45:14-82.2 to 45:14-82.13, Sec.13 Approp.
LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2023 **CHAPTER:** 106

NJSA: 45:14-82.2 to 45:14-82.13, Sec.13 Approp.: Establishes certain data reporting requirements for prescription drug supply chain; establishes Drug Affordability Council; appropriates $1,500,000.

BILL NO: S1615 (Substituted for A2840 (2R))

SPONSOR(S) Singleton, Troy and others

DATE INTRODUCED: 2/14/2022

COMMITTEE: **ASSEMBLY:** --

SENATE: Commerce
Budget & Appropriation

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** 06/30/2023

SENATE: 06/30/2023

DATE OF APPROVAL: 7/10/2023

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (S1615 ScaSa (2R) enacted) Yes

S1615

INTRODUCED BILL: (Includes sponsor(s) statement) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: No

SENATE: Yes Commerce
Budget & Appropriation

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: Yes

LEGISLATIVE FISCAL ESTIMATE: Yes 03/24/2022
05/23/2023

A2840 (2R)

INTRODUCED BILL: (Includes sponsor(s) statement) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes Financial Institutions & Insurance
Health
Appropriations

SENATE: No

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes 06/13/2022
06/29/2023

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or mailto:refdesk@njstatelib.org

REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: Yes

Susan K. Livio - NJ Advance Media, 'Murphy signs laws to stem high cost of prescription drugs', *Jersey Journal, The*(online), 12 Jul 2023 003

CL/JA

§§1-12
C.45:14-82.2
to 45:14-82.13
§13
Approp.
§14 Note to
§§1-9

P.L. 2023, CHAPTER 106, ***approved July 10, 2023***
Senate, No. 1615 ***(Second Reprint)***

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

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.

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 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] pricing¹ 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 20¹ days ¹[before] following¹ the date of market introduction:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and ¹[WAC] pricing¹ 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] 9¹ of P.L. , c. (C.) (pending before the Legislature as this bill).

3. a. A pharmacy ¹[benefit] benefits¹ 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 of¹ the

specific drugs or drug groups for which reporting is required [1]and 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 [1]the[1] 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).

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 of[1] the specific drugs or drug groups for which reporting is required [1]and a wholesaler 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 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] pricing[1] 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.

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][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] 545¹ 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.

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

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 and Ruiz

SYNOPSIS

Establishes certain data reporting requirements for prescription drug supply chain; requires Division of Consumer Affairs to issue annual report on emerging trends in prescription drug pricing; appropriates $900,000.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 3/16/2023)

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 5 of P.L. , c. (C.) (pending before the Legislature as this bill).

"Manufacturer" means a business registering under P.L.1961, c.52 (C.24:6B-1 et seq.) 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.

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

"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 purchaser.

"Reporting entity" means any manufacturer, carrier, pharmacy benefits manager, wholesaler, 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 the manufacturer's list price to wholesalers or direct purchasers in New Jersey 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.

"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.

"Wholesaler" means a business registering under P.L.1961, c.52 (C.24:6B-1 et seq.) that is engaged in the sale of prescription drugs to persons other than a consumer or patient.

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 WAC unit during any 12-month period, or if it is increasing the WAC of a generic drug priced at $10 or more per WAC unit by more than 10 percent during any 12-month period. The notice shall be provided in writing at least 60 days prior to the planned effective date of the increase.

b. A manufacturer shall notify the division if it intends to introduce: (1) a new drug in the State that has a WAC of $670 per WAC unit or more; 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 at least 60 days prior to market introduction.

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, at least 30 days before the price increase:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and WAC 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 WAC 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, at least 60 days before the date of market introduction:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and WAC 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. Disclosure of all information reported under this section shall be subject to protections defined in section 8 of P.L. , c. (C.) (pending before the Legislature as this bill).

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

(1) minimum and maximum WAC for each indicated drug and drug group for which the pharmacy benefit 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 WAC units of each indicated drug and drug group that the pharmacy benefit 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 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 8 of P.L. , c. (C.) (pending before the Legislature as this bill).

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

(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 WAC 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 8 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, 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 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

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

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.

6. a. The reporting entity shall certify required reporting under sections 2 through 5 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 $20,000 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 of starting at $21,000 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 5 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 5 of P.L. , c. (C.) (pending before the Legislature as this bill).

e. The division may call one or more public hearings and may subpoena any reporting entity pursuant to sections 2 through 5 of P.L. , c. (C.) (pending before the Legislature as this bill).

7. 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) Each 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). 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.

(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). All assessments shall be due to the division within 30 days of receipt of the request for payment.

8. 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 benefit 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 may not reveal information specific to any individual reporting entity.

b. 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 may share such information with 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.

9. 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.

10. 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 180 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.).

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

12. 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.

STATEMENT

This bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost of $670 per unit or more or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost by more than 10 percent per unit for any brand-name drug or any generic drug priced at more than $10 per unit.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $900,000 to implement the provisions of the bill.

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 1615

STATE OF NEW JERSEY

DATED: MARCH 14, 2022

The Senate Commerce Committee reports favorably Senate Bill No. 1615.

This bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost of $670 per unit or more or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost by more than 10 percent per unit for any brand-name drug or any generic drug priced at more than $10 per unit.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $900,000 to implement the provisions of the bill.

As reported by the committee, this bill is identical to Assembly Bill No. 2840.

SENATE BUDGET AND APPROPRIATIONS COMMITTEE

STATEMENT TO

SENATE, No. 1615

with committee amendments

STATE OF NEW JERSEY

DATED: MAY 11, 2023

The Senate Budget and Appropriations Committee reports favorably and with committee amendments Senate Bill No. 1615.

As amended, this bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost that exceeds the Medicare Part D specialty threshold, or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost by more than: (1) 10 percent per pricing unit for any brand-name drug; or (2) any generic drug priced at more than $100 per pricing unit by more than 10 percent during any 12-month period.

Additionally, the bill establishes a Drug Affordability Council in, but not of, the Department of Law and Public Safety. The purpose of this five public member 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. The five public members of the council are appointed as follows: three members appointed by the Governor; one member appointed by the Governor upon recommendation of the President of the Senate; and one member appointed by the Governor upon recommendation of the Speaker of the General Assembly. Each public

member of the council is required to have expertise in health care economics, health care policy, or clinical medicine.

