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SYNOPSIS

Establishes prescription drug pricing disclosure requirements and measures to reduce prescription drug costs.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

AN ACT concerning prescription drugs and supplementing various parts of the statutory law.

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

1. As used in section 1 and sections 3 through 7 of this act:

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

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

"Essential off-patent or generic drug or biological product" means any prescription drug or biological product, including any drug-device or biological product-device combination product for the delivery of the prescription drug or biological product:

(1) that is made available for sale in the State;

(2) for which all exclusive marketing rights, if any, granted under the 52 Stat. 1040, 21 U.S.C. s.301 et seq., section 351 of the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. s.262, and federal patent law, have expired;

(3) that is actively manufactured and marketed by three or fewer manufacturers; and

(4) that appears on the current Model List of Essential Medicines adopted by the World Health Organization or has been designated by the Commissioner of Health as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs a person's ability to engage in activities of daily living.

"FDA" means the federal Food and Drug Administration.

"Price gouging" means any unconscionable increase in the price of a prescription drug or biological product.

"Unconscionable increase" means an increase in the price of a prescription drug or biological product that:

(1) is excessive and not justified by the cost of producing the drug or biological product or the cost of appropriate expansion of access to the drug or biological product to promote the public health; and

(2) results in consumers for whom the drug or biological product has been prescribed having no alternative but to purchase the drug or biological product at an excessive price because of the importance of the drug to the health of the consumers and insufficient competition in the market for the drug or biological product.

"Wholesale acquisition cost" means, with respect to a drug or biological product, the manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other 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 drug or biological product pricing data.

2. a. A pharmacy benefits manager shall disclose in the contract between the pharmacy benefits manager and the purchaser each of the following:

(1) The basis of the methodology and sources utilized to establish multiple source generic pricing. Applicable lists shall be updated and provided to the purchaser whenever there is a change;

(2) If a pharmacy benefits manager utilizes a multiple source generic list for drugs and biological products dispensed at retail, but does not utilize a similar list for drugs dispensed by mail. This practice shall be disclosed to the purchaser in writing either in the contract or no later than 21 business days from the implementation of the practice; and

(3) Whether or not the pharmacy benefits manager is using the identical multiple source generic drug and biological products list with respect to billing the purchaser as it does when reimbursing all network pharmacies. If multiple source generic drug and biological products lists are used, the pharmacy benefits manager shall disclose any difference between the amount paid to any pharmacy and the amount charged to the purchaser.

b. A pharmacy benefits manager shall provide a toll-free telephone number through which a contracted pharmacy or a consumer may contact the pharmacy benefits manager and speak with a New Jersey-licensed pharmacist to resolve issues pertaining to benefits coverage, drug and biological products pricing and prescription drug and biological products safety. Callers shall not be placed on hold for longer than five minutes. The pharmacy benefits manager shall resolve concerns within 24 hours after receiving the inquiry.

3. a. There is established in the Division of Consumer Affairs in the Department of Law and Public Safety the Prescription Drug and Biological Product Review Commission, which shall consist of nine members: the Commissioners of Health and Human Services and the Director of the Division of Consumer Affairs, or their designees, who shall serve ex officio; two public members appointed by the Governor; one public member appointed by the President of the Senate; one public member appointed by the Senate Minority Leader; one public member appointed by the Speaker of the General Assembly; and one public member appointed by the Assembly Minority Leader. The public members shall have a significant health care background.

b. Each public member shall serve for a term of five years, except that of the six members first appointed, the first two appointed shall serve for terms of five years, the second two appointed shall serve for terms of four years, and the third two

appointed shall serve for terms of three years. Each member shall hold office for the term of appointment and until their successor is appointed and qualified.

c. Any vacancy in the membership of the commission shall be filled for the unexpired term in the manner provided for the original appointment. Members are eligible for reappointment to the commission.

d. The commission shall organize as soon as possible after the appointment of its members and shall annually elect a chairperson and vice-chairperson from among its members, and a secretary who need not be a member of the commission. The commission shall meet at least four times a year and may hold additional meetings as necessary to discharge its duties. In addition to such meetings, the commission shall meet at the call of the chairperson or the director.

e. A majority of the membership of the commission shall constitute a quorum for the transaction of commission business.

f. Members of the commission shall serve without compensation, but shall be compensated and reimbursed for actual expenses reasonably incurred in the performance of their official duties, and provided with office and meeting facilities required for the proper conduct of the commission's business.

g. The division shall provide staff support to the commission as shall be necessary for the commission to carry out its duties.

