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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. 380, L.D. 1117, “An Act To Prevent Excessive Prices for Prescription Drugs”

Amend the bill in section 1 in c. 166 in §2036 by striking out all of subsection 2 (page 1, lines 33 to 37 and page 2, lines 1 to 5 in L.D.) and inserting the following:

2. Determination of excessive price increases. A price increase of a generic or off-patent prescription drug is excessive for purposes of this section when the price increase, adjusted for inflation using the Consumer Price Index, exceeds 20% of the wholesale acquisition cost per pricing unit of the immediately preceding calendar year and the cost of the drug is at least \$10 per pricing unit.'

Amend the bill in section 1 in c. 166 in §2036 by striking out all of subsection 5 (page 2, lines 14 to 42 and page 3, lines 1 to 16 in L.D.) and inserting the following:

5. Enforcement. The following provisions govern the enforcement of this section.

A. The Maine Health Data Organization shall notify the Attorney General of any price increase for a generic or off-patent prescription drug that is an excessive price increase in violation of this section. The Attorney General shall notify any prescription drug manufacturer of any generic or off-patent prescription drug that has been identified as having an excessive price increase as described in subsection 2.

B. When providing the notice required under paragraph A to the Attorney General, the Maine Health Data Organization shall also provide the following information regarding a prescription drug manufacturer of a generic or off-patent prescription drug identified as having an excessive price increase:

- (1) An itemization of the components of the cost of producing the drug;
- (2) Information identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase during the preceding year in the price of the drug; and

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1 (3) Any other information that the prescription drug manufacturer has indicated
2 that the manufacturer believes to be pertinent to a determination of whether a
3 violation of this section has occurred.

4 C. The Attorney General may require a prescription drug manufacturer and wholesale
5 distributor to produce any records or documents that may be relevant to a determination
6 of whether a violation of this section has occurred.

7 D. Upon an action brought by the Attorney General, the Superior Court may issue an
8 order to:

9 (1) Compel the prescription drug manufacturer of the generic or off-patent
10 prescription drug to produce records or documents requested by the Attorney
11 General under paragraph C that may be relevant to a determination of whether a
12 violation of this section has occurred;

13 (2) Restrain or enjoin a violation of this section, including an order requiring that
14 prices be restored to levels that comply with this section;

15 (3) Require the prescription drug manufacturer to provide an accounting to the
16 Attorney General of all revenues generated in violation of this section;

17 (4) Restore to any consumer, including any 3rd-party payor, any money acquired
18 as a result of an excessive price increase in violation of this section. With respect
19 to this subparagraph, every individual transaction in violation of this section is
20 determined to be a separate violation;

21 (5) Require that all revenues generated in violation of this section be remitted to
22 the State to be used for efforts designed to reduce the cost to consumers of
23 acquiring prescription drugs, if a prescription drug manufacturer is unable to
24 determine the individual transactions necessary to provide the restitution described
25 in subparagraph (4);

26 (6) Assess a civil penalty of up to \$30,000 per day for each violation of this section;
27 and

28 (7) Provide for any other appropriate relief, including attorney's fees and costs
29 reasonably incurred by the Attorney General in bringing an action against a
30 prescription drug manufacturer found in violation of this section.'

31 Amend the bill in section 1 in c. 166 in §2037 by striking out all of subsection 3 (page
32 3, lines 27 to 31 in L.D.) and inserting the following:

33 '**3. Penalty.** The Superior Court, upon an action brought by the Attorney General, may
34 assess a civil penalty of not less than \$500,000 on any prescription drug manufacturer of a
35 generic or off-patent prescription drug that the Attorney General determines has withdrawn
36 that generic or off-patent prescription drug from sale or distribution in this State, whether
37 directly or through a wholesale distributor, in violation of this section.'

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

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SUMMARY

This amendment changes the criteria for determining an excessive price increase of a generic or off-patent prescription drug. Under the amendment, a price increase is excessive when the price increase exceeds 20% of the wholesale acquisition cost per pricing unit of the immediately preceding calendar year and the cost of the drug is at least \$10 per pricing unit. The bill proposes different criteria.

The amendment requires the Maine Health Data Organization to identify a generic or off-patent prescription drug that has an excessive price increase and to provide notice to the Attorney General. The bill requires the notice to be provided by other state agencies that purchase or provide prescription drug benefits.

The amendment increases the maximum civil penalty for a violation from \$10,000 per day per violation to \$30,000 per day per violation. The amendment also makes technical changes to the enforcement process by clarifying that a court must issue any enforcement order or civil penalty upon an action brought by the Attorney General.

FISCAL NOTE REQUIRED

(See attached)