The bill requires the council to review the reports issued and data collected by the division pursuant to the bill and to submit annually recommendations for legislative, regulatory or other action to the Governor and the Legislature that seek to advance the goal of more affordable and accessible prescription drugs for New Jersey residents.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $1,500,000 to implement the provisions of the bill.

COMMITTEE AMENDMENTS:

The committee amended the bill to:

(1) modify the notification requirements that a manufacturer must make to the division if the manufacturer is increasing the wholesale acquisition cost of a generic drug;

(2) allow a manufacturer to provide the division with national data of a drug and drug group in lieu of State-specific data upon proof satisfactory to the division that the State-specific data is unavailable to the manufacturer;

(3) revise timelines for wholesalers to report data to the division on certain drugs and drug groups;

(4) require carriers to report annually to the division: (1) the total enrollee cost sharing in the last calendar year; and (2) the highest year-over-year increase in enrollee cost sharing per use of any drug in the drug group;

(5) revise the information that a pharmacy services administrative organization must provide to the division;

(6) revise civil penalties for entities that do not comply with the division’s reporting requirements;

(7) prohibit the division from varying the annual assessment amount that a reporting entity must pay to the division based on the type of entity paying the assessment;

(8) revise the division’s public reporting requirements;

(9) establish a Drug Affordability Council to review the reports and data complied pursuant to the bill and to formulate legislative and regulatory policy recommendations concerning prescription drugs;

(10) increase the appropriation from $900,000 to $1,500,000; and

(11) make certain technical changes.

FISCAL IMPACT:

Fiscal information for this bill is currently unavailable.

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

SENATE, No. 1615

STATE OF NEW JERSEY
220th LEGISLATURE

DATED: MAY 23, 2023

SUMMARY

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

Type of Impact: Increase in State expenditures in FY 2024; annual increases in State expenditures and revenues thereafter.

Agencies Affected: Department of Law and Public Safety.

Office of Legislative Services Estimate

Fiscal Impact	FY 2024	FY 2025 and Thereafter
State Cost Increase	Up to $1.5 million	Indeterminate
State Revenue Increase	None	Indeterminate

- The Office of Legislative Services (OLS) finds that the bill will increase State expenditures by up to $1.5 million in FY 2024 for the implementation costs of the Division of Consumer Affairs related to the new data reporting requirements established in the bill for drug manufacturers, insurance carriers, pharmacy benefits managers, drug wholesalers, and pharmacy services administrative organizations, and the creation of the Drug Affordability Council. Thereafter, the State will incur indeterminate annual operating costs for the division and the council related to their new responsibilities under the bill.

- Each reporting entity enumerated above is to be charged an annual assessment fee by the division sufficient to support the operational costs of the division stemming from this bill, including costs of the Drug Affordability Council. The division is to remit any surplus assessment fees collected during a calendar year to the reporting entities. The OLS at this point cannot determine the annual operating costs of the division and the council stemming from their duties under the bill or ascertain the revenues the State will receive from the annual assessment fee.

Office of Legislative Services
State House Annex
P.O. Box 068
Trenton, New Jersey 08625

Legislative Budget and Finance Office
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- The State also may collect an indeterminate amount of annual revenue from civil penalties from reporting entities that do not comply the bill's provisions, but a significant level of willful non-compliance is not anticipated.

BILL DESCRIPTION

This bill establishes data reporting requirements for pharmacy benefits managers, wholesale drug distributors, insurance carriers, and drug manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year these reporting entities must register with the division and fulfill certain reporting requirements. Once the division compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill establishes a Drug Affordability Council to formulate legislative and regulatory policy recommendations that will protect New Jersey residents, the State and local governments, health benefits plans, healthcare providers, licensed pharmacies, and other stakeholders within the State health care system from the high costs of prescription drug products. The bill requires the council to review the reports issued and data collected by the division pursuant to the bill and to submit annually recommendations for legislative, regulatory, or other action to the Governor and the Legislature that seek to advance the goal of more affordable and accessible prescription drugs for New Jersey residents.

The bill requires reporting entities to pay an annual assessment set by the division to support the operational costs of the division's activities, including funding necessary to support the Drug Affordability Council. Operational costs include staff salaries, administrative expenses, data system expenses, and consulting fees of the division to effectuate the bill. The division is not permitted to vary the amount of the annual assessments based on the type of reporting entity. If the total assessment collected exceeds the operational costs of the division in a calendar year, the division is required to remit the surplus back to the reporting entities.

The bill establishes civil penalties for failing to report as determined by the Division of Consumer Affairs. Civil penalties may be imposed in the amount of $10,000 for the first day that the reporting entity is found to be in violation and, for subsequent days of non-compliance, an amount starting at $11,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $1.5 million to implement the provisions of the bill.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS finds that the bill will increase State expenditures by up to $1.5 million in FY 2024 for the implementation costs of the Division of Consumer Affairs related to the new data reporting requirements established in the bill for drug manufacturers, insurance carriers, pharmacy benefits

managers, drug wholesalers, and pharmacy services administrative organizations, and the creation of the Drug Affordability Council. Thereafter, the State will incur indeterminate annual operating costs for the council and the Division of Consumer Affairs, as the bill requires: 1) registration of each reporting entity with the division and the establishment of a data reporting intake procedure; 2) an analysis of the submitted data and the issuance of an annual report; 3) the hosting of public hearings on the findings; and 4) administratively supporting the Drug Affordability Council.

Each reporting entity enumerated above is to be charged an annual assessment fee by the division sufficient to support the operational costs of the division as they relate to this bill, including costs of the Drug Affordability Council. The OLS assumes that the division will begin to levy the assessment fee in FY 2025 per the bill's provisions. The division is to remit any surplus assessment fees collected during a calendar year to the reporting entities. The OLS at this point cannot determine the annual operating costs of the division and the council stemming from their duties under the bill or ascertain the revenues the State will receive from the annual assessment fee.

