129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

Legislative Document **No. 1499**

S.P. 461 In Senate, April 4, 2019

An Act To Establish the Maine Prescription Drug Affordability Board

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by President JACKSON of Aroostook.
Cosponsored by Speaker GIDEON of Freeport and
Senators: CLAXTON of Androscoggin, FOLEY of York, GRATWICK of Penobscot, SANBORN, H. of Cumberland, VITELLI of Sagadahoc, Representatives: FECTEAU of Biddeford, MOONEN of Portland, TEPLER of Topsham.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 5 MRSA c. 167 is enacted to read:

CHAPTER 167

MAINE PRESCRIPTION DRUG AFFORDABILITY BOARD

§2041. Maine Prescription Drug Affordability Board established

1. Board established. The Maine Prescription Drug Affordability Board, as established in section 12004-G, subsection 14-I and referred to in this chapter as "the board," shall carry out the purposes of this chapter.

2. Membership. The board has 5 members with expertise in health care economics or clinical medicine, who are appointed as follows:

A. Two members are appointed by the President of the Senate. The President of the Senate shall also appoint one alternate board member who will participate in deliberations of the board in the event a member appointed by the President of the Senate elects to be recused as provided in subsection 8;

B. Two members are appointed by the Speaker of the House of Representatives. The Speaker of the House of Representatives shall also appoint one alternate board member who will participate in deliberations of the board in the event a member appointed by the Speaker of the House of Representatives elects to be recused as provided in subsection 8; and

C. One member is appointed by the Governor. The Governor shall also appoint one alternate board member who will participate in deliberations of the board in the event the member appointed by the Governor elects to be recused as provided in subsection 8.

3. Terms. Members are appointed to 5-year terms. Of the initial appointees, the member appointed by the Governor serves an initial term of 5 years, one member appointed by the President of the Senate and one member appointed by the Speaker of the House of Representatives serves an initial term of 4 years and one member appointed by the President of the Senate and one member appointed by the Speaker of the House of Representatives serves an initial term of 3 years.

4. Quorum. A majority of board members constitutes a quorum.

5. Chair. The Governor shall name the chair.

6. Meetings. The board shall meet in public session at least every 6 weeks to review prescription drug information submissions. Meetings may be cancelled or postponed at the discretion of the chair if there are no pending submissions.

A. Each public meeting must be announced 2 weeks in advance, and materials for the meeting must be made public at least one week in advance.

B. Each public meeting must provide opportunity for comment from the public in attendance at the meeting, and the board shall provide the opportunity for the public to submit written comments on pending decisions.

C. The board may allow expert testimony at public meetings and any meeting conducted in executive session as permitted by paragraph F.

D. The board shall publicly deliberate on whether to conduct a full cost review of a prescription drug pursuant to this chapter.

E. The board shall publicly review a prescription drug cost analysis and take a public vote on whether to impose a cost or payment limit on payors for a prescription drug.

F. The board may meet in executive session, except that any decision of the board must be made in public.

7. Public access to data. All information submitted to the board relating to a prescription drug price notice and prescription drug cost review is available to the public, except for proprietary information that is designated by the board as confidential upon application of the person submitting the information. After public notice and comment, the board shall establish parameters for what is considered proprietary information and designated confidential, including specific consideration for information submitted related to a prescription drug not yet available in the market.

8. Conflicts of interest. The following provisions govern any conflict of interest for a member of the board or advisory council established pursuant to subsection 11 or staff or contractor of the board.

A. When appointing a member of the board or the advisory council established pursuant to subsection 11, the appointing authority shall consider any conflict of interest disclosed by the prospective member. A member shall elect to be recused from any board activity in the case in which the member or an immediate family member of the member has a conflict of interest directly related to the prescription drug under review. For the purposes of this paragraph, "conflict of interest" means an association, including a financial or personal association, that has the potential to bias or have the appearance of biasing an individual's decisions in matters related to the board or the conduct of the board's activities.

B. A board member or staff or contractor to the board with a conflict of interest with regard to a prescription drug under review shall elect to be recused from the review. For purposes of this paragraph, "conflict of interest" means any instance in which a member of the board or an immediate family member has received or could receive either of the following:

(1) A direct financial benefit of any amount deriving from the results or findings of a study or determination by or for the board; or

(2) A financial benefit from individuals or companies that own or manufacture prescription drugs, services or items to be studied by the board that in the aggregate exceeds $5,000 per year. For purposes of this subparagraph, "financial benefit" includes honoraria, fees, stock or other financial benefit and the current value of the member's or immediate family member's already existing stock

holdings, in addition to any direct financial benefit deriving from the results or findings of a review conducted under this section.

C. A conflict of interest must be disclosed in the following manner:

(1) By the board in the employment of board senior staff;

(2) By the Governor, President of the Senate or Speaker of the House of Representatives when appointing members to the board and advisory council established pursuant to subsection 11;

(3) By the board, describing any recusals as part of any final decision resulting from a review of a prescription drug; and

(4) By the 5th day after a conflict is identified or, if a public meeting of the board will occur within that 5-day period, in advance of the public meeting.