4. a. The commission shall develop a list of critical prescription drugs and biological products made available in New Jersey for which there is a substantial public interest in understanding the development of pricing for the drugs or biological products. In developing the list, the commission shall consider the following factors:

(1) the cost of the drug or biological product to public health care programs including, but not limited to, the Medicaid and NJ FamilyCare programs;

(2) the current cost of the drug or biological product in the State;

(3) the extent of utilization of the drug or biological product within the State;

(4) the availability and cost of comparable or therapeutically equivalent courses of treatment;

(5) the rate at which the drug or biological product is deemed to produce successful outcomes when used to treat the conditions for which it is most commonly prescribed; and

(6) other objectively quantifiable factors as the commission determines to be relevant to evaluating the significance of the availability of the drug or biological product in New Jersey.

The commission may additionally consider recommendations for drugs and biological products to be included in the list as may be submitted by: government agencies; members of the public; and

professional organizations representing the pharmaceutical industry; health care practitioners; pharmaceutical manufacturers; and managed care plans, prescription drug benefit managers, and other insurers. The list shall be reviewed and updated at least once every three years.

b. For each prescription drug and biological product that the commission places on the critical prescription drug and biological product list pursuant to subsection a. of this section, the commission shall require the manufacturer of the drug or biological product to report the following information to the commission:

(1) total cost of production, and approximate cost of production per dose;

(2) research and development costs of the drug or biological product, including:

(a) research and development costs that are paid with public funds;

(b) after-tax research and development costs paid by the manufacturer; and

(c) research and development costs paid by third parties;

(3) marketing and advertising costs for the drug or biological product, apportioned by marketing activities that are directed to consumers, marketing activities that are directed to prescribers, and the total cost of all marketing and advertising that is directed primarily to New Jersey consumers and prescribers;

(4) the prices for the drug or biological product that are charged to purchasers outside the United States, by country, for a representative set of countries determined by the commission;

(5) prices charged to typical New Jersey purchasers, including, but not limited to, pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;

(6) true net typical prices charged to pharmacy benefit managers for distribution in New Jersey, net of any rebates or other payments from the manufacturer to the pharmacy benefit manager and the pharmacy benefit manager to the manufacturer; and

(7) any rebates that are available to consumers, which information shall be made publically available on the division's website.

c. The commission shall adopt, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), rules and regulations to further define and enforce the provisions of this section, which may include monetary penalties for failure to comply with the requirements of this section.

d. Information reported pursuant to subsection b. of this section shall not be deemed to be a public or government record under P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.). Any public reporting of information submitted pursuant to subsection b. of this section shall be aggregated to protect the financial, competitive, or proprietary nature of the information.

e. The commission shall prepare an annual report on prescription drug and biological product prices and their role in overall health care spending in the State based on the data submitted to the commission pursuant to subsection b. of this section and in conformance with the provisions of subsection d. of this section. As part of the report, the commission may include recommendations for actions to lower prescription drug and biological product costs and spending across the State while maintaining access to, and the quality of, health care. The commission shall submit the report to the Governor, and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the Legislature, and shall make the report available on the division's website.