The State also may collect an indeterminate amount of annual revenue from civil penalties from reporting entities that do not comply the bill's provisions, but a significant level of willful non-compliance is not anticipated. Civil penalties may be imposed in the amount of $10,000 for the first day that the reporting entity is found to have violated the bill's provisions and, for subsequent days of non-compliance, an amount starting at $11,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day.

Section:	*Law and Public Safety*
Analyst:	*Kristin Brunner Santos* *Lead Fiscal Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

SENATE, No. 1615

STATE OF NEW JERSEY
220th LEGISLATURE

DATED: MAY 23, 2023

SUMMARY

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

Type of Impact: Increase in State expenditures in FY 2024; annual increases in State expenditures and revenues thereafter.

Agencies Affected: Department of Law and Public Safety.

Office of Legislative Services Estimate

Fiscal Impact	FY 2024	FY 2025 and Thereafter
State Cost Increase	Up to $1.5 million	Indeterminate
State Revenue Increase	None	Indeterminate

- The Office of Legislative Services (OLS) finds that the bill will increase State expenditures by up to $1.5 million in FY 2024 for the implementation costs of the Division of Consumer Affairs related to the new data reporting requirements established in the bill for drug manufacturers, insurance carriers, pharmacy benefits managers, drug wholesalers, and pharmacy services administrative organizations, and the creation of the Drug Affordability Council. Thereafter, the State will incur indeterminate annual operating costs for the division and the council related to their new responsibilities under the bill.

- Each reporting entity enumerated above is to be charged an annual assessment fee by the division sufficient to support the operational costs of the division stemming from this bill, including costs of the Drug Affordability Council. The division is to remit any surplus assessment fees collected during a calendar year to the reporting entities. The OLS at this point cannot determine the annual operating costs of the division and the council stemming from their duties under the bill or ascertain the revenues the State will receive from the annual assessment fee.

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- The State also may collect an indeterminate amount of annual revenue from civil penalties from reporting entities that do not comply the bill's provisions, but a significant level of willful non-compliance is not anticipated.

BILL DESCRIPTION

This bill establishes data reporting requirements for pharmacy benefits managers, wholesale drug distributors, insurance carriers, and drug manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year these reporting entities must register with the division and fulfill certain reporting requirements. Once the division compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill establishes a Drug Affordability Council to formulate legislative and regulatory policy recommendations that will protect New Jersey residents, the State and local governments, health benefits plans, healthcare providers, licensed pharmacies, and other stakeholders within the State health care system from the high costs of prescription drug products. The bill requires the council to review the reports issued and data collected by the division pursuant to the bill and to submit annually recommendations for legislative, regulatory, or other action to the Governor and the Legislature that seek to advance the goal of more affordable and accessible prescription drugs for New Jersey residents.

The bill requires reporting entities to pay an annual assessment set by the division to support the operational costs of the division's activities, including funding necessary to support the Drug Affordability Council. Operational costs include staff salaries, administrative expenses, data system expenses, and consulting fees of the division to effectuate the bill. The division is not permitted to vary the amount of the annual assessments based on the type of reporting entity. If the total assessment collected exceeds the operational costs of the division in a calendar year, the division is required to remit the surplus back to the reporting entities.

The bill establishes civil penalties for failing to report as determined by the Division of Consumer Affairs. Civil penalties may be imposed in the amount of $10,000 for the first day that the reporting entity is found to be in violation and, for subsequent days of non-compliance, an amount starting at $11,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $1.5 million to implement the provisions of the bill.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS finds that the bill will increase State expenditures by up to $1.5 million in FY 2024 for the implementation costs of the Division of Consumer Affairs related to the new data reporting requirements established in the bill for drug manufacturers, insurance carriers, pharmacy benefits

managers, drug wholesalers, and pharmacy services administrative organizations, and the creation of the Drug Affordability Council. Thereafter, the State will incur indeterminate annual operating costs for the council and the Division of Consumer Affairs, as the bill requires: 1) registration of each reporting entity with the division and the establishment of a data reporting intake procedure; 2) an analysis of the submitted data and the issuance of an annual report; 3) the hosting of public hearings on the findings; and 4) administratively supporting the Drug Affordability Council.

Each reporting entity enumerated above is to be charged an annual assessment fee by the division sufficient to support the operational costs of the division as they relate to this bill, including costs of the Drug Affordability Council. The OLS assumes that the division will begin to levy the assessment fee in FY 2025 per the bill's provisions. The division is to remit any surplus assessment fees collected during a calendar year to the reporting entities. The OLS at this point cannot determine the annual operating costs of the division and the council stemming from their duties under the bill or ascertain the revenues the State will receive from the annual assessment fee.

The State also may collect an indeterminate amount of annual revenue from civil penalties from reporting entities that do not comply the bill's provisions, but a significant level of willful non-compliance is not anticipated. Civil penalties may be imposed in the amount of $10,000 for the first day that the reporting entity is found to have violated the bill's provisions and, for subsequent days of non-compliance, an amount starting at $11,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day.

Section:	*Law and Public Safety*
Analyst:	*Kristin Brunner Santos* *Lead Fiscal Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

STATEMENT TO

[First Reprint]

SENATE, No. 1615

with Senate Floor Amendments
(Proposed by Senator SINGLETON)

ADOPTED: JUNE 26, 2023

This floor amendment:

(1) revises the annual assessment requirement for entities and requires the Director of the Division of Consumer Affairs to determine the annual assessment for pharmacy services administrative organizations;

(2) includes civil penalties for persons who willfully disclose confidential information; and

(3) makes certain technical changes.

ASSEMBLY, No. 2840

STATE OF NEW JERSEY

220th LEGISLATURE

INTRODUCED FEBRUARY 28, 2022

Sponsored by:
Assemblyman JOHN F. MCKEON
District 27 (Essex and Morris)
Assemblywoman ANGELA V. MCKNIGHT
District 31 (Hudson)
Assemblyman WILLIAM F. MOEN, JR.
District 5 (Camden and Gloucester)
Assemblyman PAUL D. MORIARTY
District 4 (Camden and Gloucester)

Co-Sponsored by:
Assemblywomen Mosquera and Reynolds-Jackson

SYNOPSIS

Establishes certain data reporting requirements for prescription drug supply chain; requires Division of Consumer Affairs to issue annual report on emerging trends in prescription drug pricing; appropriates $900,000.

