  
29 through 9 of this act shall remain inoperable until the first day of  
30 the thirteenth month next following the date of enactment. The New  
31 Jersey Division of Consumer Affairs may take such anticipatory  
32 rulemaking and other administrative action in advance of the  
33 operative date of this act as shall be necessary for the  
34 implementation of this act.