SPECIAL ADOPTION

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
Prescription Drug Price Transparency
Specially Adopted and Concurrently Proposed New Rules: N.J.A.C. 13:45K

Special New Rules Adopted and Concurrent Proposed New Rules Authorized: October 15, 2024, by Cari Fais, Acting Director, New Jersey Division of Consumer Affairs.
Filed: October 15, 2024, as R.2024 d.108.
Authority: N.J.S.A. 45:14-82.2 et seq. (P.L. 2023, c. 106).
Calendar Reference: See Summary below for explanation of exception to calendar requirement.
Concurrent Proposal Number: PRN 2024-133.
Effective Date: October 15, 2024.
Expiration Date: October 10, 2026.

Submit written comments by January 17, 2025, to:

Cari Fais, Acting Director
State of New Jersey
Division of Consumer Affairs
Office of the Director
PO Box 45027
Newark, New Jersey 07101

or electronically at: http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx

In accordance with P.L. 2023, c. 106 (the Act), the New Jersey Division of Consumer Affairs (Division) has adopted new rules regarding the registration of and reporting by five types of entities in the prescription drug supply chain that became effective on October 15, 2024, upon acceptance for filing by the Office of Administrative Law. The specially adopted new rules shall be effective for a period not to exceed 545 days from their effective date (October 15, 2024). Concurrently, these new rules are being proposed for readoption in accordance with the requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. Therefore, the initial expiration date of the specially adopted new rules, based on a filing date of October 15, 2024, is April 13, 2026, which date is extended 180 days to October 10, 2026, pursuant to N.J.S.A. 52:14B-5.1.c(2).

The agency special adoption and concurrent proposal follows:

Summary

The Act tasks the Division with registering five types of entities in the prescription drug supply chain, collecting data and information from them, and preparing an annual report. The five types of entities are manufacturers, carriers, pharmacy benefits managers, wholesalers, and pharmacy services administrative organizations. The Drug Affordability Council, created by the Act, will use these annual reports to formulate legislative and regulatory policy recommendations. The Division has specially adopted and concurrently proposes to readopt N.J.A.C. 13:45K to implement the Act.

New N.J.A.C. 13:45K-1.1 states that the purpose of Chapter 45K is to implement the Act, which requires registration, notification, and reporting to the Division by

reporting entities to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing.

New N.J.A.C. 13:45K-1.2 sets forth definitions. The definitions at N.J.A.C. 13:45K-1.2 are derived from the definitions in the Act, except for “biological product,” “Data Collection Manual,” “drug group,” “generic drug,” and “prescription drug.” “Biological product” or “biologics” has the same meaning as “biological product,” as that term is defined at 42 U.S.C. § 262(i)(1). “Data Collection Manual” means the Drug Price Transparency Data Collection Manual that was issued in October 2024, and is incorporated into the new chapter by reference, as amended and supplemented, and available on the Division website. “Drug group” means a group of one or more prescription drugs that share a unique generic drug description or nontrade name. “Generic drug” means a prescription drug that is marketed or distributed pursuant to an abbreviated new drug application approved pursuant to 21 U.S.C. § 355(j); as an authorized generic drug as defined pursuant to 42 CFR 447.502; or as a drug that entered the market prior to 1962 and was not originally marketed pursuant to a new drug application. The definition of “prescription drug” is drawn from N.J.S.A. 45:14-41 and clarified to reference the definitions of “drugs” and “biological products” at 21 U.S.C. § 321(g) and 42 U.S.C. § 262(i)(1), respectively. The definition of “prescription drug” does not include veterinary products.

New N.J.A.C. 13:45K-1.2 also clarifies certain definitions in the Act. The definition of “brand-name drug” in the Act is clarified to exclude authorized generic drugs, which are not brand-name drugs, and to cite the proper subsection in the U.S. Code. The definition of “manufacturer” is clarified to include a business which creates, makes, or produces prescription drugs that are biological products. The definition of “manufacturer” also clarifies that a business that: (1) creates, makes, or produces prescription drugs, or contracts with another party that creates, makes, or produces prescription drugs on the business's behalf; and that (2) sells, causes to be sold, or distributes prescription drugs in this State shall constitute a "manufacturer" regardless of whether it has a physical presence in the State. The definition of “new drug” is clarified to include supplemental new drug applications, as well as original new drug applications. The definition of “pharmacy benefits manager” is clarified to include only the pharmacy benefits managers that administer prescription drug benefits for New Jersey residents. The definition of “pricing unit” is clarified to include the smallest amount of a prescription drug that can be administered, as well as dispensed.

