HB5300

LRB10224818BMS35502b

102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

HB5300

Introduced 1/31/2022, by Rep. Will Guzzardi - Kathleen Willis, Theresa Mah, Rita Mayfield, Kelly M. Cassidy, et al.

SYNOPSIS AS INTRODUCED:

New Act
30 ILCS 105/5.970 new
215 ILCS 5/356z.41

Creates the Insulin for All Act. Provides that the Department of Public Health shall offer a discount program that allows participants to purchase insulin at a discounted, post-rebate price. Sets forth provisions concerning an insulin urgent-need program. Provides that by July 1, 2022, each manufacturer shall establish procedures to make insulin available to eligible individuals who are in urgent need of insulin or who are in need of access to an affordable insulin supply. Sets forth provisions concerning insulin urgent-need program exceptions, eligibility, forms, applications, claims and reimbursement, copayments, information sheets, navigators, and penalties. Sets forth provisions concerning an insulin patient assistance program and manufacturer responsibilities and process of the patient assistance program. Sets forth provisions concerning dispute resolution, reports, and penalties for insulin programs. Creates the Insulin Assistance Fund. Defines terms. Amends the Illinois Insurance Code. In provisions concerning cost sharing in prescription insulin drugs, provides that an insurer that provides coverage for prescription insulin drugs under the terms of a health coverage plan the insurer offers shall limit the total amount that an insured is required to pay for a 30-day supply of covered prescription insulin drugs at an amount not to exceed $35 (rather than $100). Makes a conforming change in the State Finance Act. Makes other changes. Effective immediately.

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A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Insulin for All Act.

Section 5. Definitions. As used in this Act:

"Board of Pharmacy" means the State Board of Pharmacy of the Department of Financial and Professional Regulation.

"Department" means the Department of Public Health.

"Diabetes" means:

(1) complete insulin deficiency or type 1 diabetes;

(2) insulin resistant with partial insulin deficiency or type 2 diabetes; or

(3) elevated blood glucose levels induced by pregnancy or gestational diabetes.

"Discount program" means a process developed by the Department that allows participants to purchase insulin at a discounted, post-rebate rate.

"Individual with diabetes" means an individual who has been diagnosed with diabetes and who uses insulin to treat diabetes.

"Insulin" means a prescription drug that contains insulin.

"Manufacturer" means a manufacturer engaged in the

manufacturing of insulin that is self-administered on an outpatient basis.

"Navigator" has the meaning described in Section 1311(i) of the Patient Protection and Affordable Care Act, Public Law 111-148, and further defined through amendments to the Act and regulations issued under the Act.

"Participant" means a resident of this State who:

(1) uses insulin to treat diabetes;

(2) does not receive health coverage under the medical assistance program under the Illinois Public Aid Code; and

(3) enrolls in the discount program.

"Pharmacy" means a pharmacy located in this State.

"Prescription drug" means a drug that is required by federal or State law or rule to be dispensed only by prescription or that is restricted to administration only by practitioners.

"Rebate" means a refund, discount, or other price concession that is paid by a pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription drug's utilization or effectiveness. "Rebate" does not include an administrative fee.

"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.

Section 10. Insulin discount program.

(a) The Department shall offer a discount program that allows participants to purchase insulin at a discounted, post-rebate price.

(b) The discount program shall:

(1) provide a participant with a card or electronic document that identifies the participant as eligible for the discount;

(2) provide a participant with information about pharmacies that will honor the discount;

(3) allow a participant to purchase insulin at a discounted, post-rebate price; and

(4) provide a participant with instructions to pursue a reimbursement of the purchase price from the participant's health insurer.

(c) The discount program shall charge a price for insulin that allows the program to retain only enough of any rebate for the insulin to make the State risk pool whole for providing discounted insulin to participants.

Section 15. Insulin urgent-need program.

(a) To be eligible to receive an urgent-need supply of insulin under this Section, an individual must attest to:

(1) being a resident of this State;

(2) not being enrolled in a medical assistance program under the Illinois Public Aid Code;

(3) not being enrolled in 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 $35 or less, regardless of the type or amount of insulin prescribed;

(4) not having received an urgent-need supply of insulin through this program within the previous 12 months, unless authorized under subsection (n) or (o); and

(5) being in urgent need of insulin.

(b) The Department shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the individual to attest to the eligibility requirements described in subsection (a). The form shall be accessible through the Department's website. The Department shall also 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. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(c) If an individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also:

(1) have a valid insulin prescription; and

(2) present the pharmacist with identification

indicating Illinois residency in the form of a valid Illinois 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 must provide the pharmacist with proof of residency.

(d) Upon receipt of a completed and signed application, a pharmacist shall dispense the prescribed insulin in an amount that will provide the individual with a 30-day supply. The pharmacy shall notify the health care practitioner who issued the prescription order no later than 72 hours after the insulin is dispensed.

