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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.

A handwritten signature in black ink, appearing to read 'D M Grant'.

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.

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

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

3 **§13725. Insulin Safety Net Program**

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

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

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

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

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

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

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

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

31 (1) Is a resident of this State;

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

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

38 (4) Has an urgent need of insulin.

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

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

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

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

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

20 F. The pharmacy may collect an insulin copayment from the eligible individual to
21 cover the pharmacy's costs of processing and dispensing in an amount not to exceed
22 \$35 for the 30-day supply of insulin dispensed under paragraph C.

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

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

34 **4. Manufacturer's patient assistance.** Pursuant to the requirements of the program,
35 as established by the board, a manufacturer shall establish a patient assistance program to
36 provide access to insulin to any eligible individual who meets the requirements of this
37 subsection and who demonstrates a continued need for insulin. Each manufacturer's patient
38 assistance program must meet the requirements of this subsection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

31 G. If an individual disagrees with a manufacturer's determination of eligibility under
32 this subsection, the individual may contact the board to request the use of a 3-person
33 panel to review eligibility. The panel is composed of 3 members of the board. The
34 individual requesting the review shall submit to the board, with the request, all
35 documents submitted by the individual to the manufacturer. The board shall provide
36 the panel with the documents submitted by the individual. The panel shall render a
37 decision within 10 business days of receipt of all the necessary documents from the
38 individual. The decision of the panel is final. If the panel determines that the individual
39 is eligible for the manufacturer's patient assistance program, the manufacturer shall
40 provide the individual with an eligibility statement in accordance with this subsection.

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

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

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

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

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

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

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

41 SUMMARY

42 This bill establishes the Insulin Safety Net Program, which is modeled after a similar
43 program in Minnesota. The bill requires the Maine Board of Pharmacy to oversee the
44 program. The bill requires that, by January 1, 2022, manufacturers of insulin establish

1 procedures to make insulin available to pharmacies for dispensing to eligible individuals
2 who are in urgent need of insulin or who need access to an affordable insulin supply. The
3 bill requires annual reporting to the Legislature on the number of Maine residents accessing
4 insulin through the program and the cost to manufacturers. The bill includes provision to
5 repeal the program in 5 years.