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OF THE

STATE OF MAINE

AS PASSED BY THE

ONE HUNDRED AND TWENTY-EIGHTH LEGISLATURE

SECOND SPECIAL SESSION
June 19, 2018 to September 13, 2018

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IN ACCORDANCE WITH THE MAINE REVISED STATUTES ANNOTATED,
TITLE 3, SECTION 163-A, SUBSECTION 4.

Augusta, Maine
2019

§8734. Registration requirements

Beginning January 1, 2020, a manufacturer and wholesale drug distributor subject to this subchapter shall register annually with the organization in a manner prescribed by the organization.

§8735. Compliance

1. Certification of accuracy. A manufacturer, wholesale drug distributor or pharmacy benefits manager that submits a notification or report to the organization pursuant to this subchapter shall submit with the notification or report a signed written certification of the notification's or report's accuracy.

2. Civil penalty. A manufacturer, wholesale drug distributor or pharmacy benefits manager that violates this subchapter commits a civil violation for which a fine of $30,000 may be adjudged for each day of the violation.

3. Audit. The organization may audit the data submitted by a manufacturer, wholesale drug distributor or pharmacy benefits manager pursuant to this subchapter. The manufacturer, wholesale drug distributor or pharmacy benefits manager shall pay for the costs of the audit.

4. Corrective action plan. The organization may require a manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter to develop a corrective action plan to correct any deficiencies the organization finds with the manufacturer's, wholesale drug distributor's or pharmacy benefits manager's compliance with this subchapter.

§8736. Public report

Beginning November 1, 2020 and annually thereafter, the organization shall produce and post on its publicly accessible website an annual report, including information developed from the notifications and disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State. The report may not disclose information attributable to any particular manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter and may not make public any information that is confidential pursuant to section 8733. The organization shall submit the report required by this section to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.

§8737. Rulemaking

The organization may adopt rules to implement this subchapter. Rules adopted pursuant to this section are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 9. Maine Revised Statutes headnote amended; revision clause. In the Maine Revised Statutes, Title 22, chapter 1683, before section 8701, the headnote "subchapter 1, general provisions" is enacted and the Revisor of Statutes shall implement this revision when updating, publishing or republishing the statutes.

Sec. 10. Initial rulemaking. Notwithstanding the Maine Revised Statutes, Title 22, section 8737, the Maine Health Data Organization may adopt emergency rules that are otherwise in accordance with section 8737 to implement the provisions of Title 22, chapter 1683, subchapter 3 and may adopt routine technical rules to implement that subchapter before April 1, 2020.

See title page for effective date.

CHAPTER 471

S.P. 461 - L.D. 1499

An Act To Establish the Maine Prescription Drug Affordability Board

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 may not be affiliated with or represent the interests of a public payor, as that term is defined in section 2042, and who are appointed as follows:

A. Two members 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 7, paragraph B;

B. Two members 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 7, paragraph B; and

C. One member 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 7, paragraph B.

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 serve 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 serve 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. Beginning no later than March 1, 2020, the board shall meet in public session at least every 12 weeks to review prescription drug information and to make recommendations pursuant to section 2042. Meetings may be cancelled or postponed at the discretion of the chair.

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 D.

D. Notwithstanding the requirements of Title 1, section 405, the board may meet in executive session, except that any decision of the board must be made in public.

7. Conflicts of interest. The following provisions govern any conflict of interest for a member of the board, a member of the advisory council established pursuant to subsection 10 or any staff member or contractor of the board.

A. When appointing a member of the board or the advisory council established pursuant to subsection 10, 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. 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 of the board with a conflict of interest shall elect to be recused. For purposes of this paragraph, "conflict of interest" means any instance in which a member of the board or an immediate family member of the 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 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 10;

(3) By the board, describing any recusals as part of any final decision relating to 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 10, a member of the board or staff or a contractor of 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 10 who accepts a gift, bequest or donation of services or property that suggests a conflict of interest or has the appearance of creating bias in the work of the advisory council shall disclose the gift, bequest or donation publicly.

8. Staff. The board may employ an executive director, whose salary, to the extent feasible, must comport with state personnel rules and requirements.

9. Compensation. A member of the board and a member of the advisory council appointed pursuant to subsection 10, paragraph L are entitled to legislative per diem and reimbursement for expenses as provided in section 12004-G, subsection 14-I.

