STATE OF MAINE
ONE HUNDRED AND THIRTIETH LEGISLATURE
COMMITTEE ON HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

TO: Sen. Anne Carney, Senate Chair
Rep. Thomas Harnett, House Chair
Joint Standing Committee on Judiciary

FROM: Sen. Heather B. Sanborn, Senate Chair HSB
Rep. Denise A. Tepler, House Chair DAT
Joint Standing Committee on Health Coverage, Insurance and Financial Services

DATE: June 2, 2021

RE: Public Records Exception Review of LD 673

We are writing to request review of LD 673, An Act To Create the Insulin Safety Net Program, pursuant to Title 1, section 434, subsection 2. LD 673 establishes the Insulin Safety Net Program, which is modeled after a similar program in Minnesota, and would be overseen by the Maine Board of Pharmacy. 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 includes a provision to repeal the program in 5 years.

The committee held a public hearing on the bill in compliance with the public hearing requirement of Title 1, section 434, subsection 1. The committee voted 8-5 in favor of the bill as amended; the minority report would amend the bill by changing it to a study of issues related to availability and affordability of insulin. The provision requiring review is found in the bill on page 13; the committee amendment proposes to make technical changes that do not affect the public records exception. A copy of the bill is attached.

P.9 of packet

There is a provision in LD 673 that protects as confidential any health information or records provided to the board if the information or records identify or permit the identification of an individual who is seeking to access the program. The provision further requires that, if any information is provided to a manufacturer by an individual applying for the manufacturer's patient assistance program, the manufacturer is prohibited from selling, sharing or disseminating that information unless the individual has provided the manufacturer with a signed authorization. See proposed 32 MRSA §13725, subsection 8 on page 5 of the bill.

We have reviewed the statutory criteria in Title 1, section 434, subsection 2 and we offer the following comments on LD 673:

A. Whether the record protected by the proposed exception needs to be collected and maintained.

B. The value to the agency or official or to the public in maintaining a record protected by the proposed exception.

A & B. Health information for individuals that seek to access the insulin safety net program will need to be collected to determine eligibility for the program.

C. Whether federal law requires a record covered by the proposed exception to be confidential.

C. The provision in LD 673 is consistent with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which generally protects as confidential personally-identifiable health care information.

D. Whether the proposed exception protects an individual's privacy interest and, if so, whether that interest substantially outweighs the public interest in the disclosure of records.

D. We believe that the confidentiality of this information is necessary to protect an individual's privacy. While there is a strong interest in personal privacy, we note that information that does not identify or permit the identification of an individual would not be confidential.

E. Whether public disclosure puts a business at a competitive disadvantage and, if so, whether that business's interest substantially outweighs the public interest in the disclosure of records.

E. We do not believe paragraph E is applicable.

F. Whether public disclosure compromises the position of a public body in negotiations and, if so, whether that public body's interest substantially outweighs the public interest in the disclosure of records.

F. We do not believe paragraph F is applicable.

G. Whether public disclosure jeopardizes the safety of a member of the public or the public in general and, if so, whether that safety interest substantially outweighs the public interest in the disclosure of records.

G. The protection of health information and records without identifying or permit the identification of an individual provides the appropriate balancing of any safety interest and any public interest in disclosure.

H. Whether the proposed exception is as narrowly tailored as possible.

H. Yes, we believe the language is crafted in this manner. While the language generally protects the confidentiality of any personally-identifiable health information, the language would permit disclosure of information in the aggregate or any other manner that does not identify or permit the identification of an individual.

I. Any other criteria that assist the review committee in determining the value of the proposed exception as compared to the public's interest in the record protected by the proposed exception.

I. We do not offer any further comments.

Thank you for your consideration of our comments. Please contact us or our legislative analyst, Colleen McCarthy Reid, if you have any questions or need additional information. We look forward to discussing this with your committee.

Enclosures: LD 673

cc: Members, Joint Standing Committee on Health Coverage, Insurance and Financial Services
Sen. Cathy Breen

130th MAINE LEGISLATURE

FIRST REGULAR SESSION-2021

Legislative Document **No. 673**

S.P. 260 In Senate, March 4, 2021

An Act To Create the Insulin Safety Net Program

Received by the Secretary of the Senate on March 2, 2021. Referred to the Committee on Health Coverage, Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator BREEN of Cumberland.
Cosponsored by Representative MADIGAN of Waterville and
Senators: CLAXTON of Androscoggin, President JACKSON of Aroostook, MAXMIN of Lincoln, RAFFERTY of York, Representatives: McDONALD of Stonington, WHITE of Waterville, WILLIAMS of Bar Harbor.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 32 MRSA §13725 is enacted to read:

§13725. Insulin Safety Net Program

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Eligible individual" means an individual who has been determined to qualify for assistance under the program pursuant to subsection 3 or 4.

