ASSEMBLY, No. 583

STATE OF NEW JERSEY

218th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2018 SESSION

Sponsored by:
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District 4 (Camden and Gloucester)
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District 17 (Middlesex and Somerset)
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SYNOPSIS

Establishes Prescription Drug Review Commission; requires production costs be reported for certain prescription drugs.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

(Sponsorship Updated As Of: 8/26/2019)

AN ACT concerning prescription drug cost reporting and supplementing P.L.1977, c.240 (C.24:6E-1 et seq.).

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

1. a. There is established in the Division of Consumer Affairs in the Department of Law and Public Safety the Prescription Drug 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 of the Division of Consumer Affairs.

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 of Consumer Affairs shall provide such staff support to the commission as shall be necessary for the commission to carry out its duties.

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

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

(2) the current cost of the drug in the State;

(3) the extent of utilization of the drug within the State;

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

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

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

The commission may additionally consider recommendations for drugs 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 that the commission places on the critical prescription drug list pursuant to subsection a. of this section, the commission shall require the manufacturer of the drug 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, 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, 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 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; and

(6) true net typical prices charged to prescription drug 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.

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 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 costs and spending across the State while maintaining access to, and the quality of, health care. The commission shall submit the report to the Legislature pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), and shall make the report available on the website of the Division of Consumer Affairs in the Department of Law and Public Safety.

3. a. The commission shall identify, using information submitted to the commission pursuant to section 2 of P.L. , c. (C.) (pending before the Legislature as this bill), those prescription drugs 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 in light of the number of years the drug has been made available for distribution.

b. If the commission determines that the cost of a prescription drug is excessively high, the commission may set the maximum allowable price that the manufacturer can charge for that prescription drug 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 in light of the number of years the drug has been made available for distribution.

4. This act shall take effect immediately.

STATEMENT

This bill establishes the Prescription Drug 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 for which drug manufacturers will be required to report certain information concerning development, production, and marketing costs. If the commission determines that a drug is priced excessively high in New Jersey, it will have the authority to establish a maximum price for the drug in the State.

The commission will consist of nine members: the Commissioners of Health and Human Services and the Director of the Division of Consumer Affairs, or their designees, who will serve ex officio; and six public members with a significant health care background, two of whom will be appointed by the Governor; and the remaining four of whom will be appointed one each by the President of the Senate, the Senate Minority Leader, the Speaker of the General Assembly, and the Assembly Minority Leader. The public members will serve for a term of five years, except that of the six members first appointed, the first two appointed will serve for terms of five years, the second two appointed will serve for terms of four years, and the third two appointed will serve for terms of three years. Vacancies in the membership of the commission will be filled for the unexpired term in the manner provided for the original appointment, and members will be eligible for reappointment to the commission.

The commission will organize as soon as possible after the appointment of its members, and will meet at least four times a year and hold additional meetings as may be necessary. In addition to such meetings, the commission will be required to meet at the call of the chairperson or the Director of the Division of Consumer Affairs. A majority of the membership of the commission will constitute a quorum for the transaction of business.

Members will serve without compensation, but will be reimbursed for expenses reasonably incurred in the performance of their official duties. The commission will be provided with office and meeting facilities, and the Division of Consumer Affairs will provide staff support.

In developing the list of critical prescription drugs, the commission will consider: the cost of the drug in the State, including the cost to public health care programs; the extent of utilization of the drug within the State; the availability and cost of comparable or therapeutically equivalent courses of treatment; the rate of successful treatment outcomes for the drug; and such other objectively quantifiable factors as the commission determines to be relevant. The commission may additionally consider recommendations for drugs 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 that the commission places on the critical prescription drug list, the manufacturer of the drug 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 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; and true net typical prices charged to prescription drug benefit managers.

The commission may establish monetary penalties for failure to comply with the provisions of the bill.

Drug pricing information reported to the commission would not constitute a public or government record under the "Open Public Records Act," and any public reporting of the information would be aggregated to protect the financial, competitive, or proprietary nature of the information.

The commission will prepare an annual report on prescription drug prices and their role in overall health care spending in the State based on the data submitted under the bill. The report, which may include recommendations for actions to lower prescription drug costs and spending across the State while maintaining access to, and the quality of, health care, will be submitted to the Legislature and made available on the website of the Division of Consumer Affairs.

Using information submitted under the bill, the commission will identify prescription drugs 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 in light of the number of years the drug has been made available for distribution. For prescription drugs 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 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 in light of the number of years the drug has been made available for distribution.