



# 129th MAINE LEGISLATURE

## FIRST REGULAR SESSION-2019

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Legislative Document

No. 1499

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S.P. 461

In Senate, April 4, 2019

### **An Act To Establish the Maine Prescription Drug Affordability Board**

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

A handwritten signature in black ink, appearing to read 'D M Grant'.

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: FECTION of  
Biddeford, MOONEN of Portland, TEPLER of Topsham.

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

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

3 **CHAPTER 167**

4 **MAINE PRESCRIPTION DRUG AFFORDABILITY BOARD**

5 **§2041. Maine Prescription Drug Affordability Board established**

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

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

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

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

20 C. One member is appointed by the Governor. The Governor shall also appoint one  
21 alternate board member who will participate in deliberations of the board in the event  
22 the member appointed by the Governor elects to be recused as provided in subsection  
23 8.

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

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

31 **5. Chair.** The Governor shall name the chair.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15           **§2042. Required manufacturer notice of introductory price and price increases**

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

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

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

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

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

8           **§2043. Criteria for selection of prescription drugs for review of cost**

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

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

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

20           **§2044. Determining excess costs to payors and consumers**

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

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

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

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

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

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

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

- 1           D. The average monetary price concession, discount or rebate the manufacturer  
2           provides to payors in the State or is expected to provide to payors in the State for  
3           therapeutic alternatives;
- 4           E. The cost to payors based on patient access consistent with federal Food and Drug  
5           Administration labeled indications or consistent with standard medical practice;
- 6           F. The effect on patient access resulting from the cost of the prescription drug  
7           relative to insurance benefit design;
- 8           G. The current or expected value of manufacturer-supported, drug-specific, patient  
9           access programs;
- 10          H. The relative financial effects on health, medical and other social services costs, as  
11          can be quantified and compared to baseline effects of existing therapeutic  
12          alternatives; and
- 13          I. Other such factors determined relevant by the board.

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

- 17           A. Manufacturer research and development costs, as shown on the manufacturer's  
18           federal tax filing for the most recent tax year, multiplied by the ratio of manufacturer  
19           sales in the State to United States sales;
- 20           B. That portion of direct to consumer marketing costs eligible for favorable federal  
21           tax treatment in the most recent tax year that are specific to the prescription drug  
22           under review and that are multiplied by the ratio of total manufacturer sales in the  
23           State to total manufacturer United States sales for the prescription drug under review;
- 24           C. Gross and net manufacturer revenues for the most recent tax year; and
- 25           D. Any additional factors determined by the board relevant to the circumstances, as  
26           may be proposed by the manufacturer.

27          **§2045. Board determinations, compliance and remedies**

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

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

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

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

8 **§2046. Appeals**

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

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

13 **§2047. Annual reports**

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

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

21 **14-I.**

22 <u>Health care</u>	<u>Maine Prescription</u>	<u>Legislative Per</u>	<u>5 MRSA §2041</u>
	<u>Drug Affordability</u>	<u>Diem and Expenses</u>	
	<u>Board and advisory</u>		
25	<u>council</u>		

26 **SUMMARY**

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

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



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