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Date: (Filing No. S-)

HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

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**STATE OF MAINE
SENATE
130TH LEGISLATURE
FIRST SPECIAL SESSION**

COMMITTEE AMENDMENT “ ” to S.P. 262, L.D. 675, “An Act To Protect Maine Consumers from Unsupported Price Increases on Prescription Medicines by Creating an Independent Review Process”

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

'An Act To Protect Maine Consumers from Unsupported Price Increases on Prescription Medicines'

Amend the bill by striking out all of section 1 and inserting the following:

'Sec. 1. 5 MRSA c. 166 is enacted to read:

CHAPTER 166

PROTECTION OF CONSUMERS FROM UNSUPPORTED PRESCRIPTION DRUG PRICE INCREASES

§2035. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Consumer Price Index. "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All items, reported by the United States Department of Labor, Bureau of Labor Statistics or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

2. Identified prescription drug. "Identified prescription drug" means a prescription drug that has at any time been identified as having an unsupported price increase.

3. Prescription drug. "Prescription drug" has the same meaning as in Title 32, section 13702-A, subsection 30.

COMMITTEE AMENDMENT

1 **4. Prescription drug manufacturer.** "Prescription drug manufacturer" means a
2 business operating in this State that manufactures prescription drugs for sale to another
3 person or business in this State.

4 **5. Unsupported price increase.** "Unsupported price increase" means an increase in
5 price for a prescription drug for which there was no, or inadequate, new clinical evidence
6 to support the price increase, as demonstrated by prescription drug data collected annually
7 by the Maine Health Data Organization, or successor organization, that is published in the
8 organization's annual report required by Title 22, section 8736 and as determined pursuant
9 to section 2036.

10 **6. Wholesale acquisition cost.** "Wholesale acquisition cost" has the same meaning
11 as in 42 United States Code, Section 1395w-3a.

12 **§2036. Prescription drugs with unsupported price increases**

13 **1. Determination of prescription drugs with unsupported price increases.** The
14 determination of unsupported price increases for prescription drugs is governed as follows.

15 A. Beginning with prescription drug pricing data for calendar year 2021, within 60
16 days of the publication of the annual report by the Maine Health Data Organization
17 regarding prescription drug pricing required by Title 22, section 8736, the Maine
18 Prescription Drug Affordability Board shall identify a list of no more than 12 identified
19 drugs with price increases that have met the notification requirements of Title 22,
20 section 8732.

21 B. The Maine Prescription Drug Affordability Board shall determine the list of
22 identified drugs by:

23 (1) Reviewing the report regarding prescription drug pricing under paragraph A
24 and determining which drugs had price increases greater than the medical
25 Consumer Price Index plus 2%;

26 (2) Determining which drugs identified under subparagraph (1) had the largest net
27 price increases in the past year;

28 (3) Considering manufacturer data regarding any factors or reasoning in the price
29 increases for the manufacturer's drugs in the past year;

30 (4) Reviewing all relevant clinical literature regarding the drugs under
31 consideration; and

32 (5) Finalizing a list of 12 or fewer of the drugs that increased in price in the
33 preceding calendar year without any support for that increase.

34 C. In making the determination described in paragraph B, the Maine Prescription Drug
35 Affordability Board must use all necessary data that the board possesses and may rely
36 on research contracted by the board, or that is done by an independent research
37 institute, so long as the board determines that any contractor or independent research
38 institute meets the requirements described in paragraph B and does not use any
39 methodology that discriminates against persons with disabilities.

40 D. The Maine Prescription Drug Affordability Board shall send a list of the
41 prescription drugs determined pursuant to paragraph B to the Office of the Treasurer
42 of State as soon as the list is available.

1 **2. Sales of identified prescription drugs prohibited; penalty.** A prescription drug
2 manufacturer responsible for the sale of any identified prescription drug in this State
3 commits a civil violation for which a fine must be adjudged as provided in this subsection.

4 A. The fine is assessed on the sales within the State of identified prescription drugs
5 and is collected by the Office of the Treasurer of State.

6 B. The fine in any calendar year is equal to 80% of the difference between the revenue
7 generated by sales within the State of the identified prescription drugs and the revenue
8 that would have been generated if the prescription drug manufacturer had maintained
9 the wholesale acquisition cost from the previous calendar year, adjusted for inflation
10 using the medical Consumer Price Index.

11 C. In order for the fine to be assessed, a prescription drug manufacturer must have at
12 least \$250,000 in total annual sales within the State in the calendar year for which the
13 fine is assessed.

14 D. Within 60 days of the completion of the annual report under subsection 1, paragraph
15 D on identified prescription drugs by the Maine Prescription Drug Affordability Board,
16 the board shall determine the amount of the fine owed by each manufacturer of an
17 identified prescription drug based on the following information, including information
18 provided upon request by the Maine Health Data Organization:

19 (1) The total amount of sales of the identified prescription drug within the State;

20 (2) The total number of units sold of the identified prescription drug within the
21 State;

22 (3) The wholesale acquisition cost of the identified prescription drug in the
23 calendar year in which the fine is assessed and any changes in the wholesale
24 acquisition cost during the calendar year;

25 (4) The wholesale acquisition cost of the identified prescription drug during the
26 previous calendar year;

27 (5) A calculation of the fine owed; and

28 (6) Any other information that the Maine Prescription Drug Affordability Board or
29 the Maine Health Data Organization determines is necessary to calculate the
30 correct amount of the fine owed.