B. "Insulin" has the same meaning as in section 13786-D, subsection 1, paragraph A, except for an insulin product that has a wholesale acquisition cost of $8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire assessment time period, adjusted annually based on the Consumer Price Index Annual Average, for All Urban Consumers, CPI-U: U.S. City Averages, All Items reported by the United States Department of Labor, Bureau of Labor Statistics.

C. "Manufacturer" means a manufacturer engaged in the manufacturing of insulin that is self-administered on an outpatient basis, except for a manufacturer with an annual gross revenue of $2,000,000 or less from insulin sales in this State.

D. "Urgent need of insulin" means having readily available for use less than a 7-day supply of insulin and in need of insulin in order to avoid the likelihood of suffering significant health consequences.

2. Insulin Safety Net Program established. The board shall establish the Insulin Safety Net Program, referred to in this section as "the program," in accordance with the requirements of this section. Under the program, by January 1, 2022, each manufacturer shall establish procedures to make insulin available in accordance with this section and as required under subsections 3 and 4 to pharmacies for dispensing to eligible individuals who are in urgent need of insulin or who need access to an affordable insulin supply.

3. Urgent need safety net. The board shall, through the program, authorize a pharmacy to dispense a 30-day supply of insulin to an eligible individual in urgent need of insulin in accordance with this subsection.

A. To be eligible, an individual must demonstrate on an application form developed by the board that the individual:

(1) Is a resident of this State;

(2) Is not enrolled in MaineCare or any other health coverage or prescription drug coverage that limits the total amount of cost-sharing that the enrollee is required to pay for a 30-day supply of insulin, including copayments, deductibles or coinsurance, to $75 or less, regardless of the type or amount of insulin prescribed;

(3) Has not received an urgent-need supply of insulin through the program within the previous 12 months; and

(4) Has an urgent need of insulin.

B. The board shall make the application form accessible through the board's publicly accessible website and make the form available to pharmacies and health care providers

who prescribe or dispense insulin, hospital emergency departments, urgent care clinics and community health clinics.

C. In addition to a completed, signed and dated application, an individual shall also present to a pharmacy a valid insulin prescription and identification indicating residency in the form of a valid Maine identification card, driver's license or permit. If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian shall provide the pharmacy with proof of residency. Upon receipt of the information required by this paragraph, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual a 30-day supply.

D. The pharmacy shall notify the health care practitioner who issued the prescription order presented under paragraph C no later than 72 hours after the insulin is dispensed.

E. The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment for insulin dispensed under paragraph C that is in accordance with the standards developed by a national council for prescription drug programs for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

F. The pharmacy may collect an insulin copayment from the eligible individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed $35 for the 30-day supply of insulin dispensed under paragraph C.

G. The pharmacy shall provide each eligible individual an information sheet provided by the board with contact information related to ongoing insulin coverage options, including assistance in: applying for MaineCare; applying for a qualified health plan offered through the federally facilitated marketplace, subject to open and special enrollment periods; accessing information on providers who participate in prescription drug discount programs, including providers who are authorized to participate in the federal program under section 340b of the federal Public Health Service Act, United States Code, Title 42, section 256b; and accessing insulin manufacturers' patient assistance programs and other assistance programs through nonprofit organizations.

H. The pharmacy shall retain a copy of the application form submitted by the individual under paragraph A to the pharmacy for reporting and auditing purposes.

4. Manufacturer's patient assistance. Pursuant to the requirements of the program, as established by the board, 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.

A. Each manufacturer shall provide the board with information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing the patient assistance program.