10. Advisory council. A 12-member advisory council is established to advise the board on establishing annual spending targets pursuant to section 2042, subsection 1 and determining methods for meeting those spending targets pursuant to section 2042, subsection 3. The advisory council consists of:

A. The Governor or the governor's designee;

B. The Commissioner of Administrative and Financial Services or the commissioner's designee;

C. The Commissioner of Corrections or the commissioner's designee;

D. The Commissioner of Health and Human Services or the commissioner's designee;

E. The Attorney General or the Attorney General's designee;

F. The Executive Director of Employee Health and Benefits, within the Department of Administrative and Financial Services, Bureau of Human Resources, or the executive director's designee;

G. A representative from the Maine State Employees Association, appointed by the Governor, based on a nomination by the association;

H. A representative from the Maine Education Association, appointed by the Governor, based on a nomination by the association;

I. A representative from the Maine Municipal Association, appointed by the Governor, based on a nomination by the association;

J. A representative from the University of Maine System, appointed by the Governor, based on a nomination by the system;

K. A representative from the Maine Community College System, appointed by the Governor, based on a nomination by the system; and

L. A representative of consumer interests, appointed by the Governor, who serves a 3-year term.

11. Funds and grants. The board may apply for and receive funds, grants or contracts from public and private sources.

12. Assessment. The board may recommend that a public payor, as defined in section 2042, subsection 1, pay an annual assessment to support the administrative costs of the board.

§2042. Powers and duties of the board

1. Prescription drug spending targets. The board has the following powers and duties. For the purposes of this section, the term "public payor" means any division of state, county or municipal government that administers a health plan for employees of that division of state, county or municipal government or an association of state, county or municipal employers that administers a health plan for its employees, except for the MaineCare program. The board shall:

A. Beginning for the year 2021 and in consultation with the advisory council established under section 2041, subsection 10, determine annual spending targets for prescription drugs purchased by public payors based upon a 10-year rolling average of the medical care services component of the United States Department of Labor, Bureau of Labor Statistics Consumer Price Index medical care services index plus a reasonable percentage for inflation and minus a spending target determined by the board for pharmacy savings;

B. Determine spending targets on specific prescription drugs that may cause affordability challenges to enrollees in a public payor health plan; and

C. Determine which public payors are likely to exceed the spending targets determined under paragraph A.

2. Prescription drug spending data. The board may consider the following data to accomplish its duties under this section:

A. A public payor's prescription drug spending data, which the 3rd-party administrator or insurer for the public payor's health plan shall provide to the board on behalf of the public payor upon request notwithstanding any provision of law to the contrary, including:

(1) Expenditures and utilization data for prescription drugs for each plan offered by a public payor;

(2) The formulary for each plan offered by a public payor and prescription drugs common to each formulary;

(3) Pharmacy benefit management services and other administrative expenses of the prescription drug benefit for each plan offered by a public payor; and

(4) Enrollee cost sharing for each plan offered by a public payor; and

B. Data compiled by the Maine Health Data Organization under Title 22, chapter 1683.

Prescription drug spending data provided to the board under this subsection is confidential to the same extent it is confidential while in the custody of the entity that provided the data to the board.

3. Recommendations. Based upon the prescription drug spending data received under subsection 2, the board, in consultation with a representative of each public payor identified under subsection 1, paragraph A, shall determine methods for the public payor to meet the spending targets established under subsection 1. The board shall determine whether the following methods reduce costs to individuals purchasing prescription drugs through a public payor and allow public payors to meet the spending targets established under subsection 1:

A. Negotiating specific rebate amounts on the prescription drugs that contribute most to spending that exceeds the spending targets;

B. Changing a formulary when sufficient rebates cannot be secured under paragraph A;

C. Changing a formulary with respect to all of the prescription drugs of a manufacturer within a formulary when sufficient rebates cannot be secured under paragraph A;

D. Establishing a common prescription drug formulary for all public payors;

E. Prohibiting health insurance carriers in the State from offering on their formularies a prescription drug or any of the prescription drugs manufactured by a particular manufacturer when the methods described in paragraph B or C are implemented;

F. Purchasing prescription drugs in bulk or through a single purchasing agreement for use among public payors;

G. Collaborating with other states and state prescription drug purchasing consortia to purchase prescription drugs in bulk or to jointly negotiate rebates;

H. Allowing health insurance carriers providing coverage to small businesses and individuals in the State to participate in the public payor prescription drug benefit for a fee;

I. Procuring common expert services for public payors, including but not limited to pharmacy benefit management services and actuarial services; and

J. Any other method the board may determine.

4. Report. The board shall report its recommendations, including prescription drug spending targets, and the progress of implementing those recommendations to the joint standing committee of the Legislature having jurisdiction over health coverage and insurance matters no later than October 1, 2020 and on January 30th annually thereafter. The joint standing committee may report out legislation based upon the report.

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

Sec. 3. 22 MRSA §8712, sub-§6 is enacted to read:

6. Data shared with Maine Prescription Drug Affordability Board. The organization may share data collected under this chapter with the Maine Prescription Drug Affordability Board, established under Title 5, section 12004-G, subsection 14-I, as long as any data shared pursuant to this subsection is not further disseminated.

See title page for effective date.