[Second Reprint]

SENATE, No. 1615

STATE OF NEW JERSEY

220th LEGISLATURE

INTRODUCED FEBRUARY 14, 2022

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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)

AN ACT concerning prescription drug prices, supplementing Title 45 of the Revised Statutes, and making an appropriation.

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

1. As used in P.L. , c. (C.) (pending before the Legislature as this bill):

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

"Brand name drug" means a prescription drug approved under 21 USC s.355(b) or 42 USC s.262.

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

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

"Drug group" means a group of drugs defined by the division for the purpose of facilitating revenue and cost reporting by manufacturers, carriers, pharmacy benefits managers, and wholesalers under sections 2 through [1]**[**5**]** 6[1] of P.L. , c. (C.) (pending before the Legislature as this bill).

[1]"Logistics provider" means an entity that receives a prescription drug product from the original or contract manufacturer, warehouses and delivers the prescription drug product at the direction of the manufacturer, and does not purchase, sell, trade, or take title to the prescription drug product.[1]

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

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

[1]"Medicare Part D specialty threshold" means the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

"New drug" means a prescription drug that has received initial approval under an original new drug application under 21 U.S.C. 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:
[1]Senate SBA committee amendments adopted May 11, 2023.
[2]Senate floor amendments adopted June 26, 2023.

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

"Pharmacy benefits manager" means a corporation, business, or other entity, or unit within a corporation, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, a self-insurance plan or other third-party payer, either directly or through an intermediary, administers prescription drug benefits on behalf of a [1][purchaser] carrier, self-funded plan, or other third-party payer.

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

"Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed[1].

"Reporting entity" means any manufacturer, carrier, pharmacy benefits manager, wholesaler, [1]pharmacy services administrative organization,[1] or any other entity required to report to the division under P.L. , c. (C.) (pending before the Legislature as this bill).

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

[1]["WAC unit" means the lowest identifiable quantity of the drug or biological that is dispensed, in the State exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group as indicated by the division, it is the total number of WAC units dispensed in this State in the drug group.][1]

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

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

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

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

c. A manufacturer that notifies the division pursuant to subsection a. of this section shall report to the division the following minimum data, and any other data that may be specified by the division, [1][at least 30] within 20[1] days [1][before] following[1] the price increase:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and [1][WAC] pricing[1] unit of the brand-name drug or generic drug, as applicable;

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

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

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

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

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

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

d. A manufacturer that notifies the division pursuant to subsection b. of this section shall report to division the following minimum data, and any other data that may be specified by the division, 1[at least 60] within 20 1 days 1[before] following 1 the date of market introduction:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and 1[WAC] pricing 1 unit of the new drug;

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

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

(4) WAC at market introduction.

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

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

3. a. A pharmacy 1[benefit] benefits 1 manager shall, to the extent allowed by law, report 1[annually] 1 to the division the following minimum data, and other data that may be specified by the division 1[, within 60 days after receiving notification by the division indicating]. The division shall annually notify pharmacy benefits managers of 1 the specific drugs or drug groups for which reporting is required 1and a pharmacy benefits manager shall have 60 days following such notification to report to the division the following 1:

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

(2) volume in 1[WAC] pricing 1 units of each indicated drug and drug group that the pharmacy 1[benefit] benefits 1 manager negotiated

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

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

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

(5) total net income received in the last calendar year for each drug and drug group as indicated by ¹the¹ division, for business in the State, 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 ¹[8] 9¹ of P.L. , c. (C.) (pending before the Legislature as this bill).

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

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

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

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

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

(5) total net income received in the last calendar year for each drug and drug group as indicated by the division, for business in the State, 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 [1]⟦8⟧ 9[1] 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 [1]and enrollee cost sharing[1], 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 [1]⟦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; [1]⟦and⟧[1]

(4) the highest year-over-year increase in total spending per user of any drug in the drug group before enrollee cost sharing[1];

(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 group[1].

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) the pharmaceutical business model;

(b) supply chain business models;

(c) the practice of medicine and clinical training;

(d) consumer and patient perspectives;

(e) health care cost trends and drivers;

(f) clinical and health services research; and

(g) the State's health care marketplace.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

¹[11.] 13.¹ There is appropriated from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety ¹[$900,000] $1,500,000¹ to implement the provisions of this act.

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