MAINE STATE LEGISLATURE

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1			L.D. 673
2	Date: (0)14/21	MAJORITY	(Filing No. S-272)
3	HEALTH COVERA	GE, INSURANCE AND FI	NANCIAL SERVICES
4	Reproduced and distribu	uted under the direction of the S	Secretary of the Senate.
5		STATE OF MAINE	
6		SENATE	
7		130TH LEGISLATURE	
8		FIRST SPECIAL SESSIO)N
9 10	Insulin Safety Net Program	,,	D. 673, "An Act To Create the
11 12	I D) by striking out the fo	llowing: " <u>January</u> " and inserting	n the 3rd line (page 1, line 22 in g the following: 'March'
13 14 15 16	Amend the bill in section 26 and 27 in L.D.) by strik authorize a pharmacy to dispense	on 1 in §13725 in subsection 3 in good the following: "The bospense a 30-day supply of insulation 1 in §13725 in subsection 3	in the first 2 lines (page 1, lines ard shall, through the program, in" and inserting the following: ermitted under section 13786-D, lin paragraph C in the last line
18 19 20	(page 2, line 9 in L.D.) by individual does not have a refill of insulin pursuant to	y inserting after the following: valid prescription, a pharmaci section 13786-D.'	ist may dispense an emergency
21 22 23 24 25 26	Amend the bill in section (page 2, line 24 in L.D.) by the Health Insurance Content 56-A, subchapter 2-A, in telephone number and einformation and assistance	ion 1 in §13725 in subsection 3 in subsection 3 in serting after the following: "sumer Assistance Program established the program's publication address, so that the individual individual in the service of the service	in paragraph G in the 2nd line information the following: 'for ablished in Title 24-A, chapter y accessible website, toll-free lividual may access additional
27 28 29	(page 2, line 33 in L.D.)) by striking out the following	3 in paragraph H in the last line g: "auditing" and inserting the
30 31 32	34 and 35 in L.D.) by str	riking out the following: "Purson the board, a" and inserting the	in the first 2 lines (page 2, lines uant to the requirements of the following: 'A'
33 34 35 36	4 4 40 to 1 D \	by striking out the following: nce Consumer Assistance Prog	4 in paragraph A in the first line "board with" and inserting the gram established in Title 24-A,

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COMMITTEE AMENDMENT "A" to S.P. 260, L.D. 673 (5-278)

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1 2	Amend the bill in section 1 in §13725 in subsection 4 by striking out all of paragraph G (page 4, lines 31 to 40 in L.D.) and inserting the following:
3 4 5 6 7 8 9 10 11 12 13	'G. If an individual disagrees with a manufacturer's determination of eligibility under this subsection, the individual may contact the board to request a review of eligibility. The review of eligibility must be conducted by the board administrator, in consultation with a board member. The individual requesting the review shall submit to the board, with the request, all documents submitted by the individual to the manufacturer. The board shall provide the reviewer or reviewers with the documents submitted by the individual. The review of eligibility must be completed within 10 business days of receipt of all the necessary documents from the individual. The review decision is final. If the review determines that the individual is eligible for the manufacturer's patient assistance program, the manufacturer shall provide the individual with an eligibility statement in accordance with this subsection.'
14 15	Amend the bill in section 1 in §13725 in subsection 5 in the 6th line (page 5, line 1 in L.D.) by striking out the following: "panel" and inserting the following: 'reviewer'
16 17 18 19	Amend the bill in section 1 in §13725 in subsection 6 in the first line (page 5, line 5 in L.D.) by striking out the following: "The" and inserting the following: 'In consultation with the Health Insurance Consumer Assistance Program, established in Title 24-A, chapter 56-A, subchapter 2-A, the'
20	Amend the bill by inserting after section 1 the following:
21 22	'Sec. 2. 32 MRSA §13742-A, sub-§1, ¶E, as amended by PL 2019, c. 165, §28, is further amended to read:
23	E. Failing to comply with section 13800; or
24 25	Sec. 3. 32 MRSA §13742-A, sub-§1, ¶F, as enacted by PL 2019, c. 165, §29, is 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 32	This section governs insulin product registration fees. As used in this section, "unit of insulin" means the lowest identifiable quantity of insulin that is dispensed.
33 34 35 36	1. Registration fee. Except as provided in subsection 2, a manufacturer that produces insulin that is sold, delivered or distributed in this State shall pay an annual registration fee of \$75,000 to the board on December 31st of each year in addition to any license renewal fee required to be paid by the manufacturer under this chapter.
37 38 39 40 41	2. Exception. A manufacturer whose aggregate total of insulin sold, delivered or distributed in this State does not exceed 500,000 units of insulin in the year in which a registration fee under subsection 1 is due is not required to pay the registration fee. To qualify for the exception under this subsection, a manufacturer must demonstrate to the board, by January 31st of the year following the year in which the registration fee is due,

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COMMITTEE AMENDMENT " A." to S.P. 260, L.D. 673 (5-278)

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

This section is repealed January 1, 2027.