(e) A pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that is in accordance with the National Council for Prescription Drug Program standards 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) A pharmacy may collect an insulin copayment from an 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.

(g) The pharmacy shall also provide each eligible individual with the information sheet described in subsection (i) and a list of trained navigators provided by the Department for the individual to contact if the individual is in need of accessing ongoing insulin coverage options, including assistance in:

(1) applying for medical assistance;

(2) applying for a qualified health plan, subject to open and special enrollment periods;

(3) accessing information on providers who participate in prescription drug discount programs, including providers who are authorized to participate in the 340B program under Section 340b of the Public Health Services Act, Section 256b of Title 42 of the United States Code; and

(4) accessing insulin manufacturers' patient assistance programs, copayment assistance programs, and other foundation-based programs.

(h) A pharmacist shall retain a copy of the application form submitted by the individual to the pharmacy for reporting and auditing purposes.

(i) The Department shall develop an information sheet to post on its website and provide a link to the information sheet on the board's website for pharmacies, health care practitioners, hospital emergency departments, urgent care clinics, and community health clinics. The information sheet

shall contain:

(1) a description of the urgent-need insulin program, including how to access the program;

(2) a description of each insulin manufacturer's patient assistance program and cost-sharing assistance program, including contact information on accessing the assistance programs for each manufacturer;

(3) information on how to contact a trained navigator for assistance in applying for medical assistance, a qualified health plan, or an insulin manufacturer's patient assistance programs;

(4) information on how to contact the Department if a manufacturer determines that an individual is not eligible for the manufacturer's patient assistance program; and

(5) notification that an individual in need of assistance may contact their local county social service department for more information or assistance in accessing ongoing affordable insulin options.

(j) The Department shall also inform each individual who accesses urgent-need insulin under this Section or who accesses a manufacturer's patient assistance program that the individual may participate in a survey conducted by the Department regarding satisfaction with the program. The Department shall provide contact information for the individual to learn more about the survey and how to participate. This information may be included on the

information sheet described in subsection (i).

(k) The Department shall develop a training program for navigators to provide navigators with information and resources necessary to assist individuals in accessing appropriate long-term insulin options.

(l) The Department shall compile a list of navigators who have completed the training program and who are available to assist individuals in accessing affordable insulin coverage options. The list shall be made available through the Department's website and to pharmacies and health care practitioners who dispense and prescribe insulin.

(m) If a navigator assists an individual in accessing an insulin manufacturer's patient assistance program, the Department, within the available appropriation, shall pay the navigator a one-time application assistance bonus of no less than $25.

(n) If an individual has applied for the medical assistance program under the Illinois Public Aid Code but has not been determined eligible or has been determined eligible but coverage has not become effective, or 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 (o) of Section 20 but the panel has not rendered a decision, the individual may access urgent-need insulin if the individual is in urgent need of insulin as defined in Section 5.

(o) To access an additional 30-day supply of insulin, an individual must attest to the pharmacy that the individual meets the requirements of subsection (n) and must comply with subsection (c).

Section 20. Insulin patient assistance program.

(a) Each manufacturer shall make a patient assistance program available to any individual who meets the requirements of this Section. Each manufacturer's patient assistance program must meet the requirements of this Section. Each manufacturer shall provide the Department with information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing their patient assistance program.

(b) A manufacturer's patient assistance program must cover every individual who:

(1) is an Illinois resident with a valid Illinois identification card or driver's license or permit that indicates Illinois residency; if the individual is under the age of 18, the individual's parent or legal guardian must provide proof of residency;

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

(3) is not enrolled in a medical assistance program under the Illinois Public Aid Code;

(4) is not eligible to receive health care through a

federally funded program or to receive prescription drug benefits through the Department of Veterans Affairs; and

(5) is not 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 $35 or less, regardless of the type or amount of insulin needed.

(c) Notwithstanding the requirement in paragraph (4) of subsection (b), 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 paragraphs (1), (2), and (3) of subsection (b).

(d) An individual who is interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer; apply through the individual's health care practitioner, if the practitioner participates; or contact a trained navigator for assistance in finding a long-term insulin supply solution, including assistance in applying to a manufacturer's patient assistance program.

(e) 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 of eligibility

within 10 business days after receipt of the application. If necessary, the manufacturer may request additional information from the applicant. If additional information is needed, the manufacturer must notify the applicant within 5 business days after receipt of the application as to what information is being requested. Within 3 business days after receipt of the requested additional 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 must include the reasons for denying eligibility in the notification. The individual may seek an appeal of the determination in accordance with subsection (o).

(f) If an 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.

(g) 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 through the use of the manufacturer's copayment assistance program, in which case the manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy. An eligible

individual may not be required to pay more than the copayment amount specified under subsection (f) of Section 15.