CURRENT VERSION OF TEXT

As introduced.

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

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 5 of P.L. , c. (C.) (pending before the Legislature as this bill).

"Manufacturer" means a business registering under P.L.1961, c.52 (C.24:6B-1 et seq.) 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.

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

"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 purchaser.

"Reporting entity" means any manufacturer, carrier, pharmacy benefits manager, wholesaler, 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 the manufacturer's list price to wholesalers or direct purchasers in New Jersey 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.

"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.

"Wholesaler" means a business registering under P.L.1961, c.52 (C.24:6B-1 et seq.) that is engaged in the sale of prescription drugs to persons other than a consumer or patient.

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 WAC unit during any 12-month period, or if it is increasing the WAC of a generic drug priced at $10 or more per WAC unit by more than 10 percent during any 12-month period. The notice shall be provided in writing at least 60 days prior to the planned effective date of the increase.

b. A manufacturer shall notify the division if it intends to introduce: (1) a new drug in the State that has a WAC of $670 per WAC unit or more; 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 at least 60 days prior to market introduction.

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, at least 30 days before the price increase:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and WAC 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 WAC 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, at least 60 days before the date of market introduction:

(1) the national drug code, proprietary drug name, non-proprietary drug name, and WAC 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. Disclosure of all information reported under this section shall be subject to protections defined in section 8 of P.L. , c. (C.) (pending before the Legislature as this bill).

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

(1) minimum and maximum WAC for each indicated drug and drug group for which the pharmacy benefit 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 WAC units of each indicated drug and drug group that the pharmacy benefit 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 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 8 of P.L. , c. (C.) (pending before the Legislature as this bill).

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

(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 WAC 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 8 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, 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 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

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

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.

6. a. The reporting entity shall certify required reporting under sections 2 through 5 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 $20,000 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 of starting at $21,000 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 5 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 5 of P.L. , c. (C.) (pending before the Legislature as this bill).

e. The division may call one or more public hearings and may subpoena any reporting entity pursuant to sections 2 through 5 of P.L. , c. (C.) (pending before the Legislature as this bill).

7. 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) Each 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). 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.

(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). All assessments shall be due to the division within 30 days of receipt of the request for payment.

8. 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 benefit 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 may not reveal information specific to any individual reporting entity.

b. 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 may share such information with 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.

9. 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.

10. 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 180 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.).

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

12. 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.

STATEMENT

This bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost of $670 per unit or more or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost by more than 10 percent per unit for any brand-name drug or any generic drug priced at more than $10 per unit.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $900,000 to implement the provisions of the bill.

ASSEMBLY FINANCIAL INSTITUTIONS AND INSURANCE COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2840

STATE OF NEW JERSEY

DATED: MARCH 14, 2022

The Assembly Financial Institutions and Insurance Committee reports favorably Assembly Bill No. 2840.

This bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost of $670 per unit or more or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost by more than 10 percent per unit for any brand-name drug or any generic drug priced at more than $10 per unit.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $900,000 to implement the provisions of the bill.

This Assembly Bill No. 2840, as reported by this committee, is identical to Senate Bill No.1615.

ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2840

with committee amendments

STATE OF NEW JERSEY

DATED: MAY 24, 2022

The Assembly Health Committee reports favorably and with committee amendments Assembly Bill No. 2840.

As amended by the committee, this bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost of $670 per unit or more or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost by more than 10 percent per unit for any brand-name drug or any generic drug priced at more than $10 per unit.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $900,000 to implement the provisions of the bill.

COMMITTEE AMENDMENTS:

The committee amendments:

(1) add and amend certain definitions for terms used in the bill;

(2) add reporting requirements for pharmacy services administrative organizations, including disclosure of: the negotiated reimbursement rates for the 25 drugs with highest reimbursements; the 25 prescription drugs with the highest year-to-year change in reimbursement rates; and the schedule of fees charged to pharmacies;

(3) add reporting requirements for manufacturers of insulin products, including disclosure of certain sales and pricing features of those products;

(4) replace the $670 price threshold for manufacturer reporting of new drugs with the Medicare Part D specialty threshold;

(5) prohibit the division from disclosing any information specific to an individual reporting entity or that the division determines has the potential to compromise the financial, competitive, or proprietary nature of the information. The confidentiality provisions of the bill apply to any downstream third party that may receive or otherwise have access to confidential information;

(6) provide that a person who is authorized to access information submitted by an individual reporting entity to the division who knowingly discloses such information to any person or entity who is not authorized to access the information is guilty of a crime of the fourth degree and subject to a civil penalty in an amount not to exceed $10,000; and

(7) provide that records, documents, or data provided pursuant to the bill are not be considered government records.

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

[First Reprint]

ASSEMBLY, No. 2840

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 22, 2023

The Assembly Appropriations Committee reports favorably and with committee amendments Assembly Bill No. 2840 (1R).

As amended, this bill establishes data reporting requirements for pharmacy benefits managers (PBMs), wholesale drug distributors, insurance issuers, manufacturers, and pharmacy services administrative organizations so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the department and report on measures such as the volume, sales, revenue and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing: a new drug with a wholesale acquisition cost that exceeds the Medicare Part D specialty threshold, or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched. The price increase reporting requirement applies in any case where a manufacturer increases the wholesale acquisition cost of brand name or generic drugs by certain specified amounts.

Additionally, the bill establishes a Drug Affordability Council in, but not of, the Department of Law and Public Safety. The purpose of this five public member 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. The five public members of the council are appointed as follows: three members appointed by the Governor; one member appointed by the Governor upon recommendation of the President of

the Senate; and one member appointed by the Governor upon recommendation of the Speaker of the General Assembly. Each public member of the council is required to have expertise in health care economics, health care policy, or clinical medicine.

The bill requires the council to review the reports issued and data collected by the division pursuant to the bill and to submit annually recommendations for legislative, regulatory or other action to the Governor and the Legislature that seek to advance the goal of more affordable and accessible prescription drugs for New Jersey residents.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $1,500,000 to implement the provisions of the bill.