The definition of “wholesale acquisition cost” or “WAC” is clarified to remove a timeframe, because the timeframe in the Act’s definition (“the most recent month for which the information is available”) is in conflict with the timeframes in other provisions of the Act. For example, N.J.S.A. 45:14-82.3.c(3) requires manufacturers to report WAC for the year of market introduction, WAC at market introduction, WAC in the previous calendar year, and current WAC. N.J.S.A. 45:82.4.a(1) and 45:82.5.a(1) require pharmacy benefits managers and wholesalers, respectively, to report minimum and maximum WAC in the last calendar year.

The Act’s definition of “wholesaler” applies to a wholesale drug business as defined at N.J.S.A. 24:6B-12, which is a wholesaler of non-prescription drugs. The Act requires the Division to use the reported data to prepare a report “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." See N.J.S.A. 45:14-82.10 (emphasis added). Accordingly, the Division proposes to clarify the definition of "wholesaler" in the new rules to encompass wholesalers of prescription drugs required to be licensed pursuant to N.J.S.A. 24:6B-15.

New N.J.A.C. 13:45K-1.3 addresses the registration of reporting entities and their payment of an assessment to the Division. New N.J.A.C. 13:45K-1.3(a) requires reporting entities to register with the Division by January 31 of each year and report changes in registration information within 30 days pursuant to the Data Collection Manual. New N.J.A.C. 13:45K-1.3(b) sets forth the annual assessment for manufacturers, pharmacy benefits managers, wholesalers, and carriers at $4,740. The Act requires that the Division not vary the assessment for these reporting entities. New N.J.A.C. 13:45K-1.3(c) sets forth the annual assessment for pharmacy services administrative organizations at $1,170.

The Act requires the Division to allow reporting entities to make partial payments of the annual assessment. New N.J.A.C. 13:45K-1.3(d) provides that a reporting entity may pay the assessment in full or in equal monthly installments, with final payment to be made by December 31 of each reporting year. New N.J.A.C. 13:45K-1.3(e) states that a carrier is required to register with the Division if it issues a health benefits plan with a prescription drug benefit. New N.J.A.C. 13:45K-1.3(f) states that an entity that includes more than one type of reporting entity must register and pay an assessment fee for each type of reporting entity it encompasses.

New N.J.A.C. 13:45K-1.4 addresses notifications and reporting by manufacturers. New N.J.A.C. 13:45K-1.4(a) addresses manufacturer notification and reporting of price increases. New N.J.A.C. 13:45K-1.4(b) addresses manufacturer notification and reporting of the introduction of a new drug or biosimilar. Consistent with the Act, new N.J.A.C. 13:45K-1.4(c) permits manufacturers to certify that they do not have access to State-specific data and have no way of obtaining it and providing proof satisfactory to the Division, and to instead report national data to the Division within the 20-day timeframe applicable to State-specific data. New N.J.A.C. 13:45K-1.4(d) requires a manufacturer to certify that the reporting pursuant to this section is accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

New N.J.A.C. 13:45K-1.5 addresses reporting by pharmacy benefits managers. New N.J.A.C. 13:45K-1.5(a) provides that the Division will notify pharmacy benefits managers annually of the specific drugs or drug groups for which reporting is required, and the pharmacy benefits manager has 60 days to report to the Division the information at N.J.S.A. 45:14-82.4.a and any other data requested by the Division to make clear the major components of prescription drug pricing, along the supply chain and the impacts on insurance premiums and consumer cost sharing. New N.J.A.C. 13:45K-1.5(b) requires a pharmacy benefits manager to certify that the reporting pursuant to this section is accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