(h) The individual shall submit to a pharmacy the statement of eligibility provided by the manufacturer under subsection (f). Upon receipt of an individual's eligibility status, 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.

(i) The pharmacy must include with the order to the manufacturer the following information:

(1) the pharmacy's name and shipping address;

(2) the pharmacy's office telephone number, fax number, e-mail address, and contact name; and

(3) any specific days or times when deliveries are not accepted by the pharmacy.

(j) Upon receipt of an order from a pharmacy and the information described in subsection (i), 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.

(k) Except as authorized under subsection (l), 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. The

pharmacy may not seek reimbursement for the insulin received from the manufacturer or from any third-party payer.

(l) 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 $35 for each 90-day supply if the insulin is sent to the pharmacy.

(m) The pharmacy may submit to a manufacturer a reorder for an individual if the individual's eligibility statement has not expired. Upon receipt of a reorder from a pharmacy, the manufacturer must 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.

(n) Notwithstanding subsection (j), a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option.

(o) If an individual disagrees with a manufacturer's determination of eligibility under subsection (e), the individual may contact the Board of Pharmacy to request the use of a 3-person panel to review eligibility. The panel shall be 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 after 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, the manufacturer shall provide the individual with an eligibility statement in accordance with subsection (e).

Section 25. Reports.

(a) By February 15 of each year, beginning February 15, 2023, each manufacturer shall report to the Board of Pharmacy the following:

(1) The number of Illinois residents in the preceding calendar year who accessed and received insulin on an urgent-need basis under this Act.

(2) The number of Illinois residents in the preceding calendar year who participated in the manufacturer's patient assistance program, including the number of Illinois residents who the manufacturer determined were ineligible for their patient assistance program.

(3) The value of the insulin provided by the manufacturer under paragraphs (1) and (2) of this subsection.

As used in this subsection, "value" means the wholesale acquisition cost of the insulin provided.

(b) By March 15 of each year, beginning March 15, 2023, the Board of Pharmacy shall submit the information reported in subsection (a) to the General Assembly. The board shall also

include in the report any administrative penalties assessed under Section 30, including the name of the manufacturer and amount of the penalty assessed.

Section 30. Penalties.

(a) If a manufacturer fails to comply with this Act, the Department may assess an administrative penalty of $200,000 per month of noncompliance, with the penalty increasing to $400,000 per month if the manufacturer continues to be in noncompliance after 6 months, and increasing to $600,000 per month if the manufacturer continues to be in noncompliance after one year. The penalty shall remain at $600,000 per month for as long as the manufacturer continues to be in noncompliance.

(b) A manufacturer is also subject to the administrative penalties specified in subsection (a) if the manufacturer fails to:

(1) provide a hotline for individuals to call or access between 8 a.m. and 10 p.m. on weekdays and between 10 a.m. and 6 p.m. on Saturdays; and

(2) list on the manufacturer's website the eligibility requirements for the manufacturer's patient assistance programs for Illinois residents.

(c) Any penalty assessed under this Act shall be deposited into the Insulin Assistance Fund, a special fund that is created in the State treasury.

Section 105. The State Finance Act is amended by adding Section 5.970 as follows:

(30 ILCS 105/5.970 new)

Sec. 5.970. The Insulin Assistance Fund.

Section 110. The Illinois Insurance Code is amended by changing Section 356z.41 as follows:

(215 ILCS 5/356z.41)

Sec. 356z.41. Cost sharing in prescription insulin drugs; limits; confidentiality of rebate information.

(a) As used in this Section, "prescription insulin drug" means a prescription drug that contains insulin and is used to control blood glucose levels to treat diabetes but does not include an insulin drug that is administered to a patient intravenously.

(b) This Section applies to a group or individual policy of accident and health insurance amended, delivered, issued, or renewed on or after the effective date of this amendatory Act of the 101st General Assembly.

(c) An insurer that provides coverage for prescription insulin drugs pursuant to the terms of a health coverage plan the insurer offers shall limit the total amount that an insured is required to pay for a 30-day supply of covered

prescription insulin drugs at an amount not to exceed $35 ~~$100~~, regardless of the quantity or type of covered prescription insulin drug used to fill the insured's prescription.

(d) Nothing in this Section prevents an insurer from reducing an insured's cost sharing by an amount greater than the amount specified in subsection (c).

(e) The Director may use any of the Director's enforcement powers to obtain an insurer's compliance with this Section.

(f) The Department may adopt rules as necessary to implement and administer this Section and to align it with federal requirements.

(g) On January 1 of each year, the limit on the amount that an insured is required to pay for a 30-day supply of a covered prescription insulin drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the Consumer Price Index of the Bureau of Labor Statistics of the United States Department of Labor.

(Source: P.A. 101-625, eff. 1-1-21.)

Section 999. Effective date. This Act takes effect upon becoming law.