D. Conflicts of interest must be publicly posted on the website of the board. The information disclosed must include the type, nature and magnitude of the interests of the individual involved, except to the extent that the individual elects to be recused from participation in any activity with respect to which the potential conflict exists.

E. The board, the advisory council established pursuant to subsection 11, a member of the board or staff of or any contractor to the board may not accept gifts, bequests or donations of services or property that suggest a conflict of interest or have the appearance of creating bias in the work of the board or advisory council.

F. A member of the advisory council established pursuant to subsection 11 who accepts a gift, bequest or donation of services or property that suggests a conflict of interest or has the appearance of creating a bias in the work of the advisory council shall disclose the gift, bequest or donation publicly.

9. Staff. The board may employ an executive director and any necessary staff. Staff positions and salary, to the extent feasible, must comport with state personnel rules and requirements.

10. Compensation. A member of the board or the advisory council established pursuant to subsection 11 is entitled to legislative per diem and reimbursement for expenses as provided in section 12004-G, subsection 14-I.

11. Advisory council. An 11-member advisory council is established to advise the board on prescription drug cost issues and represent stakeholder views in accordance with this subsection.

A. The advisory council members must be selected based on their knowledge of one or more of the following: the pharmaceutical business model; practice of medicine or clinical knowledge and training; patients' perspectives; health care cost trends and drivers; clinical and health services research; or the state health care marketplace generally.

B. Members of the advisory council are appointed as follows:

(1) Four members are appointed by the President of the Senate: one member representing physicians; one member representing nurses; one member representing hospitals; and one member representing health insurers;

(2) Four members are appointed by the Speaker of the House of Representatives: one member representing a statewide health care advocacy coalition; one member representing a statewide advocacy coalition for seniors; one member with expertise in health services research specializing in prescription drugs; and one member representing the public; and

(3) Three members are appointed by the Governor: one member representing pharmaceutical manufacturers; one member representing employers; and one member representing pharmacists.

C. Members of the advisory council are appointed to 3-year terms.

D. The Governor shall name the chair, and the chair shall designate a cochair from among the other members of the advisory council.

§2042. Required manufacturer notice of introductory price and price increases

1. Patented prescription drug. A prescription drug manufacturer shall notify the board if the manufacturer is increasing the wholesale acquisition cost of a patent-protected brand-name prescription drug by more than 10% or by more than $3,000 per course of treatment during any 12-month period or if the manufacturer intends to introduce to market a brand-name prescription drug that has a wholesale acquisition cost of $30,000 per year or per course of treatment. The notice must be provided in writing at least 30 days prior to the planned effective date of the increase or introduction and include a justification as detailed in subsection 5.

2. Biosimilar drugs. A prescription drug manufacturer shall notify the board if the manufacturer intends to introduce to market a biosimilar drug that has a wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilar drug is introduced to market. The notice must be provided in writing at least 30 days prior to the planned effective date of the increase or introduction and include a justification as detailed in subsection 5.

3. Generic prescription drugs and off-patent sole source brand-name prescription drugs. A prescription drug manufacturer shall notify the board if the manufacturer is increasing the wholesale acquisition cost of a generic or off-patent sole source brand-name prescription drug by more than 25% or by more than $300 per course of treatment during any 12-month period or if the manufacturer intends to introduce to market a generic prescription drug that has a wholesale acquisition cost of $1,200 or more annually. The notice must be provided in writing at least 30 days prior to the planned effective date of the increase or introduction and include a justification as detailed in subsection 5.

4. Other drugs requiring notice to board. After consultation with the advisory council, the board shall require a prescription drug manufacturer to provide notice to the board as described in this section for other prescription drugs that create challenges to affordability for the state health care system.

5. Justification. As part of the notice required by a manufacturer under this section, the manufacturer shall justify the proposed price increases or introductory price specified in this section by providing all documents and research related to the manufacturer's selection of the price increase or introductory price, including, but not limited to, life cycle management; net average price in the State that is net of all price concessions but does not include in-kind concessions; market competition and context; projected revenue; and, if available, the estimated value and cost-effectiveness of the prescription drug.

§2043. Criteria for selection of prescription drugs for review of cost

1. Public comment. The board shall keep the public informed about notices provided by manufacturers as required under section 2042. The board shall provide the public an opportunity to request board review of the cost of any prescription drug that is the subject of a notice under section 2042.

2. Role of chair. The board chair shall review the public comments under subsection 1 and decide whether to undertake a review of a particular prescription drug that is the subject of a notice under section 2042. The chair may decide that the board will undertake a review in the absence of public comments.

3. Role of board members. A board member may request a vote on whether to undertake a review under subsection 2 if there is not consensus with the decision of the chair.