B. To be eligible to participate in a manufacturer's patient assistance program, an individual must:

(1) Be a Maine resident with a valid identification card that indicates Maine residency in the form of a Maine identification card or driver's license or permit. If the individual is under the age of 18, the individual's parent or legal guardian shall provide proof of residency;

(2) Have a family income that is equal to or less than 400 percent of the federal poverty guidelines; and

(3) Not be enrolled in MaineCare or eligible to receive health care coverage through a federally funded program or to receive prescription drug benefits through the United States Department of Veterans Affairs or not be enrolled in prescription drug coverage through an individual or group health plan that limits the total amount of cost-sharing that an enrollee is required to pay for a 30-day supply of insulin, including copayments, deductibles or coinsurance, to $75 or less, regardless of the type or amount of insulin needed.

Notwithstanding the requirement in this paragraph, an individual who is enrolled in Medicare Part D is eligible for a manufacturer's patient assistance program if the individual has spent $1,000 on prescription drugs in the current calendar year and meets the eligibility requirements in subparagraphs (1) and (2).

C. An individual who is interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer or through the individual's health care practitioner, if the practitioner participates in the manufacturer's patient assistance program.

D. Upon receipt of an application for the manufacturer's patient assistance program, the manufacturer shall process the application and determine eligibility. The manufacturer shall notify the applicant of the determination within 10 business days of receipt of the application. If necessary, the manufacturer may request additional information from the applicant. If additional information is needed, the manufacturer shall notify the applicant within 5 business days of receipt of the application as to what information is being requested. Within 3 business days of receipt of the requested information, the manufacturer shall determine eligibility and notify the applicant of the determination. If the individual has been determined to be not eligible, the manufacturer shall include the reasons for denying eligibility in the notification. The individual may seek an appeal of the determination in accordance with this section. If the individual is determined to be eligible, the manufacturer shall provide the individual with an eligibility statement or other indication that the individual has been determined eligible for the manufacturer's patient assistance program. An individual's eligibility is valid for 12 months and is renewable upon a redetermination of eligibility.

E. If the eligible individual has prescription drug coverage through an individual or group health plan, the manufacturer may determine that the individual's insulin needs are better addressed by providing financial assistance for copayments and other cost-sharing requirements of the individual's individual or group health plan. The manufacturer shall establish a copayment assistance program to provide such financial assistance. The manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy. Under the manufacturer's copayment assistance program, an eligible individual may not be required to pay more than a copayment of $35 for a 30-day supply of insulin.

F. The eligible individual shall submit to a pharmacy the eligibility statement provided by the manufacturer under paragraph D. Upon receipt of an individual's eligibility status, the pharmacy shall dispense insulin in accordance with this paragraph.

(1) The pharmacy shall submit an order containing the name of the insulin product and the daily dosage amount as contained in a valid prescription to the product's manufacturer. The pharmacy shall include with the order to the manufacturer the following information: the pharmacy's name and shipping address; office telephone number, fax number, e-mail address and contact name; and any specific days or times when deliveries are not accepted by the pharmacy.

(2) Upon receipt of an order from a pharmacy and the information described in this paragraph, the manufacturer shall send to the pharmacy a 90-day supply of insulin as ordered, unless a lesser amount is requested in the order, at no charge to the individual or pharmacy. Except as authorized under paragraph E, the pharmacy shall provide the insulin to the individual at no charge to the individual. The pharmacy may not provide insulin received from the manufacturer to any individual other than the individual associated with the specific order.

(3) The pharmacy may not seek reimbursement for the insulin received from the manufacturer or from any 3rd-party payor. The pharmacy may collect a copayment from the individual to cover the pharmacy's costs for processing and dispensing in an amount not to exceed $50 for each 90-day supply if the insulin is sent to the pharmacy.

(4) The pharmacy may submit to a manufacturer a reorder for an individual if the individual's eligibility statement under paragraph D has not expired. Upon receipt of a reorder from a pharmacy, the manufacturer shall send to the pharmacy an additional 90-day supply of the product, unless a lesser amount is requested, at no charge to the individual or pharmacy if the individual's eligibility statement has not expired.

(5) Notwithstanding subparagraph (2), a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option.

G. If an individual disagrees with a manufacturer's determination of eligibility under this subsection, the individual may contact the board to request the use of a 3-person panel to review eligibility. The panel is composed of 3 members of the board. 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 panel with the documents submitted by the individual. The panel shall render a decision within 10 business days of receipt of all the necessary documents from the individual. The decision of the panel is final. If the panel 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.