COMMITTEE AMENDMENTS:

The committee amended the bill to:

(1) modify the notification requirements that a manufacturer must make to the division if the manufacturer is increasing the wholesale acquisition cost of a generic drug;

(2) allow a manufacturer to provide the division with national data of a drug and drug group in lieu of State-specific data upon proof satisfactory to the division that the State-specific data is unavailable to the manufacturer;

(3) revise timelines for pharmacy benefits managers and wholesalers to report data to the division on certain drugs and drug groups;

(4) require carriers to report annually to the division: (1) the total enrollee cost sharing in the last calendar year; and (2) the highest year-over-year increase in enrollee cost sharing per use of any drug in the drug group;

(5) revise the information that a pharmacy services administrative organization must provide to the division;

(6) revise civil penalties for entities that do not comply with the division's reporting requirements and for persons who willfully disclose confidential information;

(7) prohibit the division from varying the annual assessment amount that a reporting entity must pay to the division based on the type of entity paying the assessment and allow the division to accept partial payments for assessments and remit certain funds in the event of an operational cost surplus;

(8) revise the division's public reporting requirements;

(9) revise the annual assessment requirement and require the Director of the Division of Consumer Affairs to determine the annual assessment for pharmacy services administrative organizations;

(10) establish a Drug Affordability Council to review the reports and data complied pursuant to the bill and to formulate legislative and regulatory policy recommendations concerning prescription drugs;

(11) remove reporting requirements for manufacturers of insulin products;

(12) increase the appropriation from $900,000 to $1,500,000; and

(13) make certain technical changes.

FISCAL IMPACT:

Fiscal information for this bill is currently unavailable.

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

ASSEMBLY, No. 2840

STATE OF NEW JERSEY
220th LEGISLATURE

DATED: JUNE 13, 2022

SUMMARY

Synopsis: Establishes certain data reporting requirements for prescription drug supply chain; requires Division of Consumer Affairs to issue annual report on emerging trends in prescription drug pricing; appropriates $900,000.

Type of Impact: Annual Increase in State Expenditures; Potential Increase in Annual State Revenues.

Agencies Affected: Department of Law and Public Safety; the Judiciary; Office of the Public Defender.

Office of Legislative Services Estimate

Fiscal Impact	FY 2023	FY 2024 and Thereafter
State Cost Increase	Up to $900,000	Indeterminate
Potential State Revenue Increase	Indeterminate	Indeterminate

- The Office of Legislative Services (OLS) finds that the bill will increase State expenditures by up to $900,000 in FY 2023 for salaries, benefits, and one-time start-up costs related to the new data reporting process and required annual report. Thereafter, the State will incur indeterminate annual operating costs for ongoing administrative expenses of the Division of Consumer Affairs in the Department of Law and Public Safety. The bill appropriates $900,000 to support the activities of the division under the bill.

- The State also will incur an indeterminate amount of cost increases to prosecute, defend, and adjudicate individuals who commit the crime of the fourth degree established in the bill. A presumption of non-incarceration applies to first-time offenders of crimes of the fourth degree, and so it is unlikely that there will be any cost increases for the Department of Corrections or the State Parole Board associated with this bill.

- Indeterminate State revenue will accrue from criminal and civil penalties collected from entities and individuals violating the provisions of this bill. However, the State has had difficulty collecting such penalties historically.

BILL DESCRIPTION

This bill establishes data reporting requirements for pharmacy benefits managers, wholesale drug distributors, insurance issuers, and manufacturers so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each of these reporting entities must register with the division and report on measures such as the volume, sales, revenue, and year-over-year change in prescription drug transactions. Once the division compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill establishes civil penalties for failing to report as determined by the Division of Consumer Affairs. Civil penalties may be imposed in the amount of $20,000 for the first day that the reporting entity is found to be in violation and for subsequent days of non-compliance, an amount starting at $21,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day. In addition, a person who is authorized to access information submitted by an individual reporting entity to the division who knowingly discloses such information to any person or entity who is not authorized to access the information is guilty of a crime of the fourth degree and subject to a civil penalty in an amount not to exceed $10,000.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $900,000 to implement the provisions of the bill.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS finds that the bill will increase State expenditures by up to $900,000 in FY 2023 for salaries, benefits, and one-time start-up costs related to the new data reporting process and required annual report. Thereafter, the State will incur indeterminate annual operating costs for ongoing administrative expenses of the division. The bill appropriates $900,000 to support the activities of the Division of Consumer Affairs.

Expenditure Increases: The Division of Consumer Affairs will experience recurring workload increases, as the bill requires: 1) establishment of data reporting intake; 2) analysis of the information and an issuance of an annual report; and 3) the hosting of a public hearing on the findings. The bill provides an appropriation of $900,000 to support the additional administrative activities of the division.

The State also will incur an indeterminate amount of cost increases to prosecute, defend, and adjudicate individuals who commit the crime of the fourth degree established in the bill. The timing and magnitude of these increases are indeterminate because it is not known how frequently

the crime established by this bill will be prosecuted and tried in a given fiscal year. A crime of the fourth degree is adjudicated in State court and is punishable by a term of imprisonment of up to 18 months, a fine up to $10,000, or both. A presumption of non-incarceration applies to first-time offenders of crimes of the fourth degree, and so it is unlikely that there will be any cost increases for the Department of Corrections or the State Parole Board associated with this bill.

Revenue Gains: Additional indeterminate annual State revenue may potentially accrue from criminal and civil penalties collected from violators of the bill's provisions. Civil penalties may be imposed in the amount of $20,000 for the first day that the reporting entity is found to have violated and for subsequent days of non-compliance, an amount starting at $21,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day.

In addition, unauthorized disclosure of certain confidential information may be subject to a civil penalty in an amount not to exceed $10,000. The State has had difficulty collecting such penalties historically, however.

Section:	*Law and Public Safety*
Analyst:	*Kristin Brunner Santos* *Lead Fiscal Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

LEGISLATIVE FISCAL ESTIMATE

[Second Reprint]

ASSEMBLY, No. 2840

STATE OF NEW JERSEY
220th LEGISLATURE

DATED: JUNE 29, 2023

SUMMARY

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

Type of Impact: Increase in State Expenditures in FY 2024; Annual Increases in State Expenditures and Revenues Thereafter.