§2044. Determining excess costs to payors and consumers

1. Review of excess costs. Once a decision has been made to undertake a cost review pursuant to section 2043, the review undertaken by the board must determine if appropriate utilization, fully consistent with the federal Food and Drug Administration label or consistent with standard medical practice, of a prescription drug has led or will lead to excess costs for health care systems in the State. For the purposes of this section, "excess costs" means:

A. Costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other therapeutic options or alternative treatments; or

B. Costs of appropriate utilization of a prescription drug that are not sustainable to public and private health care systems over a 10-year time frame.

2. Phase one determination. The board may consider the following factors in determining cost and excess cost:

A. The price at which the prescription drug has been or will be sold in the State;

B. The average monetary price concession, discount or rebate the manufacturer provides to payors in the State or is expected to provide to payors in the State as reported by manufacturers;

C. The price at which therapeutic alternatives have been or will be sold in the State;

D. The average monetary price concession, discount or rebate the manufacturer provides to payors in the State or is expected to provide to payors in the State for therapeutic alternatives;

E. The cost to payors based on patient access consistent with federal Food and Drug Administration labeled indications or consistent with standard medical practice;

F. The effect on patient access resulting from the cost of the prescription drug relative to insurance benefit design;

G. The current or expected value of manufacturer-supported, drug-specific, patient access programs;

H. The relative financial effects on health, medical and other social services costs, as can be quantified and compared to baseline effects of existing therapeutic alternatives; and

I. Other such factors determined relevant by the board.

3. Phase 2 determination. If, after considering the factors in subsection 2, the board is unable to determine if a prescription drug will produce or has produced excess costs, the board may consider the following:

A. Manufacturer research and development costs, as shown on the manufacturer's federal tax filing for the most recent tax year, multiplied by the ratio of manufacturer sales in the State to United States sales;

B. That portion of direct to consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug under review and that are multiplied by the ratio of total manufacturer sales in the State to total manufacturer United States sales for the prescription drug under review;

C. Gross and net manufacturer revenues for the most recent tax year; and

D. Any additional factors determined by the board relevant to the circumstances, as may be proposed by the manufacturer.

§2045. Board determinations, compliance and remedies

1. Rate setting. In the event the board finds that the cost of the prescription drug under review pursuant to section 2043 creates excess costs as defined in section 2044, subsection 1 for payors and consumers, the board shall establish the rate of reimbursement that must be billed and paid by payors and pharmacies, health care providers administering prescriptions, wholesalers, distributors and uninsured and insured consumers.

2. Compliance with rate setting. The failure to bill and pay for a prescription drug at the rate set by the board under subsection 1 constitutes a violation of this chapter and must be referred to the Attorney General for enforcement. Upon a finding of noncompliance with the board requirements, the Attorney General may pursue any remedy available under civil and criminal law. The Attorney General may not consider a person in noncompliance with this chapter if a payor obtains price concessions from a manufacturer that result in a payor's net cost being lower than the rate established by the

board. The Attorney General shall provide guidance to stakeholders concerning activities that could be considered noncompliant and payment transactions in which prescription drug costs exceed the board-established limit.

3. Compliance with reporting. The failure of a manufacturer to submit a notice under section 2042 constitutes a violation of this chapter and must be referred to the Attorney General for enforcement. Upon a finding of noncompliance with the board requirements, the Attorney General may pursue any remedy available under civil law.

§2046. Appeals

1. Appeals. A person affected by a decision of the board may appeal the decision within 30 days. The full board shall consider the appeal and render a decision within 60 days.

2. Judicial review. A decision of the board after appeal is subject to judicial review.

§2047. Annual reports

Beginning January 1, 2021, and annually thereafter, the board shall report to the Governor, the Legislature and the public on general prescription drug price trends, the number of manufacturers required to provide notice under section 2042 because of prescription drug pricing decisions and the number of prescription drugs that were subject to board review and analysis, including the results of that analysis, as well as the number and disposition of appeals and judicial reviews.

Sec. 2. 5 MRSA §12004-G, sub-§14-I is enacted to read:

14-I.

Health care	Maine Prescription Drug Affordability Board and advisory council	Legislative Per Diem and Expenses	5 MRSA §2041

SUMMARY

This bill creates the Maine Prescription Drug Affordability Board to determine the reasonableness of the costs for certain prescription drug products. The bill requires prescription drug manufacturers to notify the board when the introductory price or proposed price increase for a brand-name or generic drug reaches a specified threshold. The board is directed to review the information submitted by manufacturers to justify the price or increase.

The bill requires the board to have a public process for each prescription drug required to be reviewed based on certain criteria. The board is directed to determine if the cost to the health care system of appropriate utilization of a drug is commensurate with its benefit to the system and whether the drug is affordable to state residents. If the board finds that the cost in the State is not affordable to state health care systems and

state residents, the board is authorized to establish a cost or payment rate for the drug to which all state programs, local governments, licensed commercial health plans, including state marketplace plans, licensed pharmacies, wholesalers and distributors must abide. These covered entities are prohibited from paying more for the drugs than the board-established rate.