New N.J.A.C. 13:45K-1.5(c) and 1.6(c) address factors that the Division shall consider in determining the drugs or drug groups for which pharmacy benefits managers and wholesalers, respectively, must report. Paragraph (c)1 of both subsections provides that the Division shall consider information from other reporting

entities. Paragraph (c)2 of both subsections provide that the Division shall consider whether a drug is listed on the New Jersey Prescription Drug Price Registry due to the frequency with which it is prescribed. Paragraph (c)3 of both subsections provide that the Division shall consider prices and price increases. Paragraph (c)4 of both subsections states that the Division shall consider whether there are alternatives to the drug and, if so, their cost and availability. Paragraph (c)5 of both subsections provides that the Division shall consider whether the drug appears on the current Model List of Essential Medicines or the Essential Medicines List for Children adopted by the World Health Organization. Paragraph (c)6 of both subsections provides that the Division shall consider the drug's efficacy in treating a life-threatening health condition or a chronic condition that substantially impairs a person's ability to engage in activities of daily living. Paragraph (c)7 of both subsections provides that the Division shall consider any other information relevant to making clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing. The Division believes that considering these factors will ensure that the Division identifies drugs and drug groups that have an impact on public health or that are important to consumers for reporting by pharmacy benefits managers and wholesalers.

New N.J.A.C. 13:45K-1.6 addresses reporting by wholesalers. New N.J.A.C. 13:45K-1.6(a) provides that the Division will notify wholesalers annually of the specific drugs or drug groups for which reporting is required, and the pharmacy benefits manager has 60 days to report to the Division the information at N.J.S.A. 45:14-82.5.a and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing. New N.J.A.C. 13:45K-1.6(b) requires a wholesaler to certify that the reporting pursuant to this section is accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

New N.J.A.C. 13:45K-1.7 addresses reporting by carriers. New N.J.A.C. 13:45K-1.7(a) requires carriers that issue a health benefits plan with a prescription drug benefit to report to the Division annually, within 60 days of the close of each calendar year, the information at N.J.S.A. 45:14-82.6.b and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing for the top 25 drugs and drug groups at N.J.S.A. 45:14-82.6.a. New N.J.A.C. 13:45K-1.7(b) requires a carrier to certify that the reporting pursuant to this section is accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

New N.J.A.C. 13:45K-1.8 addresses reporting by pharmacy services administrative organizations. New N.J.A.C. 13:45K-1.8(a) requires a pharmacy services administrative organization to report to the Division annually within 60 days of the close of each calendar year the information at N.J.S.A. 45:14-82.7.a and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing. New N.J.A.C. 13:45K-1.8(b) requires a pharmacy services administrative organization to certify that the reporting pursuant to this section is accurate and

complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

New N.J.A.C. 13:45K-1.9 requires reporting entities to comply within 60 days with a request from the Division for State-specific data for any drug or drug group on which a manufacturer reported pursuant to N.J.A.C. 13:45K-1.4(a) and (b) for which State-specific data is unavailable to the manufacturer.

As the Division has provided a 60-day comment period on this notice of special adoption and concurrently proposed readoption, this notice is exempted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3.

Social Impact

The Division believes the specially adopted rules that are proposed herein for readoption will have a positive impact by providing information to the Division to prepare an annual report on emerging trends in prescription drug prices that makes clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing. The report will be used by the Drug Affordability Council to formulate legislative and regulatory policy recommendations to benefit New Jersey consumers.

Economic Impact

The Division believes the specially adopted rules that are proposed herein for readoption will have an economic impact on reporting entities. Reporting entities will pay an annual assessment to the Division to support the operational costs of the Division's activities as required by the Act, including funding necessary to support the Drug Affordability Council. Reporting entities will also incur costs of compliance with the notification and reporting requirements in the specially adopted and proposed new rules.

The Division believes that the specially adopted rules that are proposed herein for readoption will have a positive economic impact on consumers to the extent the Division's annual report leads to policy recommendations that address the cost of prescription drugs.

Federal Standards Statement

A Federal standards analysis is not required because the specially adopted rules that are proposed herein for readoption are governed pursuant to N.J.S.A. 45:14-82.2 et seq., and there are no Federal laws or standards applicable to the specially adopted rules that are proposed herein for readoption.