Agencies Affected: Department of Law and Public Safety.

Office of Legislative Services Estimate

Fiscal Impact	FY 2024	FY 2025 and Thereafter
State Cost Increase	Up to $1,500,000	Indeterminate
State Revenue Increase	None.	Indeterminate

- The Office of Legislative Services (OLS) finds that the bill will increase State expenditures by up to $1.5 million in FY 2024 for the implementation costs of the Division of Consumer Affairs related to the new data reporting requirements established in the bill for drug manufacturers, insurance carriers, pharmacy benefits managers, drug wholesalers, and pharmacy services administrative organizations, and the creation of the Drug Affordability Council. Thereafter, the State will incur indeterminate annual operating costs for the division and the council related to their new responsibilities under the bill.

- Each reporting entity enumerated above is to be charged an annual assessment fee by the division sufficient to support the operational costs of the division stemming from this bill, including costs of the Drug Affordability Council. The division is to remit any surplus assessment fees collected during a calendar year to the reporting entities. The OLS, at this point, cannot determine the annual operating costs of the division and the council stemming from their duties under the bill or ascertain the revenues the State will receive from the annual assessment fee.

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- The State also may collect an indeterminate amount of annual revenue from civil penalties from reporting entities that do not comply with the bill's provisions, but a significant level of willful non-compliance is not anticipated.

BILL DESCRIPTION

This bill establishes data reporting requirements for pharmacy benefits manager, wholesale drug distributors, insurance issuers, manufacturers, and pharmacy services administrative organizations so that the Division of Consumer Affairs can issue an annual report on emerging trends in prescription drug pricing at each stage of the supply chain. Every year, each reporting entity must register with the department and report on measures such as the volume, sales, revenue, and year-over-year change in prescription drug transactions. Once the department compiles this information and publishes its annual report on prescription drug pricing trends, it must hold a public hearing on the findings.

The bill also mandates that a manufacturer notify the department if it is increasing the price of a prescription drug or if it is introducing a new drug with a wholesale acquisition cost that exceeds the Medicare Part D specialty threshold or a biosimilar drug that has a wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar drug is launched. The price increase reporting requirement applies when a manufacturer increases the wholesale acquisition cost of brand name or generic drugs by certain specified amounts.

Additionally, the bill establishes a Drug Affordability Council in, but not of, the Department of Law and Public Safety. The purpose of this five public-member council is to formulate legislative and regulatory policy recommendations that will protect New Jersey residents, State and local governments, health benefits plans, healthcare providers, licensed pharmacies, and other stakeholders within the State health care system from the high costs of prescription drug products. The bill requires the council to review the reports issued and data collected by the division pursuant to the bill and to submit annual recommendations for legislative, regulatory, or other action to the Governor and the Legislature that seek to advance the goal of more affordable and accessible prescription drugs for New Jersey residents.

The bill appropriates from the General Fund to the Division of Consumer Affairs in the Department of Law and Public Safety $1,500,000 to implement the provisions of the bill.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS finds that the bill will increase State expenditures by up to $1.5 million in FY 2024 for the implementation costs of the Division of Consumer Affairs related to the new data reporting requirements established in the bill for drug manufacturers, insurance carriers, pharmacy benefits managers, drug wholesalers, and pharmacy services administrative organizations, and the creation of the Drug Affordability Council. Thereafter, the State will incur indeterminate annual operating

costs for the council and the Division of Consumer Affairs, as the bill requires: 1) registration of each reporting entity with the division and the establishment of a data reporting intake procedure; 2) an analysis of the submitted data and the issuance of an annual report; 3) the hosting of public hearings on the findings; and 4) administratively supporting the Drug Affordability Council.

Each reporting entity enumerated above is to be charged an annual assessment fee by the division sufficient to support the operational costs of the division as they relate to this bill, including costs of the Drug Affordability Council. The OLS assumes that the division will begin to levy the assessment fee in FY 2025 per the bill's provisions. The division is to remit any surplus assessment fees collected during a calendar year to the reporting entities. The OLS, at this point, cannot determine the annual operating costs of the division and the council stemming from their duties under the bill or ascertain the revenues the State will receive from the annual assessment fee.

The State also may collect an indeterminate amount of annual revenue from civil penalties collected from violators of the bill's provisions. However, a significant level of willful non-compliance is not anticipated. Civil penalties may be imposed in the amount of $10,000 for the first day that the reporting entity is found to have violated and for subsequent days of non-compliance, an amount starting at $11,000 and increasing by $1,000 for each additional day of non-compliance, not to exceed $100,000 per day.

In addition, unauthorized disclosure of certain confidential information may be subject to a civil penalty not to exceed $2,500.

Section:	*Law and Public Safety*
Analyst:	*Kristin Brunner Santos* *Lead Fiscal Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

Governor Murphy Signs Legislative Package to Make Prescription Drugs More Affordable for New Jerseyans

07/10/2023

WEST ORANGE – As part of the Murphy Administration's ongoing efforts to advance health care affordability on behalf of the residents of our state, Governor Phil Murphy today si three bills he announced in partnership with legislative sponsors last year to help make prescription drugs more affordable for New Jerseyans. The three bills, which were signed alongside legislators and advocates, will work together to cap certain out-of-pocket costs, establish greater oversight of Pharmacy Benefit Managers, and promote transparency a the pharmaceutical supply chain.

"This is a huge step forward in our ongoing efforts to deliver much-needed relief to countless families throughout our state who are struggling to afford critical medications," **said Governor Murphy.** "I am proud to sign nation-leading legislation that will make a real difference in the lives of New Jerseyans as we continue to work towards making prescription and other health care services more affordable and accessible to everyone."

Today's bill package advances one of the most comprehensive prescription drug price transparency programs in the country to date. The legislation also makes New Jersey only t second state in the nation to cap out of pocket costs for asthma inhalers and EpiPens in addition to capping consumer costs for insulin.

