

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36

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
130TH LEGISLATURE
FIRST SPECIAL SESSION**

COMMITTEE AMENDMENT “ ” to S.P. 260, L.D. 673, “An Act To Create the Insulin Safety Net Program”

Amend the bill in section 1 in §13725 in subsection 2 in the 3rd line (page 1, line 22 in L.D.) by striking out the following: "January" and inserting the following: 'March'

Amend the bill in section 1 in §13725 in subsection 3 in the first 2 lines (page 1, lines 26 and 27 in L.D.) by striking out the following: "The board shall, through the program, authorize a pharmacy to dispense a 30-day supply of insulin" and inserting the following: 'A pharmacy shall dispense a 30-day supply of insulin, as permitted under section 13786-D.'

Amend the bill in section 1 in §13725 in subsection 3 in paragraph C in the last line (page 2, line 9 in L.D.) by inserting after the following: "supply." the following: 'If an individual does not have a valid prescription, a pharmacist may dispense an emergency refill of insulin pursuant to section 13786-D.'

Amend the bill in section 1 in §13725 in subsection 3 in paragraph G in the 2nd line (page 2, line 24 in L.D.) by inserting after the following: "information" the following: 'for the Health Insurance Consumer Assistance Program established in Title 24-A, chapter 56-A, subchapter 2-A, including the program's publicly accessible website, toll-free telephone number and e-mail address, so that the individual may access additional information and assistance'

Amend the bill in section 1 in §13725 in subsection 3 in paragraph H in the last line (page 2, line 33 in L.D.) by striking out the following: "auditing" and inserting the following: 'compliance'

Amend the bill in section 1 in §13725 in subsection 4 in the first 2 lines (page 2, lines 34 and 35 in L.D.) by striking out the following: "Pursuant to the requirements of the program, as established by the board, a" and inserting the following: 'A'

Amend the bill in section 1 in §13725 in subsection 4 in paragraph A in the first line (page 2, line 39 in L.D.) by striking out the following: "board with" and inserting the following: 'Health Insurance Consumer Assistance Program established in Title 24-A, chapter 56-A, subchapter 2-A'

COMMITTEE AMENDMENT

1 Amend the bill in section 1 in §13725 in subsection 4 by striking out all of paragraph
2 G (page 4, lines 31 to 40 in L.D.) and inserting the following:

3 'G. If an individual disagrees with a manufacturer's determination of eligibility under
4 this subsection, the individual may contact the board to request a review of eligibility.
5 The review of eligibility must be conducted by the board administrator, in consultation
6 with a board member. The individual requesting the review shall submit to the board,
7 with the request, all documents submitted by the individual to the manufacturer. The
8 board shall provide the reviewer or reviewers with the documents submitted by the
9 individual. The review of eligibility must be completed within 10 business days of
10 receipt of all the necessary documents from the individual. The review decision is
11 final. If the review determines that the individual is eligible for the manufacturer's
12 patient assistance program, the manufacturer shall provide the individual with an
13 eligibility statement in accordance with this subsection.'

14 Amend the bill in section 1 in §13725 in subsection 5 in the 6th line (page 5, line 1 in
15 L.D.) by striking out the following: "panel" and inserting the following: 'reviewer'

16 Amend the bill in section 1 in §13725 in subsection 6 in the first line (page 5, line 5 in
17 L.D.) by striking out the following: "The" and inserting the following: 'In consultation with
18 the Health Insurance Consumer Assistance Program, established in Title 24-A, chapter
19 56-A, subchapter 2-A, the'

20 Amend the bill by inserting after section 1 the following:

21 **'Sec. 2. 32 MRSA §13742-A, sub-§1, ¶E,** as amended by PL 2019, c. 165, §28, is
22 further amended to read:

23 E. Failing to comply with section 13800; ~~or~~

24 **Sec. 3. 32 MRSA §13742-A, sub-§1, ¶F,** as enacted by PL 2019, c. 165, §29, is
25 amended to read:

26 F. A violation of section 13800-B; ~~or~~

27 **Sec. 4. 32 MRSA §13742-A, sub-§1, ¶G** is enacted to read:

28 G. A violation of section 13725.

29 **Sec. 5. 32 MRSA §13800-D** is enacted to read:

30 **§13800-D. Insulin product registration fee**

31 This section governs insulin product registration fees. As used in this section, "unit of
32 insulin" means the lowest identifiable quantity of insulin that is dispensed.