5. a. The commission shall identify, using information submitted to the commission pursuant to section 3 of this act, those prescription drugs and biological products that have a cost in New Jersey that is excessively high when compared with the cost of the drug in other states and countries and when compared with the overall cost of researching, developing, and producing the drug or biological product in light of the number of years the drug or biological product has been made available for distribution.

b. If the commission determines that the cost of a prescription drug or biological product is excessively high, the commission may set the maximum allowable price that the manufacturer can charge for that prescription drug or biological product when sold for use in New Jersey. The maximum price set by the commission shall be commensurate with the price of the drug in other states and countries, with full consideration of the overall cost of researching, developing, and producing the drug or biological product in light of the number of years the drug or biological product has been made available for distribution.

6. a. A prescription drug or biological product manufacturer or wholesale distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug or biological product.

b. It shall not constitute a violation of subsection a. of this section for a wholesale distributor to increase the price of an essential off-patent or generic drug or biological product if the price increase is directly attributable to additional costs for the drug or biological product imposed on the wholesale distributor by the manufacturer of the drug or biological product.

7. a. The director may notify the Attorney General of any increase in the price of an essential off-patent or generic drug or biological product whenever:

(1) the price increase, individually or in combination with other price increases:

(a) would result in an increase of 50 percent or more in the wholesale acquisition cost of the drug or biological product within the preceding one-year period; or

(b) would result in an increase of 50 percent or more in the price paid by the Medicaid program or NJ FamilyCare program for the drug or biological product within the preceding one-year period, as certified by the Director of the Division of Medical Assistance and Health Services in the Department of Human Services; and

(2) (a) a 30-day supply of the maximum recommended dosage of the drug or biological product for any indication, according to the FDA-approved label for the drug or biological product, would cost more than $80 at the wholesale acquisition cost of the drug or biological product;

(b) a full course of treatment with the drug or biological product, according to the FDA-approved label for the drug or biological product, would cost more than $80 at the wholesale acquisition cost of the drug or biological product; or

(c) if the drug or biological product is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment, or a single dose, the drug or biological product would cost more than $80 at the wholesale acquisition cost of the drug or biological product to obtain a 30-day supply or a full course of treatment.

b. At the request of the Attorney General, the manufacturer of an essential off-patent or generic drug or biological product identified in a notice provided pursuant to subsection a. of this section shall, no later than 45 days after receipt of the request, submit a statement to the Attorney General:

(1) itemizing the components of the cost of producing the drug or biological product;

(2) identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug or biological product within the one-year period preceding the date of the price increase;

(3) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug or biological product and explaining any improvement in public health associated with those expenditures; and

(4) providing any other information that the manufacturer believes to be relevant to a determination as to whether a violation of P.L. , c. (C.) (pending before the Legislature as this bill) has occurred.

c. The Attorney General may require a manufacturer or a wholesale distributor to produce any records or documents that may be relevant to a determination as to whether a violation of this act has occurred.

d. Upon petition of the Attorney General, a court may issue an order:

(1) compelling a manufacturer to submit the statement required pursuant to subsection b. of this section or a manufacturer or wholesale distributor to produce specific records or documents as requested by the Attorney General pursuant to subsection c. of this section;

(2) restraining or enjoining a violation of this act;

(3) restoring to any consumer, including any third party payor, any money acquired by a manufacturer or wholesale distributor as a result of a price increase that violates this act;

(4) requiring a manufacturer that has engaged in price gouging in the sale of an essential off-patent or generic drug or biological product to make the drug or biological product available to wholesale distributors, pharmacies, and consumers in the State, for a period of up to one year, at a price that does not exceed the price at which the drug or biological product was made available to such wholesale distributors, pharmacies, and consumers immediately prior to the violation of this act; and

(5) assessing a civil penalty of up to $10,000 against a manufacturer or wholesale distributor for each violation of this act. For the purposes of this paragraph, each sale of an essential off-patent or generic drug or biological product at a price that constitutes price gouging shall be deemed to be a separate violation.

e. The Attorney General shall not commence an action seeking relief pursuant to paragraphs (2) through (5) of subsection d. of this section unless the Attorney General has provided the manufacturer or wholesale distributor an opportunity to meet with the Attorney General to provide a justification for the increase in the price of the essential off-patent or generic drug or biological product.