The three bills the Governor signed today are:

- S-1614 – **Caps out-of-pocket costs for many residents** by extending Medicare's new $35/month insulin out of pocket cap to state-regulated markets and NJ public employe plans, as well as capping out of pocket costs for EpiPens and asthma inhalers at $25 and $50 respectively for a month's supply.
- S-1615 – **Creates a new data and transparency system** within the Division of Consumer Affairs to collect, analyze, and report on the entire process of drug pricing across th supply chain in an effort to gain greater insight into drugs with high price increases and launch prices. The bill also establishes a Drug Affordability Council to formulate legislative and regulatory policy recommendations that help advance the goal of prescription drug affordability and accessibility.
- A-536/2841 – **Establishes greater oversight of Pharmacy Benefit Managers (PBMs)**, the third-party companies who manage many prescription-drug plans, to prevent certai practices that drive up costs. This bill requires rebates to be used to lower premiums and out-of-pocket costs for consumers and prevents the practice of spread pricing (wh PBM pockets the difference between what it charges a health plan and reimburses a pharmacy). It also requires PBMs to apply for a license from the NJ Department of Ban Insurance to strengthen regulatory oversight.

With more than half of New Jersey residents concerned about the affordability of prescription drugs and one in four adults skipping or rationing their medications – an issue seen throughout the nation – the Office of Health Care Affordability and Transparency worked closely with legislative partners and other community stakeholders to advance this legisla for prescription drug affordability. Governor Murphy launched this office in 2020 to lead efforts across the Administration to make health care more affordable for residents and ad the unsustainable rise in health care costs.

To further advance prescription affordability, the Governor also included funding in the Fiscal Year 2024 budget to expand eligibility for the Pharmaceutical Assistance for the Aged Disabled (PAAD) program, which further cuts the costs of life-enhancing and life-saving prescription drugs for seniors and residents with disabilities. A companion bill signed on th same day as the budget, in addition to authorizing the eligibility expansion, will help get even more eligible New Jerseyans enrolled in both PAAD and the Senior Gold Prescription Discount program going forward.

The following legislators sponsored one or more of the three bills signed today – Senators Joseph Vitale and Troy Singleton and Assemblyman John McKeon, in addition to Senato Nellie Pou, Linda Greenstein, and Vin Gopal and Assembly Members Roy Freiman, Angela McKnight, Robert Karabinchak, Bill Moen, Gabriela Mosquera, Annette Quijano, Paul Mori Joseph Danielsen, Daniel Benson, and Verlina Reynolds-Jackson.

"Far too many New Jerseyans have experienced the stress of affording the price of a medication, often cutting back on groceries, putting off bills, and even rationing or skipping do And unfortunately, prescription drug costs are just one factor pushing health care out of reach for many residents," **said Shabnam Salih, Director of the Governor's Office of Health Affordability and Transparency.** "My Office is working to lower costs across the health care system through a comprehensive affordability agenda. This package is a critical part o work and a huge step forward that will have a real impact on New Jersey residents. It would not have been possible without the Governor's leadership and the commitment of our partners throughout the Administration, in the Legislature, and in the community."

"These reforms help to address the burdensome high cost of prescription drugs that consumers face across our state," **said New Jersey Department of Banking and Insurance Ac Commissioner Justin Zimmerman.** "Through greater oversight and increased transparency of the factors that contribute to prescription drug pricing, the state can take meaningfu steps to reduce patient costs. Additionally, the department will now require Pharmacy Benefits Managers to meet stringent standards for licensure to prevent practices that can dri prescription drug costs. The enactment of these measures demonstrates Governor Murphy's commitment to improving access to and affordability of health care for New Jersey residents."

"The high cost of prescription medication jeopardizes the health and well-being of the most vulnerable among us: low-income families, the elderly, the uninsured, and people with disabilities," **said Attorney General Matthew J. Platkin.** "I applaud Governor Murphy and the Legislature for taking these important first steps toward reining in the rising cost of prescription drugs in our state."

"The Division of Consumer Affairs is dedicated to ensuring fairness and transparency in the market and we welcome the opportunity to shine a light on the high cost of prescriptio drugs," **said Cari Fais, Acting Director of the Division of Consumer Affairs.** "Creating a system to collect, analyze, and report data on the entire process of drug pricing across the s chain is critical to gaining greater insight and promoting accountability in the drug industry. New Jersey consumers deserve nothing less."

"Across the nation, too many people are being forced to ration or go without critically needed and potentially life-saving prescription medications. I'm proud that in New Jersey we working to make the prescription drug industry more transparent," **said Assembly Speaker Craig J. Coughlin.** "The legislation being signed into law today will help us better unders how medications are priced, giving us the data necessary to respond and promote increased access to appropriate care as well as improve oversight and transparency of the entir pharmaceutical supply chain."

"New Jersey's affordability crisis affects all of us – most especially those who rely on prescription drugs to live. Now more than ever, we must work to make life-saving medicine m accessible and affordable," **said Senator Singleton.** "This package will address affordability and stimulate transparency and accountability within the pharmaceutical industry. Eac every day, someone skips a dose or cuts a pill in half just to save money. In the richest nation in the world, and one of the wealthiest states in America, this is unacceptable and sim unconscionable."

"For far too long, consumers have been excluded from the drug pricing process and left to bear the brunt of prescription cost increases. This package will bring to light the inner workings and beneficiaries within the pharmaceutical industry and work to combat rising prices," **said Senator Vitale, Chair of the Senate Health Committee.** "Inflated prescription prices without reasoning or accountability is unfair and irresponsible; these laws will ensure that pharmaceutical companies and manufacturers are open and honest with the consumers they serve."

"Many consumers have struggled to afford necessary medicine," **said Assemblyman McKeon.** "The legislation being signed into law will help us understand what's behind the rise drug prices and allow us to develop policies focused on affordability, while keeping those in the industry accountable for their actions."

"Access to prescription medications can dramatically improve one's quality of life, and in some cases they are difference between life and death," **said Assemblyman Freiman.** "The new laws will help make prescription drugs more affordable and accessible for all New Jersey families. We must fight for the future health of our communities. Nobody should have go without the medication they need to survive."

"Currently, we are facing a severe affordability crisis throughout the nation, and the stunning increase in prescription drug prices continues to play a huge role. Consumers are kept dark about these price increases, which is neglectful of the impact these increases have on residents," **said Senator Pou.** "These laws will help to keep consumers prepared and informed while holding pharmaceutical companies and manufacturers accountable."

