L.D. 1829

Date: (Filing No. S-)

HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

Reproduced and distributed under the direction of the Secretary of the Senate.

STATE OF MAINE

SENATE

131ST LEGISLATURE

SECOND REGULAR SESSION

COMMITTEE AMENDMENT " " to S.P. 745, L.D. 1829, "An Act to Reduce Prescription Drug Costs by Requiring Reference-based Pricing"

Amend the bill by striking out the title and substituting the following:

'An Act to Direct the Maine Prescription Drug Affordability Board to Assess Strategies to Reduce Prescription Drug Costs and to Take Steps to Implement Reference-based Pricing'

Amend the bill by striking out everything after the enacting clause and inserting the following:

'**Sec. 1. 5 MRSA §2041, sub-§2,** as repealed and replaced by PL 2021, c. 293, Pt. A, §5, is amended to read:

2. Membership. The board has ~~5~~ 6 members with expertise in health policy, health care data, health care economics or clinical medicine, who may not be affiliated with or represent the interests of a pharmaceutical manufacturer or a public payor, ~~as that term is defined in section 2042, and who are appointed~~ as follows:

A. Two members 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 7, paragraph B;

B. Two members 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 7, paragraph B; ~~and~~

C. One member 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 7, paragraph B~~.~~; and

D. The executive director of the Maine Health Data Organization, or the executive director's designee, who serves as an ex officio nonvoting member.

Sec. 2. 5 MRSA §2041, sub-§9, as repealed and replaced by PL 2021, c. 293, Pt. A, §5, is amended to read:

9. Compensation. ~~A~~ Except for the member under subsection 2, paragraph D, 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.

Sec. 3. 5 MRSA §2041, sub-§10, as repealed and replaced by PL 2021, c. 293, Pt. A, §5, is amended to read:

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~~ Service 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.

Sec. 4. 5 MRSA §2041, sub-§12, as repealed and replaced by PL 2021, c. 293, Pt. A, §5, is repealed.

Sec. 5. 5 MRSA §2042, as repealed and replaced by PL 2021, c. 293, Pt. A, §5, is amended to read:

§2042. Powers and duties of the board

The board has the following powers and duties.

~~**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.~~

1-A. Strategies to reduce costs of prescription drugs. The board shall:

A. Review prescription drug spending and utilization data to identify causes of high spending or rising spending affecting public and private payors and impacting consumers;

B. Solicit public input to identify cost-related barriers to accessing prescription drugs; and

C. Assess strategies to reduce the cost of prescription drugs and reduce the rate of growth in prescription drug spending and to reduce cost barriers for consumers. The review of strategies must include consideration of the strategies' likely impact on consumers and overall health care costs and the feasibility of implementing such strategies. At a minimum, the board shall assess the following strategies:

(1) Empowering the board to assess the affordability of drugs and to establish upper payment limits;

(2) Implementing reference-based pricing tied to the Medicare drug price negotiation program established in United States Public Law 117-169 (August 16, 2022);

(3) Implementing new methods for the purchase of prescription drugs by public payors, including group purchasing and prescription drug formulary alignment;

(4) Implementing transparency requirements regarding discounts and rebates in prescription drug costs and regulating supply chain entities, including but not limited to pharmacy benefits managers;

(5) Regulating insurance to reduce out-of-pocket costs for prescription drugs;

(6) Establishing spending targets for prescription drugs that could be applied to one or more segments of the state-regulated commercial insurance market;

(7) Developing opportunities for engagement with providers and other health care professionals to disseminate information about prescription drug costs and pricing; and

(8) Aligning the payment for prescription drugs with actual drug acquisition costs, except for prescription drugs obtained under federal discount programs.

1-B. Other states' experiences. To accomplish the duties under subsection 1-A, the board shall consider and review the experiences of other states, including the role of prescription drug affordability boards established in other states that are authorized to assess affordability of prescription drugs and to establish upper payment limits or reference-based pricing requirements.

1-C. Upper payment limits. The board may set upper payment limits for prescription drugs as follows.

A. No later than January 1, 2026, the board shall establish by rule a methodology for setting upper payment limits in accordance with this subsection. Rules adopted pursuant to this paragraph are major substantive rules as defined in chapter 375, subchapter 2-A.

B. At a minimum, the methodology adopted by the board by rule under paragraph A must take into consideration:

(1) The cost of the prescription drug;

(2) Whether the Medicare program has negotiated a maximum fair price for the prescription drug through the Medicare drug price negotiation program established in United States Public Law 117-169 (August 16, 2022);

(3) An estimate of the potential savings to the State if an upper payment limit is required for one or more of the prescription drugs for which the Medicare program has negotiated a maximum fair price;

(4) Whether an upper payment limit would improve affordability and generate savings to the State's health care system and the extent to which an upper payment limit would reduce barriers of cost and access to prescription drugs for public and private payors and consumers in the State;

(5) A process for selecting, on an annual basis, the maximum fair prices for drugs negotiated by the Medicare program through the Medicare drug price negotiation program for which the board has established an upper payment limit;

(6) The applicability of upper payment limits to public and private payors in the State, including a process to voluntarily opt in to upper payment limits for plans regulated under the federal Employee Retirement Income Security Act of 1974;

(7) The applicability of upper payment limits to purchases of prescription drugs in the State, including consideration of the supply chain for prescription drugs; and

(8) Other relevant criteria that the board determines necessary after input from the advisory council established by section 2041, subsection 10 or other stakeholders.