31 E. The Maine Prescription Drug Affordability Board shall notify the Office of the
32 Treasurer of State of the manufacturers of identified prescription drugs subject to fines
33 under this subsection and the amount of each fine owed. The Office of the Treasurer
34 of State shall then notify each prescription drug manufacturer that sales within the State
35 of identified prescription drugs are subject to the fine described in this subsection for
36 the calendar year following the identified prescription drug's appearance in the annual
37 report on identified prescription drugs by the Maine Prescription Drug Affordability
38 Board under subsection 1, paragraph D.

39 F. Upon an action brought by the Attorney General on behalf of the Office of the
40 Treasurer of State, the Superior Court may issue an order to assess a fine on a
41 prescription drug manufacturer for a violation of this subsection. The Office of the
42 Treasurer of State shall, upon evidence of a court order, collect all fines assessed under
43 this paragraph and a prescription drug manufacturer shall pay any fine assessed

1 annually by April 15th for the previous calendar year. Upon notice that a fine has been
2 ordered by the Superior Court, a manufacturer subject to a fine may obtain review of
3 the fine by that court by filing a petition in accordance with Title 5, section 11002, and
4 the Maine Rules of Civil Procedure, Rule 80C.

5 **3. Fund established.** The Unsupported Prescription Drug Price Increases Fund,
6 referred to in this section as "the fund," is established as a nonlapsing fund in the Office of
7 the Attorney General to offset the costs of enforcing this chapter. The State Controller
8 shall credit to the fund any fines assessed for violations of this section payable pursuant to
9 this section. Beginning in fiscal year 2027-28, the fund must be used to benefit consumers
10 or to offset health care costs to consumers.

11 **4. Administrative costs.** Upon request from the Office of the Treasurer of State, the
12 Maine Health Data Organization or the Maine Prescription Drug Affordability Board, the
13 Attorney General may transfer money available in the fund to the Office of the Treasurer
14 of State, the Maine Health Data Organization or the Maine Prescription Drug Affordability
15 Board for the administrative costs of performing the duties required by subsections 1 and
16 2. The Attorney General may grant a request only upon finding that there will be no
17 significant negative impact on the availability of funds to meet the requirements of
18 subsection 3.

19 **5. Annual report.** Beginning June 1, 2023 and annually thereafter until June 1, 2026,
20 the Attorney General shall submit a report to the joint standing committee of the Legislature
21 having jurisdiction over prescription drug matters that describes the amount of revenue
22 received from fines paid in accordance with subsection 2, segregated by manufacturer and
23 identified prescription drug; the current amount available to the Attorney General for the
24 purposes described in subsection 3; how the fine revenue has been used; and any funds
25 made available to the Office of the Treasurer of State, the Maine Health Data Organization
26 or the Maine Prescription Drug Affordability Board for administrative costs pursuant to
27 subsection 4.

28 **§2037. Prohibition on withdrawal of identified prescription drugs for sale**

29 **1. Withdrawal from sale prohibited.** Except as provided in subsection 2, it is a
30 violation of this chapter for any prescription drug manufacturer or distributor of an
31 identified prescription drug to withdraw that prescription drug from sale or distribution
32 within this State for the purpose of avoiding the fine set forth in section 2036.

33 **2. Notice required.** A prescription drug manufacturer that intends to withdraw an
34 identified prescription drug from sale or distribution within the State for the purpose of
35 avoiding the fine set forth in section 2036, subsection 1 must provide 180 days' prior notice
36 to the Attorney General of the withdrawal in order to avoid the penalty under subsection 3.

37 **3. Penalty.** The Superior Court, upon an action brought by the Attorney General, may
38 assess a civil penalty of not less than \$500,000 on any person, including any manufacturer
39 or distributor of an identified prescription drug, that it determines has withdrawn an
40 identified prescription drug from sale or distribution in this State in violation of this
41 section.'

42 Amend the bill by inserting after section 2 the following:

43 '**Sec. 3. Appropriations and allocations.** The following appropriations and
44 allocations are made.

1 **ATTORNEY GENERAL, DEPARTMENT OF THE**
2 **Unsupported Prescription Drug Price Increases Fund N401**

3 Initiative: Provides base allocations to the newly established Unsupported Prescription
4 Drug Price Increases Fund.

5 OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
6 All Other	\$500	\$500
7		
8 OTHER SPECIAL REVENUE FUNDS TOTAL	<u>\$500</u>	<u>\$500</u>

9
10 Amend the bill by relettering or renumbering any nonconsecutive Part letter or section
11 number to read consecutively.

12 **SUMMARY**

13 This amendment, as in the bill, makes prescription drug manufacturers subject to fines
14 for the sale of prescription drugs in this State identified as having an unsupported price
15 increase. The amendment changes the process for determining an unsupported price
16 increase and the data on which it is based and the number of drugs annually that may be
17 subject to fines. The amendment directs the Maine Prescription Drug Affordability Board
18 to identify a list of no more than 12 drugs with an unsupported price increase based on
19 prescription drug data reported by the Maine Health Data Organization. The Maine
20 Prescription Drug Affordability Board is then required to determine which drugs on that
21 list have what constitutes an unsupported price increase. The bill requires that the
22 determination of what constitutes an unsupported price increase be demonstrated by the
23 analyses of prescription drugs prepared annually by the Institute for Clinical and Economic
24 Review, or successor organization.

25 The amendment adds an appropriations and allocations section.

26 **FISCAL NOTE REQUIRED**

27 **(See attached)**