33 **1. Registration fee.** Except as provided in subsection 2, a manufacturer that produces
34 insulin that is sold, delivered or distributed in this State shall pay an annual registration fee
35 of \$75,000 to the board on December 31st of each year in addition to any license renewal
36 fee required to be paid by the manufacturer under this chapter.

37 **2. Exception.** A manufacturer whose aggregate total of insulin sold, delivered or
38 distributed in this State does not exceed 500,000 units of insulin in the year in which a
39 registration fee under subsection 1 is due is not required to pay the registration fee. To
40 qualify for the exception under this subsection, a manufacturer must demonstrate to the
41 board, by January 31st of the year following the year in which the registration fee is due.

1 in a manner determined by the board, that the aggregate total of insulin produced by the
 2 manufacturer that was sold, delivered or distributed within this State in the year in which
 3 the manufacturer seeks to claim the exception did not exceed 500,000 units. The board may
 4 adopt rules to implement this section. Rules adopted pursuant to this subsection are routine
 5 technical rules as defined in Title 5, chapter 375, subchapter 2-A.

6 This section is repealed January 1, 2027.

7 **Sec. 6. Appropriations and allocations.** The following appropriations and
 8 allocations are made.

9 **PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF**

10 **Administrative Services - Professional and Financial Regulation 0094**

11 Initiative: Allocates funds for technology-related costs associated with establishing one
 12 Comprehensive Health Planner position to manage the Insulin Safety Net Program.

13 OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
14 All Other	\$2,729	\$3,347
15		
16 OTHER SPECIAL REVENUE FUNDS TOTAL	\$2,729	\$3,347

17 **Licensing and Enforcement 0352**

18 Initiative: Allocates funds for the per diem costs for one member of the Maine Board of
 19 Pharmacy to review a manufacturer's determination of eligibility for the manufacturer's
 20 patient assistance program.

21 OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
22 Personal Services	\$630	\$840
23		
24 OTHER SPECIAL REVENUE FUNDS TOTAL	\$630	\$840

25 **Licensing and Enforcement 0352**

26 Initiative: Allocates funds for one Comprehensive Health Planner position and related All
 27 Other costs to manage the Insulin Safety Net Program.

28 OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
29 POSITIONS - LEGISLATIVE COUNT	1,000	1,000
30 Personal Services	\$72,628	\$101,474
31 All Other	\$9,278	\$4,477
32		
33 OTHER SPECIAL REVENUE FUNDS TOTAL	\$81,906	\$105,951

34
 35 **PROFESSIONAL AND FINANCIAL**
 36 **REGULATION, DEPARTMENT OF**
 37 **DEPARTMENT TOTALS**

38		
39 OTHER SPECIAL REVENUE FUNDS	\$85,265	\$110,138
40		
41 DEPARTMENT TOTAL - ALL FUNDS	\$85,265	\$110,138

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

3 **SUMMARY**

4 This amendment, which is the majority report of the committee, makes the following
5 changes to the bill.

6 1. It changes the date by which manufacturers must have established procedures to
7 make insulin available to pharmacies under the Insulin Safety Net Program from January
8 1, 2022 to March 1, 2022.

9 2. It makes clarifying changes related to the dispensing of insulin by a pharmacist.

10 3. It requires that the information provided to individuals receiving insulin through the
11 Insulin Safety Net Program include contact information for the Health Insurance Consumer
12 Assistance Program.

13 4. It directs insulin manufacturers to provide contact information related to their patient
14 assistance programs to the Health Insurance Consumer Assistance Program.

15 5. It removes the requirement that a 3-member panel of the board conduct a review
16 when an individual disagrees with a manufacturer's determination of eligibility for a patient
17 assistance program. Instead, it requires that the review of eligibility be conducted by the
18 board administrator in consultation with a board member.

19 6. It clarifies that a violation of the requirements of the Insulin Safety Net Program is
20 subject to disciplinary action by the board.

21 7. It adds a requirement that certain insulin manufacturers pay an annual registration
22 fee of \$75,000.

23 8. It adds an appropriations and allocations section.

24 **FISCAL NOTE REQUIRED**

25 **(See attached)**