Jobs Impact

The Division does not anticipate that the specially adopted rules that are proposed herein for readoption will have an impact on the number of jobs in the State.

Agriculture Industry Impact

The Division does not believe that the specially adopted rules that are proposed herein for readoption will have any impact on the agriculture industry of this State.

Regulatory Flexibility Analysis

The specially adopted rules that are proposed herein for readoption impose registration, reporting, and compliance requirements on reporting entities, as described in the Summary above. Any reporting entity that is a "business which is resident in this State, independently owned and operated and not dominant in its field, and which employs fewer than 100 full-time employees" constitutes a "small business" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. (RFA), N.J.S.A. 52:14B-17. The Division does not have data, such as the number of individuals employed by reporting entities, to estimate the number of small businesses affected by this rulemaking. However, given the types of reporting entities, the Division estimates that few small businesses will be affected by this rulemaking. To the extent a reporting entity qualifies as a "small business" pursuant to the RFA, the following analysis applies pursuant to N.J.S.A. 52:14B-19.

The requirements imposed on reporting entities that are small businesses, the associated costs of compliance to these small businesses, and the professional services that these small businesses retain to comply with the specially adopted rules that are proposed herein for readoption are the same as those imposed on businesses generally, and are described in the Summary and Economic Impact above. Some reporting entities may choose to engage the services of a third party to assist with the registration and reporting process. The costs associated with engaging these services are difficult to estimate and will vary depending upon the amount of work that the reporting entity will require and the rate charged for these services. The reporting requirements of the specially adopted rules that are proposed herein for readoption serve to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing and to provide the Drug Affordability Council with the information needed to make recommendations regarding prescription drug pricing. The Division believes that the specially adopted and proposed new rules establish the minimum standards necessary to implement the Act and must be applied uniformly to all reporting entities, regardless of size.

Housing Affordability Impact Analysis

The specially adopted and proposed new rules will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the specially adopted and proposed new rules would evoke a change in the average costs associated with housing because the rulemaking concerns prescription drug price transparency.

Smart Growth Development Impact Analysis

The specially adopted and proposed new rules will have an insignificant impact on smart growth and there is an extreme unlikelihood that the specially adopted and proposed new rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan because the rulemaking concerns prescription drug price transparency.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Division has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the specially adopted and concurrently proposed new rules follows:

CHAPTER 45K

PRESCRIPTION DRUG PRICE TRANSPARENCY

SUBCHAPTER 1. PRESCRIPTION DRUG PRICE REPORTING

13:45K-1.1 Purpose and scope

The purpose of this chapter is to implement the provisions at P.L. 2023, c. 106 (N.J.S.A. 45:14-82.2 et seq.), which requires registration, notification, and reporting to the Division by reporting entities to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing.

13:45K-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Biological product" or "biologics" has the meaning of biological product as defined at 42 U.S.C. § 262(i)(1).

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

"Brand-name drug" means a prescription drug approved pursuant to:

1. 21 U.S.C. § 355(b), except for an authorized generic drug as defined at 42 CFR 447.502; or

2. 42 U.S.C. § 262(a)(2)(C).

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

"Data Collection Manual" means the Drug Price Transparency Data Collection Manual that was issued in October 2024, and is incorporated herein by reference, as amended and supplemented, and available on the Division website at https://www.njconsumeraffairs.gov/.

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

"Drug group" means a group of one or more prescription drugs that share a unique generic drug description or nontrade name.

"Generic drug" means a prescription drug that is marketed or distributed:

1. Pursuant to an abbreviated new drug application approved pursuant to 21 U.S.C. § 355(j);

2. As an authorized generic drug as defined at 42 CFR 447.502; or

3. As a drug that entered the market prior to 1962 and was not originally marketed pursuant to a new drug application.

"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.

“Manufacturer” means a business registering pursuant to P.L. 1961, c. 52 (N.J.S.A. 24:6B-1 et seq.), as a drug manufacturing business as defined in section 13 at P.L. 1961, c. 52 (N.J.S.A. 24:6B-12), or a business which creates, makes, or produces prescription drugs that are biological products. A business that: (1) creates, makes, or produces prescription drugs, or contracts with another party that creates, makes, or produces prescription drugs on the business's behalf; and that (2) sells, causes to be sold, or distributes prescription drugs in this State shall constitute a "manufacturer" regardless of whether it has a physical presence in the State.