Sec. 6. Appropriations and allocations. The following appropriations and allocations are made.

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF

Administrative Services - Professional and Financial Regulation 0094

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

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

Licensing and Enforcement 0352

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

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

Licensing and Enforcement 0352

25 Initiative: Allocates funds for one Comprehensive Health Planner position and related All 26 Other costs to manage the Insulin Safety Net Program. 27 2022-23

27	Office costs to manage and a	2021-22	2022-23
28	OTHER SPECIAL REVENUE FUNDS	1.000	1.000
29	POSITIONS - LEGISLATIVE COUNT	\$72,628	\$101,474
30	Personal Services	\$9,278	\$4,477
31	All Other		
32	TOTAL	\$81,906	\$105,951
33	OTHER SPECIAL REVENUE FUNDS TOTAL	• •	

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35	PROFESSIONAL AND FINANCIAL

35 36 37	REGULATION, DEPARTMENT OF DEPARTMENT TOTALS	2021-22	2022-23
38	OTHER SPECIAL REVENUE FUNDS	\$85,265	\$110,138

39	OTHER SPECIAL REVENUE FORDS		
40	THE TAXABLE CONTRACTOR	\$85,265	\$110,138
41	DEPARTMENT TOTAL - ALL FUNDS	Ψου,=	

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	to S.P. 260, L.D. 673 (5-278)
1 2	Amend the bill by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.
3	SUMMARY
4 5	This amendment, which is the majority report of the committee, makes the followin changes to the bill.
6 7 8	1. It changes the date by which manufacturers must have established procedures to make insulin available to pharmacies under the Insulin Safety Net Program from January 1, 2022 to March 1, 2022.
9	2. It makes clarifying changes related to the dispensing of insulin by a pharmacist.
10 11 12	3. It requires that the information provided to individuals receiving insulin through the Insulin Safety Net Program include contact information for the Health Insurance Consumer Assistance Program.
13 14	4. It directs insulin manufacturers to provide contact information related to their patient assistance programs to the Health Insurance Consumer Assistance Program.
15 16 17 18	5. It removes the requirement that a 3-member panel of the board conduct a review when an individual disagrees with a manufacturer's determination of eligibility for a patient assistance program. Instead, it requires that the review of eligibility be conducted by the board administrator in consultation with a board member.
19 20	6. It clarifies that a violation of the requirements of the Insulin Safety Net Program is subject to disciplinary action by the board.
21 22	7. It adds a requirement that certain insulin manufacturers pay an annual registration fee of \$75,000.
23	8. It adds an appropriations and allocations section.
24	FISCAL NOTE REQUIRED
25	(500 -44-1 1)

(See attached)

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130th MAINE LEGISLATURE

LD 673

LR 1953(02)

An Act To Create the Insulin Safety Net Program

Fiscal Note for Bill as Amended by Committee Amendment "4" (5.278) Committee: Health Coverage, Insurance and Financial Services Fiscal Note Required: Yes

Fiscal Note

Current biennium revenue increase - Other Special Revenue Funds

	FY 2021-22	FY 2022-23	Projections FY 2023-24	Projections FY 2024-25
Appropriations/Allocations Other Special Revenue Funds	\$85,265	\$110,138	\$116,401	\$123,041
Fransfers Other Special Revenue Funds	\$0	\$0	\$0	\$0

Fiscal Detail and Notes

This bill includes Other Special Revenue Funds allocations to the Department of Professional and Financial Regulation totaling \$85,265 in fiscal year 2021-22 and \$110,138 in fiscal year 2022-23 to establish the Insulin Safety Net Program within the Office of Professional and Occupational Licensing, Maine Board of Pharmacy.

Of this amount, Other Special Revenue Funds allocations of \$81,906 in fiscal year 2021-22 and \$105,951 in fiscal year 2022-23 are provided to the Licensing and Enforcement program to establish one Comprehensive Health Planner position and related All Other costs to manage the program. Additional allocations of \$630 and \$840 in fiscal years 2021-22 and 2022-23, respectively, are included for the per diem costs for one board member to review a manufacturer's determination of eligibility for the manufacturer's patient assistance program if requested by the applicant. Finally, Other Special Revenue Funds allocations of \$2,729 in fiscal year 2021-22 and \$3,347 in fiscal year 2022-23 are included for the Administrative Services Division for technology-related costs associated with establishing the Comprehensive Health Planner position. The Office of Professional and Occupational Licensing will transfer funds from its Licensing and Enforcement program (which includes funds for the Maine Board of Pharmacy) to the Administrative Services Division to fund the allocations.

This legislation will result in an increase in dedicated revenue to the Maine Board of Pharmacy from the required \$75,000 registration fee that certain insulin manufacturers must pay each year until it is repealed on January 1, 2027.