f. Any information provided by a manufacturer pursuant to subsection b. of this section, or by a manufacturer or wholesale distributor pursuant to subsection c. of this section, shall be deemed confidential and shall not be disclosed to the public or otherwise subject to public access, inspection, or copying, unless such confidentiality is waived by the manufacturer or wholesale distributor.

g. It shall not be a defense to an action brought by the Attorney General pursuant to subsection d. of this section that a manufacturer alleged to have violated this act did not sell the essential off-patent or generic drug or biological product directly to a consumer in this State.

8. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety shall, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt rules and regulations as shall be necessary to implement the provisions of this act.

9. This act shall take effect on the 180th day after the date of enactment and shall apply to all contracts or agreements for pharmacy benefits management services that are executed or renewed on or after the effective date. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety may take any administrative action in advance as may be necessary to implement the provisions of this act.

STATEMENT

This bill provides for prescription drug disclosure requirements and measures to reduce costs for prescription drugs and biological products costs.

Under the bill, pharmacy benefits managers (PBMs) are required to disclose certain information about prescription drug and biological product pricing and generic substitutions to benefit plan purchasers. The bill requires PBMs to establish a toll-free telephone number through which consumers and pharmacists can quickly obtain information regarding coverage, pricing and prescription drug and biological product safety.

With respect to purchasers of pharmacy benefits management services, this bill requires PBMs to disclose, in the contract entered into between the purchaser and the PBM, the methodology and sources utilized to determine multiple source generic drug and biological product pricing. That pricing information shall be updated whenever a change occurs and must be provided to the purchaser. If a PBM uses a multiple source generic list for drugs and biological product dispensed at retail, but not for drugs and biological products dispensed by mail, this must be disclosed in the contract as well, or within 21 business days from the implementation of the practice. In addition, the bill requires PBMs to disclose to purchasers whether the multiple source generic pricing list used to bill the purchaser is the same as the list used to reimburse pharmacies. If the lists are not the same, the difference between the amount paid to the pharmacy and the amount charged to the purchaser shall be disclosed.

This bill also requires PBMs to provide a toll-free telephone number for consumers and contracted pharmacies to speak with a New Jersey-licensed pharmacist concerning benefits coverage, drug and biological product pricing and prescription drug safety. Callers may not be placed on hold for longer than five minutes, and concerns must be resolved within 24 hours.

This bill establishes the Prescription Drug and Biological Product Review Commission in the Division of Consumer Affairs in the Department of Law and Public Safety, which will be tasked with developing a list of critical prescription drugs and biological products for which drug and biological product manufacturers will

be required to report certain information concerning development, production, and marketing costs. If the commission determines that a drug or biological product is priced excessively high in New Jersey, it will have the authority to establish a maximum price for the drug or biological product in the State. The commission will consist of nine members.

In developing the list of critical prescription drugs and biological products, the commission will consider: the cost of the drug or biological product in the State, including the cost to public health care programs; the extent of utilization of the drug or biological product within the State; the availability and cost of comparable or therapeutically equivalent courses of treatment; the rate of successful treatment outcomes for the drug or biological product; other objectively quantifiable factors as the commission determines to be relevant. The commission may additionally consider recommendations for drugs and biological products to be included in the list made by government agencies, members of the public, and professional organizations. The commission will be required to review and update the list at least once every three years.

For each prescription drug and biological product that the commission places on the critical prescription drug list, the manufacturer of the drug or biological product will be required to report information concerning: the total cost of production and approximate cost of production per dose; research and development costs; marketing and advertising costs; the prices for the drug or biological product that are charged to purchasers outside the United States for a representative set of countries determined by the commission; prices charged to typical New Jersey purchasers; true net typical prices charged to pharmacy benefit managers; and any rebates that are available to consumers which information is to be made publically available.