As prescription drug prices continue to skyrocket, approximately 30 million Americans are diagnosed with diabetes and are subjected to pay three times what people living overseas would pay for the same drug," **said Senator Greenstein.** "This law is a major step forward in our efforts to mitigate the current drug affordability crisis, and will make insulin, asthma inhalers, and other critical treatments affordable for New Jersey residents."

"Too many residents are forced to delay or all together forego taking a prescription due to the cost," **said Senator Gopal.** "This legislation will regulate the behind-the-scene business practices of pharmacy benefits managers to be more transparent, require licenses, data and records reporting, and cost establishment modifications to help address the prescription drug affordability crisis facing our state."

"AARP commends Governor Murphy and the NJ Legislature for enacting legislation today that will meaningfully respond to the skyrocketing costs of prescription medications," **said Crystal McDonald, AARP New Jersey Associate State Director of Advocacy.** "High prescription drug prices hit older Americans particularly hard. More than two out of three NJ voters 50 plus are concerned they won't be able to afford the medicines they need in the future. S1615 will give our State the data and tools to ensure transparency across the pharmaceutical supply chain and establish a Drug Affordability Council - responsible for actionable recommendations to lower drug costs. S1614 will cap the out-pocket-costs on insulin, asthma inhalers, and epi-pens for many insured New Jerseyans – keeping these life-saving drugs within financial reach of so many. We applaud Governor Murphy, Senator Singleton, Senator Vitale and Assemblyman McKeon for championing this legislation."

"It's been a long road, but we finally have a law that puts us on the path of making prescription drugs more affordable for New Jerseyans," **said New Jersey Citizen Action Healthcare Program Director Laura Waddell.** "A Drug Affordability Council will help rein in prices at the pharmacy counter and ensure patients don't have to choose between paying for lifesaving medicines or for other essential needs. We thank Senator Singleton and Assemblyman McKeon for tirelessly championing this legislation, and applaud Governor Murphy and all our elected leaders who supported meaningful drug pricing reform. We also thank all our New Jersey for Affordable Drugs campaign partners and the countless grassroots advocates and activists whose work made this day possible. NJCA looks forward to continue working with both Governor Murphy and our Legislature throughout implementation."

"GSPO is proud to have supported this critically-needed package of bills. Many of the new laws' provisions are unparalleled and incredibly forward-thinking," **said Executive Director Garden State Pharmacy Owners Brian Oliveira, PharmD.** "The leadership demonstrated by the sponsors, co-sponsors, and Governor Murphy's Office will assuredly benefit New Jersey patients and providers. We look forward to working closely with the Administration on implementation of the laws."

"I am pleased to extend the New Jersey Pharmacists Association's (NJPhA) sincere thanks to Governor Murphy, the bill sponsors, and co-sponsors for their hard work in bringing this extensive prescription drug transparency package to fruition," **said Rupal Mansukhani, Pharm.D - NJPhA President.** "It will assist New Jersey pharmacies and pharmacists in providing the highest level of care to patients. These new laws are forward thinking with innovative provisions that protect patients, providers, and plan sponsors."

"The American Diabetes Association celebrates New Jersey's passage of critical legislation aimed at lessening the financial burden of insulin costs for people living with diabetes," **Monica Billger, State Government Affairs Director for the American Diabetes Association.** "While Congress passed a $35 cap for Medicare recipients last year, an affordability gap remained for many others with diabetes. New Jersey, along with 24 other states and the District of Columbia, are taking the lead to close the gap and improve affordability and access to life-saving insulin."

"I applaud Gov. Murphy's actions to lower the cost of prescription drugs for patients. The out-of-pocket caps on insulin, epi pens, and asthma inhalers will dramatically lower cost barriers to life-saving drugs for many families who depend on them," **said Center for American Progress' Senior Vice President of Inclusive Growth, Emily Gee.** "The state's new measures to tighten oversight of pharmacy benefit managers (PBM) and shed light on pricing throughout the drug supply chain are crucial for improving competition and reducing costs for New Jersey residents."

"Drug prices are outrageously high, and Americans are demanding action. Today, Governor Murphy is taking important steps to meet that demand by working to protect patients," **said Alex Lawson, Executive Director of Social Security Works.** "These actions should be a model for governors across the country, as well as federal policymakers."

"Nurses for America applauds Governor Murphy's progressive and innovative package of bills to advance drug affordability and access in New Jersey," **said Sherry Pomeroy PhD, Faith Community Nurse.** "As nurses we care for individuals, families & communities across the lifespan who struggle to afford medications critical to their overall health & well-being such as insulin, asthma inhalers, and epinephrine pens. The ability to obtain and afford medications needed to treat a wide variety of health conditions is a basic health care right."

"We have known for years that insulins suffer from some of the greatest disconnects between the list prices and the real prices of those medicines, with much of the fluffed up costs paid by patients and employers being cannibalized by intermediaries within the drug channel, **said Antonio Ciacca, CEO, 46brooklyn Research**. "Within drug classes where these price distortions are most pronounced, it is a good thing for patients that they won't have to continue to overpay for medicines in order to generate discounts that are pocketed by others."

"PBMs are supposed to be working on behalf of patients and plan sponsors to make prescription drugs more affordable," **continued Ciaacia.** "However, due to a lack of transparency and significant conflicts of interest, PBMs often make our dysfunctional drug pricing system even worse. A 536/2841 is on the leading edge of these state PBM reforms, with a number of innovative approaches that attempt to curtail anti-competitive behavior and drug price manipulation. This seems like a very worthwhile effort to provide greater oversight and accountability to an important aspect of our healthcare delivery system."

"You shouldn't have to choose between paying the rent or getting a prescription filled — yet for many people, this is a reality," **shared Mona Shah, Senior Director of Policy and Strategy Community Catalyst**. "Important policy changes are necessary to create a more equitable health system, and we applaud Governor Murphy as well as our partners at NJ Citizen Action for their meaningful work to make prescription drugs more affordable. This will give people, families, and communities the relief so clearly needed. At Community Catalyst, we won't stop fighting until everyone has what they need to be healthy, and health is a right for all."