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

“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 through an original or supplemental new drug application pursuant to 21 U.S.C. § 355(b), under an abbreviated new drug application pursuant to 21 U.S.C. § 355(j), or under a biologics license application pursuant to 42 U.S.C. § 262. In cases where multiple products are included on an application, each product shall be considered a new prescription drug.

“Pharmacy benefits manager” or “PBM” means a corporation, business, or other entity, or unit within a corporation, business, or other entity that, pursuant to a contract or pursuant to 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 for New Jersey residents on behalf of a carrier, self-funded plan, or other third-party payer.

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

“Prescription drug” means a drug, as defined at 21 U.S.C. § 321(g), or a biological product as defined at 42 U.S.C. § 262(i)(1), which, pursuant to Federal law, is required to be labeled prior to being delivered to the pharmacist, with “Rx Only” or is required by any applicable Federal or State law, rule, or regulation to be dispensed pursuant to a prescription drug order or is restricted to use by a practitioner only.

“Pricing unit” means the smallest amount of a prescription drug that could be dispensed or administered.

“Reporting entity” means any manufacturer, carrier, pharmacy benefits manager, wholesaler, pharmacy services administrative organization, or any other entity required to report to the Division pursuant to P.L. 2023, c. 106 (N.J.S.A. 45:14-82.2 et seq.).

“Wholesale acquisition cost” or “WAC” means, with respect to a prescription drug, the manufacturer’s list price for the drug to wholesalers or direct purchasers in New Jersey, as defined at 42 U.S.C. § 1395w-3a(c)(6)(B), excluding any discounts, rebates, or reductions in price as reported in wholesale price guides or other publications of prescription drug pricing.

“Wholesaler” means a business required to be licensed pursuant to N.J.S.A. 24:6B-15. “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.

13:45K-1.3 Registration and assessment
(a) Pursuant to the Data Collection Manual, a reporting entity shall register with the Division by January 31 of each calendar year and report any changes in registration information within 30 days. The Division may require such information and documentation as is necessary or useful for effectuating the registration requirements at P.L. 2023, c. 106.
(b) A manufacturer, pharmacy benefits manager, wholesaler, and carrier required to register with the Division pursuant to this chapter shall pay an annual assessment of $4,740.
(c) A pharmacy services administrative organization required to register with the Division pursuant this chapter shall pay an annual assessment of $1,170.
(d) A reporting entity may pay the assessment to the Division in full or in equal monthly installments, with final payment to be made no later than December 31 of each reporting year.
(e) A carrier is required to register with the Division if it issues a health benefits plan with a prescription drug benefit.
(f) An entity that includes more than one type of reporting entity must register and pay an assessment fee for each type of reporting entity it encompasses.

13:45K-1.4 Manufacturer reporting
(a) A manufacturer shall notify the Division of price increases pursuant to N.J.S.A. 45:14-82.3.a within 10 days. Within 20 days of the price increase, the manufacturer shall report data required at N.J.S.A. 45:14-82.3.c and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing pursuant to the Data Collection Manual.
(b) A manufacturer shall notify the Division of the introduction of a new drug or biosimilar pursuant to N.J.S.A. 45:14-82.3.b within 10 days. Within 20 days of the market introduction, the manufacturer shall report data required at N.J.S.A. 45:14-82.3.d and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing pursuant to the Data Collection Manual.
(c) If a manufacturer required to report data to the Division pursuant to N.J.S.A. 45:14-82.3.c or d does not have access to State-specific data and has no way of obtaining it, the manufacturer shall:
1. Certify and provide proof satisfactory to the Division that it does not have access to State-specific data and has no way of obtaining it; and
2. Report national data to the Division within 20 days of a price increase or introduction of a new drug or biosimilar that requires notification to the Division pursuant to N.J.S.A. 45:14-82.3.a or b.
(d) A manufacturer shall certify the reporting pursuant to this section as accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