Using information submitted under the bill, the commission will identify prescription drugs and biological products that have a cost in New Jersey that is excessively high when compared with the cost of the drug or biological product in other states and countries and when compared with the overall cost of researching, developing, and producing the drug or biological product in light of the number of years the drug or biological product has been made available for distribution. For prescription drugs and biological products with an excessively high cost, the commission will be permitted to set the maximum allowable price that the manufacturer can charge for that prescription drug or biological product in New Jersey, which is to be commensurate with the price of the drug in other states and countries, with full consideration of the overall cost of researching, developing, and producing the drug or biological product in light of the number of years the drug or biological product has been made available for distribution.

This bill also prohibits manufacturers and wholesale distributors of prescription drugs and biological products from excessively increasing the price of certain prescription drugs and biological products without justification.

Specifically, manufacturers and wholesale distributors may not engage in price gouging in the sale of an essential off-patent or generic drug or biological product. Price gouging is defined to mean an increase in the price of a drug or biological product that: (1) is excessive and not justified by the cost of producing the drug or biological product or expanding access to the drug or biological product to promote the public health; and (2) results in consumers having no alternative but to purchase the drug or biological product at an excessive price because of the importance of the drug or biological product to their health and insufficient marketplace competition. Under the bill, wholesale distributors will not be found to have violated this prohibition if the distributor increases the price of a drug or biological product in direct response to additional costs for the drug or biological product imposed on the distributor by the manufacturer.

The bill defines "essential off-patent or generic drug or biological product" to mean any prescription drug or biological product, including any drug-device or biological product-device combination product for the delivery of the prescription drug or biological product: (1) that is made available for sale in the State; (2) for which all exclusive marketing rights granted under federal law have expired; (3) that is actively manufactured and marketed by three or fewer manufacturers; and (4) that appears on the current Model List of Essential Medicines adopted by the World Health Organization or has been otherwise designated as an essential medicine by the Commissioner of Health.

The Director of the Division of Consumer Affairs in the Department of Law and Public Safety may notify the Attorney General of any increase in the price of an essential off-patent or generic drug or biological product whenever: (1) the price increase, individually or in combination with other price increases, would result in an increase of 50 percent or more in the wholesale acquisition cost for the drug or biological product or in the price paid for the drug or biological product by the State Medicaid or NJ FamilyCare programs within a one-year period; and (2) the wholesale acquisition cost of the drug or biological product is more than $80 for a 30-day supply or a full course of treatment.

At the request of the Attorney General, the manufacturer of an essential off-patent or generic drug or biological product identified in a notice provided under the bill will be required to submit, within 45 days of receiving the request, a statement to the Attorney General: (1) detailing the cost of producing the drug or biological product; (2) identifying the circumstances and timing of any cost increases in the preceding year; (3) identifying the circumstances

and timing of any expenditures made by the manufacturer to expand access to the drug or biological product, and explaining any resulting improvements in public health; and (4) any other information the manufacturer determines to be relevant to a determination as to whether a violation of the provisions of the bill has occurred.

The Attorney General may require a manufacturer or a wholesale distributor to produce any records or documents that may be relevant to a determination as to whether a violation of the bill has occurred. The Attorney General may additionally petition for a court order: compelling submission of any required statement or records; restraining or enjoining a violation of the bill; restoring to any consumer, including any third party payor, any money acquired by the manufacturer or wholesale distributor as a result of a price increase that violates the bill; requiring a manufacturer that has engaged in price gouging to make the drug or biological product available in the State, for a period of up to one year, at a price that does not exceed the price immediately prior to the violation; and assessing a civil penalty of up to $10,000 against a manufacturer or wholesale distributor who has violated the provisions of the bill. For the purposes of assessing the civil penalty, each sale of a drug or biological product at a price that constitutes price gouging will be deemed a separate violation.

Any information provided by a manufacturer or wholesale distributor under the bill will be confidential and may not be disclosed to the public or otherwise subjected to public access, inspection, or copying, unless the manufacturer or wholesale distributor waives confidentiality.