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ASSEMBLY, No. 2840

STATE OF NEW JERSEY

220th LEGISLATURE

INTRODUCED FEBRUARY 28, 2022

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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 reported by the Assembly Health Committee on May 26, 2022, with amendments.

(Sponsorship Updated As Of: 5/18/2023)

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

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

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

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

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

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

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

"Drug group" means a group of drugs defined by the division for the purpose of facilitating revenue and cost reporting by manufacturers, carriers, pharmacy benefits managers, and wholesalers under sections 2 through [1]**[**5**]** 7[1] of P.L. , c. (C.) (pending before the Legislature as this bill).

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

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

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

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

"New drug" means a prescription drug that has received initial approval under an original new drug application under 21 U.S.C. s.355(b), under an abbreviated new drug application under 21 U.S.C. s.355(j), or under a biologics license application under 42

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]Assembly AHE committee amendments adopted May 26, 2022.

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 P.L.1961, c.52 (C.24:6B-12). "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 $10 or more per [1]**[**WAC**]** pricing[1] 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 [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 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 [1]**[**WAC**]** pricing[1] unit of the brand-name drug or generic drug, as applicable;

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

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

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

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

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

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

d. A manufacturer that notifies the division pursuant to subsection b. of this section shall report to division the following minimum data, and any other data that may be specified by the division, at least 60 days before 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. Disclosure of all information reported under this section shall be subject to protections defined in section ¹[8] 10¹ 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 ¹[WAC] pricing¹ 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 ¹the¹ division, for business in the State, in total and for each payer type as relevant.

b. Disclosure of all information reported under this section shall be subject to protections defined in section ¹[8] 10¹ 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 ¹[WAC] pricing¹ units of each indicated drug and drug group that the wholesaler negotiated directly with the manufacturer in the last calendar year, for business in the State, in total and for each payer type as relevant;

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

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

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

b. Disclosure of all information reported under this section shall be subject to protections defined in section ¹[8] 10¹ 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.

[1]6. a. A pharmacy services administrative organization shall, to the extent allowed by law, report annually to the division:

(1) the negotiated reimbursement rate of the 25 prescription drugs with the highest reimbursement rates during the previous year;

(2) the 25 prescription drugs with the highest year-to-year change in reimbursement rate for the previous year; 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 10 of P.L. , c. (C.) (pending before the Legislature as this bill).[1]

[1]7. a. A manufacturer of an insulin product shall report annually to the division:

(1) the name of the insulin products currently manufactured;

(2) identification of whether the insulin products are brand name or generic drug products;

(3) total sales of insulin products to New Jersey consumers quantified in total units and total revenue;

(4) the effective date and amounts of any changes in the wholesale acquisition cost or other list prices for insulin during the prior calendar year;

(5) aggregate, company-level research and development costs for insulin over the prior calendar year;

(6) the name of each of the manufacturer's insulin products that were approved by the federal Food and Drug Administration in the previous five calendar years;

(7) the name of each of the manufacturer's insulin products that lost patent exclusivity in the United States in the previous five calendar years; and

(8) a statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost or list price increase for insulin.

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

[1]~~[6.]~~ 8.[1] a. The reporting entity shall certify required reporting under sections 2 through [1]~~[5]~~ 7[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 $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 ¹[5] 7¹ 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] 7¹ 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 ¹[5] 7¹ of P.L. , c. (C.) (pending before the Legislature as this bill).

¹[7.] 9.¹ 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) 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.

¹[8.] 10.¹ 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 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. [1](1)[1] 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. [1]The division and its agents shall not publish or otherwise disclose any information specific to or that would allow for the identification of 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 this subsection shall apply to any downstream third party that may receive or otherwise have access to this information.

(2) 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 shall be guilty of a crime of the fourth degree and shall be subject to a civil penalty in an amount not to exceed $10,000.

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.).

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.[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 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.).

[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 $900,000 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.