C. Beginning January 1, 2026 and as long as rules have been finally adopted pursuant to paragraph A, the board may establish upper payment limits for public or private payors for one or more of the first 10 prescription drugs for which the Medicare

program has negotiated maximum fair prices through the Medicare drug price negotiation program established in United States Public Law 117-169 (August 16, 2022). Beginning January 1, 2027 and annually thereafter, the board may establish upper payment limits for one or more prescription drugs for which the Medicare program has negotiated maximum fair prices through the Medicare drug price negotiation program.

D. The board may suspend an upper payment limit if it determines that there is a shortage of the prescription drug in the State.

E. The board shall publish on its publicly accessible website a list of prescription drugs for which it has set an upper payment limit.

F. The board shall determine an effective date for an upper payment limit set by the board. The upper payment limit must apply to a prescription drug subject to an upper payment limit on or after the effective date established by the board.

G. The establishment of an upper payment limit constitutes final agency action subject to judicial review pursuant to chapter 375, subchapter 7.

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~~ Prescription drug spending data~~, which the~~ not available through the Maine Health Data Organization. The board may request data under this paragraph from 3rd-party ~~administrator~~ administrators or ~~insurer for the public payor's health plan shall provide to the board on behalf of the public payor upon request~~ insurers 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~~ benefits manager 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 other available information regarding costs to consumers, including premiums and out-of-pocket costs; 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~~ assessment conducted under subsection ~~2~~ 1-A, paragraph C, 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:~~ shall recommend one or more strategies for adoption by the State in any annual report to the Legislature pursuant to subsection 4. Any recommendation of one or more strategies by the board must include guidance for implementation, enforcement and necessary funding.

~~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~~ pursuant to subsection 3 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. 6. Appropriations and allocations. The following appropriations and allocations are made.

OFFICE OF AFFORDABLE HEALTH CARE

Office of Affordable Health Care Z320

Initiative: Provides funding for contracts required to meet the new requirements of the Maine Prescription Drug Affordability Board.

GENERAL FUND	**2023-24**	**2024-25**
All Other	$0	$1,100,000
GENERAL FUND TOTAL	$0	$1,100,000

Office of Affordable Health Care Z320

Initiative: Provides funding to establish one Public Service Coordinator II position and one Planner II position to administer the new requirements of the Maine Prescription Drug Affordability Board.

GENERAL FUND	**2023-24**	**2024-25**
POSITIONS - LEGISLATIVE COUNT	0.000	2.000
Personal Services	$0	$232,358
All Other	$0	$3,985
GENERAL FUND TOTAL	$0	$236,343

OFFICE OF AFFORDABLE HEALTH CARE DEPARTMENT TOTALS	**2023-24**	**2024-25**
GENERAL FUND	**$0**	**$1,336,343**
DEPARTMENT TOTAL - ALL FUNDS	**$0**	**$1,336,343**

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Amend the bill by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.

SUMMARY

This amendment replaces the bill and makes the following changes to the laws governing the Maine Prescription Drug Affordability Board.

1. It adds the executive director of the Maine Health Data Organization as an ex officio nonvoting member.

2. It removes the authority of the board to recommend that public payors pay an assessment to support the administration of the board.

3. It changes the scope of the duties of the board to focus on an assessment of strategies to reduce prescription drug costs, reduce the rate of growth in prescription drug spending and reduce cost barriers for consumers.

4. It requires the board to review in its next annual report how states with authority to establish upper payment limits have implemented that authority, to recommend whether the board should have comparable authority and to include an estimate of savings to the State if the State applies reference-based pricing to the first 10 prescription drugs for which the Medicare program has negotiated maximum fair prices through the Medicare drug price negotiation program.

The amendment also authorizes the Maine Prescription Drug Affordability Board to set upper payment limits to be paid by public and private payors in the State for prescription drugs. The amendment requires the board to adopt, no later than January 1, 2026, rules establishing a methodology for setting upper payment limits and designates those rules as major substantive rules, which require approval of the Legislature before being finally adopted. The methodology adopted by the board must take into consideration certain minimum criteria, including the cost of the prescription drug; whether the Medicare

program has negotiated a maximum fair price for the prescription drug through the Medicare drug price negotiation program; an estimate of the potential savings to the State if an upper payment limit is required for one or more of the prescription drugs for which the Medicare program has negotiated a maximum fair price; whether an upper payment limit would improve affordability and generate savings to the State's health care system and the extent to which an upper payment limit would reduce barriers of cost and access to prescription drugs for public and private payors and consumers in the State; a process for selecting, on an annual basis, the maximum fair prices for drugs negotiated by the Medicare program through the Medicare drug price negotiation program for which the board has established an upper payment limit; the applicability of upper payment limits to public and private payors in the State, including a process to voluntarily opt in to upper payment limits; the applicability of upper payment limits to purchases of prescription drugs in the State, including consideration of the supply chain for prescription drugs; and other relevant criteria that the board determines is necessary after input from the board's advisory council or other stakeholders.

Beginning January 1, 2026 and as long as the major substantive rules have been adopted, the amendment authorizes the Maine Prescription Drug Affordability Board to establish upper payment limits for public or private payors for one or more of the first 10 prescription drugs for which the Medicare program has negotiated maximum fair prices through the Medicare drug price negotiation program. Beginning January 1, 2027 and annually thereafter, the board is authorized to establish upper payment limits for one or more prescription drugs for which the Medicare program has negotiated maximum fair prices through the Medicare drug price negotiation program. The amendment provides that the board may suspend an upper payment limit if it determines that there is a shortage of the prescription drug in the State. The amendment requires the board to determine an effective date for an upper payment limit set by the board and to publish on its publicly accessible website a list of prescription drugs for which it has set an upper payment limit. The amendment specifies that the establishment of an upper payment limit constitutes final agency action subject to judicial review pursuant to the Maine Revised Statutes, Title 5, chapter 375, subchapter 7.

FISCAL NOTE REQUIRED

(See attached)