5. Additional 30-day urgent-need insulin supply pending eligibility for other coverage or assistance. If an individual has applied for MaineCare coverage but has not been determined eligible or has been determined eligible but MaineCare coverage has not become effective or if the individual has been determined ineligible for the manufacturer's patient assistance program by the manufacturer and the individual has requested a review

pursuant to subsection 4, paragraph G but the panel has not rendered a decision, the individual is entitled to access insulin under the provisions of subsection 3 if the individual has an urgent need of insulin. To access insulin under this subsection, the individual must attest to the pharmacy that the individual meets the requirements of subsection 2.

6. Dissemination of information about program. The board shall develop an information sheet to post on its publicly accessible website and provide a link to the information sheet on the website to be used by pharmacies, health care practitioners, hospital emergency departments, urgent care clinics and community health clinics. The information sheet must contain: a description of the urgent need insulin safety net, including how to apply for the benefits of the program; a description of each insulin manufacturer's patient assistance program, including contact information for accessing the assistance programs for each manufacturer; information on how to contact the Health Insurance Consumer Assistance Program, established in Title 24-A, chapter 56-A, subchapter 2-A; and information on how to contact the board if a manufacturer determines that an individual is not eligible for the manufacturer's patient assistance program.

7. Enforcement; penalty for noncompliance. A person who violates this chapter is subject to enforcement action by the board through any board action authorized in accordance with section 13731 or any civil penalty or criminal or civil action authorized in section 13731.

8. Confidential information. Any health information or records provided to the board under this section are confidential if the information or records identify or permit the identification of an individual who is seeking to access urgently needed insulin under subsection 3 or to participate in a manufacturer's patient assistance program under this section. A manufacturer shall maintain the confidentiality of any information received from any individual applying for the manufacturer's patient assistance program under this section and is prohibited from selling, sharing or disseminating data received under this section unless required to under this section or unless the individual has provided the manufacturer with a signed authorization.

9. Reports. Beginning February 15, 2023 and annually thereafter, each manufacturer shall report to the board on the number of Maine residents who accessed and received insulin on an urgent-need basis in the preceding calendar year; the number of Maine residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of Maine residents who the manufacturer determined were ineligible for its patient assistance program; and the total value of the insulin, determined by the wholesale acquisition cost of the insulin, provided by the manufacturer in the preceding calendar year. Beginning April 15, 2023 and annually thereafter, the board shall submit a report of the aggregate information reported by manufacturers pursuant to this subsection to the joint standing committee of the Legislature having jurisdiction over health coverage, insurance and financial services matters.

10. Repeal. This section is repealed January 1, 2027.

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 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.

LD 673
HCJFS

PUBLIC RECORDS EXCEPTION REVIEW CHECKLIST

Revised 2/13/12

A. Whether the record protected needs to be collected (Conclusion of committee of jurisdiction?)		
B. The value to the agency or official or to the public in maintaining the record (Conclusion of committee of jurisdiction?)		
C. Whether federal law requires the record to be confidential		
Does the proposed exception meet one or more of the following (D, E, F, G or I)		
D. Whether the proposed exception protects an individual's privacy interest and, if so, whether that interest substantially outweighs the public interest in disclosure		
E. Whether public disclosure puts a business at a competitive disadvantage and, if so, whether that business's interest substantially outweighs the public interest in the disclosure of records		
F. Whether public disclosure compromises the position of a public body in negotiations and, if so, whether that public body's interest substantially outweighs the public interest in the disclosure of records		
G. Whether public disclosure jeopardizes the safety of a member of the public or the public in general and, if so, whether that safety interest substantially outweighs the public interest in the disclosure of records		
I. Any other criteria that assist the review committee in determining the value of the proposed exception as compared to the public's interest in the record protected by the proposed exception		
H. Whether the proposed exception is as narrowly tailored as possible		
***If the proposed exception creates broad confidentiality for an entity*: 2-A. Accountability review of agency or official.** In evaluating each proposed public records exception, the review committee shall, in addition to applying the criteria of subsection 2, determine whether there is a publicly accountable entity that has authority to review the agency or official that collects, maintains or uses the record subject to the exception in order to ensure that information collection, maintenance and use are consistent with the purpose of the exception and that public access to public records is not hindered.		
2-B. Accessibility of public records. In reviewing and evaluating whether a proposal may affect the accessibility of a public record, the review committee may consider any factors that affect the accessibility of public records, including but not limited to fees, request procedures and timeliness of responses.		