OPLA Bill Analysis
Joint Standing Committee on Health Coverage, Insurance and Financial Services
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LD 673, An Act To Create the Insulin Safety Net Program

SUMMARY:

This bill establishes the Insulin Safety Net Program, which is modeled after a similar program in Minnesota. The bill requires the Maine Board of Pharmacy to oversee the program. The bill requires that, by January 1, 2022, manufacturers of insulin establish procedures to make insulin available to pharmacies for dispensing to eligible individuals who are in urgent need of insulin or who need access to an affordable insulin supply.

The bill provides 2 ways to access insulin under the program: 1) the urgent need safety net to authorize the dispensing of a 30-day supply by a pharmacy to an eligible individual; and 2) access to a 90-day supply for those demonstrating a continued need for insulin.

The bill requires annual reporting to the Legislature on the number of Maine residents accessing insulin through the program and the cost to manufacturers. The bill includes provision to repeal the program in 5 years.

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CURRENT LAW:

Current law authorizes a pharmacist to dispense emergency refills of insulin and associated insulin-related supplies and requires that the amount of insulin dispensed be in a quantity that is the lesser of a 30-day supply and the smallest available package.

Current law also prohibits health insurance carriers from imposing a cost-sharing requirement for prescription insulin drugs in excess of $35 per prescription for a 30-day supply of insulin.

TESTIMONY: Written testimony can be found at this link

ISSUES FOR CONSIDERATION:

1. The sponsor has suggested a proposed amendment to the bill that adds a provision establishing an annual registration fee of $75,000 to be paid by an insulin manufacturer to the Board of Pharmacy, except that a manufacturer that does not sell or distribute 500,000 or more units of insulin within the State in the year in which a registration fee is due is not subject to the fee.

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2. The Office of Professional and Occupational Regulation suggested technical amendments to the bill to assist with implementation by the Board of Pharmacy:

Section 1§13725. (2): Change the effective date to February or March 2022?

Section 1§13725. (3): Instead of having the Board authorize a pharmacy to dispense the 30 day supply (which infers rulemaking) can we instead cross reference the new law ((PLC 20 (LD 60) eff 3/17/2021)) on minimum amount of emergency refills of insulin?

Section 1§13725. (3) C: What about the situation where an individual completes the application but does not have a valid prescription, or relationship with a prescriber. What should the pharmacy do in those circumstances?

Section 1§13725. (3) G: The Board does not currently maintain the information required in Section G nor does it or its staff have expertise in insurance etc. And, this required information evolves quickly over time. We suggest that it would be more appropriate to have another state agency or contractor, like Consumers for Affordable Health Care, who is more familiar with these matters develop this information document for the board to share on its website and by request.

Section 1§13725. (3) H: This section requires a pharmacy to retain a copy of the application form submitted by an individual to the pharmacy for *reporting and auditing purposes.* The use of the word "audit" implies that the statute requires active auditing of this program. An ongoing audit requirement would be a heavy lift for the Board and is not contemplated in the fiscal note. We would recommend the language be amended to "…for reporting and compliance purposes."

Section 1§13725. (4): The first sentence may imply that the Board sets the requirements of the program. The program requirements seem to be set forth in Section 4 B. We recommend deleting the first clause of that sentence as follows:

~~Pursuant to the requirements of the program,~~ A, ~~-~~manufacturer shall establish a patient assistance program to provide access to insulin to any eligible individual who meets the requirements of this subsection and who demonstrates a continued need for insulin. Each manufacturer's patient assistance program must meet the requirements of this subsection.

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2. (cont'd)

Section 1§13725. (4)(A): Instead of manufacturers providing the required information about their patient assistance program to the Board, we recommend that the bill be amended to require the manufacturer to provide the information about the patient assistance program to the agency or contractor (e.g. Consumers for Affordable Health Care) who is developing the information set forth in Section 1§13725. (3) G.

Section 1§13725. (4)(D): The proposed structure of 3 board members appeals panel poses challenges and we offer the following suggestions:

One possible solution would be to have the appeal occur at the Board's next regularly scheduled board meeting. The Board meets about once a month except July and December. Given the time frame described above for the required public notice and given that the clock starts after all documentation has been received, the next regularly scheduled board meeting may be just as expedient.

Alternatives to the 3 member panel could also include review by

The AG's office or

The Board administrator, in consultation with a board member. Although this bill is written using the Minnesota model, in communications with the Board administrator's counterpart in MN, they had one case so far and handled it administratively for efficiency purposes; they did not use the 3-member panel.

Section 1§13725. (6.) Dissemination of information about program: Similar to our suggestion for Section 3 (G), we suggest that it would be more appropriate to have another state agency or contractor, like Consumers for Affordable Health Care, develop this information for the board to share on its website and by request.

Enforcement: We recommend adding a cross-reference as Section (G) to §13742-A

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ISSUES FOR CONSIDERATION (cont'd):

3. Is this duplicative of existing financial assistance programs provided by manufacturers?

4. Concerns raised in written testimony from PhRMA and Eli Lilly that proposal may violate the Takings Clause of the U.S. Constitution. A legal challenge to Minnesota law on this issue was dismissed on summary judgement in March because the federal district court ruled the plaintiffs lacked standing to challenge the law in federal court. No information about whether decision will be appealed or pursued in state court.

FISCAL INFORMATION:

The preliminary fiscal impact statement on the bill as drafted indicated the need to allocate funding of $86,525 in fiscal year 2021-22 and $111,818 in fiscal year 2022-23for an additional position within the Board of Pharmacy, for the per diem costs for 3 board members to serve as a panel to review a manufacturer's determination of eligibility for the manufacturer's patient assistance program if requested by the applicant and for technology-related costs associated with establishing the additional position. The Maine Board of Pharmacy within the Office of Professional and Occupational Licensing has sufficient resources available to support the cost of this legislation without raising fees.