13:45K-1.5 Pharmacy benefits manager reporting

(a) The Division shall notify a pharmacy benefits manager annually of the specific drugs or drug groups for which reporting is required. Within 60 days, the pharmacy benefits manager shall report to the Division the information at N.J.S.A. 45:14-82.4.a and any other data requested by the Division to make clear the major components of prescription drug pricing, along the supply chain, and the impacts on insurance premiums and consumer cost sharing pursuant to the Data Collection Manual.
(b) A pharmacy benefits manager shall certify the reporting pursuant to this section as accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.
(c) The Division shall consider the following factors in determining the specific drugs or drug groups for which reporting is required:

1. Information from other reporting entities, including without limitation, drugs that are the subject of:

i. Manufacturer notification of price increases and introduction of new drugs or biosimilars pursuant to N.J.S.A. 45:14-82.3; and

ii. Reporting by carriers pursuant to N.J.S.A. 45:14-82.6;

2. Whether the drug is listed on the New Jersey Prescription Drug Price Registry available at https://www20.state.nj.us/LPSCA_DRUG/ due to the frequency with which it is prescribed;

3. Historical prices and price increases;

4. Whether there are alternatives to the drug and, if so, their cost and availability;

5. Whether the drug appears on the current Model List of Essential Medicines or Essential Medicines List for Children adopted by the World Health Organization available at https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists;

6. The drug's efficacy in treating a life-threatening health condition or a chronic condition that substantially impairs the person's ability to engage in activities of daily living; and

7. Any other information relevant to making clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing.

13:45K-1.6 Wholesaler reporting
(a) The Division shall notify a wholesaler annually of the specific drugs or drug groups for which reporting is required. Within 60 days, the wholesaler shall report to the Division the information at N.J.S.A. 45:14-82.5.a and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing pursuant to the Data Collection Manual.
(b) A wholesaler shall certify the reporting pursuant to this section as accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.
(c) The Division shall consider the following factors in determining the specific drugs or drug groups for which reporting is required:

1. Information from other reporting entities, including without limitation, drugs that are the subject of:

i. Manufacturer notification of price increases and introduction of new drugs or biosimilars pursuant to N.J.S.A. 45:14-82.3; and

ii. Reporting by carriers pursuant to N.J.S.A. 45:14-82.6;

2. Whether the drug is listed on the New Jersey Prescription Drug Price Registry available at https://www20.state.nj.us/LPSCA_DRUG/ due to the frequency with which it is prescribed;

3. Historical prices and price increases;

4. Whether there are alternatives to the drug and, if so, their cost and availability;

5. Whether the drug appears on the current Model List of Essential Medicines or Essential Medicines List for Children adopted by the World Health Organization available at https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists;

6. The drug's efficacy in treating a life-threatening health condition or a chronic condition that substantially impairs the person's ability to engage in activities of daily living; and

7. Any other information relevant to making clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing.

13:45K-1.7 Carrier reporting

(a) A carrier that issues a health benefits plan with a prescription drug benefit shall report to the Division annually within 60 days of the close of each calendar year the information at N.J.S.A. 45:14-82.6.b and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing for the top 25 drugs and drug groups at N.J.S.A. 45:14-82.6.a pursuant to the Data Collection Manual.

(b) A carrier shall certify the reporting pursuant to this section as accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

13:45K-1.8 Pharmacy services administrative organization reporting

(a) A pharmacy services administrative organization shall report to the Division annually within 60 days of the close of each calendar year the information at N.J.S.A. 45:14-82.7.a and any other data requested by the Division to make clear the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and consumer cost sharing pursuant to the Data Collection Manual.

(b) A pharmacy services administrative organization shall certify the reporting pursuant to this section as accurate and complete under penalty of perjury, including reporting on its behalf by subsidiaries, employees, contractors, or any third parties.

13:45K-1.9 State-specific data

In the event that State-specific data is unavailable to the manufacturer, other reporting entities shall comply within 60 days with a request from the Division for State-specific data for any drug or drug group on which a manufacturer reported pursuant to N.J.A.C. 13:45K-1.4(a) and (b).

Filed October 23, 2024