A BILL TO BE ENTITLED

AN ACT

To amend Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to public assistance, so as to make insulin accessible, under certain conditions, to an eligible individual who needs an affordable supply of insulin for up to one year, with the option to renew annually; to provide for a short title; to provide for definitions; to require a manufacturer of insulin to establish a patient assistance program and alternative plans for making insulin more affordable and accessible to qualifying Georgia residents; to provide for an individual to apply directly to the manufacturer; to require a manufacturer to promptly determine eligibility and to provide an individual with an eligibility statement; to require a pharmacy to dispense a 90 day supply of insulin to an eligible individual through such program; to allow the pharmacy to collect a co-payment not to exceed $75.00 for insulin dispensed through such program; to provide for re-orders and renewals; to provide for the development of an application form, an information sheet, and satisfaction surveys; to provide for enforcement, penalties, and appellate procedures; to provide for reporting; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to public assistance, is amended by adding a new article to read as follows:

"Article 10

49-4-200.

This article shall be known and may be cited as the 'Continuing Insulin Safety Net Act.'

49-4-201.

As used in this article, the term:

(1) 'Alternative plan' means an alternative plan established by the manufacturer as provided for in Code Section 49-4-202.

(2) 'Department' means the Department of Community Health.

(3) 'Eligible individual' means an individual qualified for assistance under the program as provided for in Code Section 49-4-203.

(4) 'Insulin' means various types of insulin analogs and insulin-like medications, regardless of activation period or whether the solution is mixed before or after dispensation. An insulin product is exempt from the provisions of this article if the wholesale acquisition cost of the insulin is $8.00 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.

(5) 'Manufacturer' means a manufacturer engaged in the production of insulin that is self-administered on an outpatient basis. Such term shall not include a manufacturer with an annual gross revenue of $2 million or less from insulin sales in this state.

(6) 'Pharmacy' shall have the same meaning as provided in Code Section 26-4-5.

(7) 'Program' means the patient assistance program established by each manufacturer as provided for in Code Section 49-4-202.

(8) 'Proper identification' means any document issued by a governmental agency containing a description of the individual, such individual's photograph, or both, and giving such individual's date of birth, and includes, without being limited to, a passport, military identification card, driver's license, or identification card authorized under Code Sections 40-5-100 through 40-5-104. Proper identification shall not include a birth certificate.

49-4-202.

(a) Each manufacturer shall make a patient assistance program that:

(1) Is made available to eligible individuals;

(2) Provides a 90 day supply of insulin at no charge to an eligible individual or pharmacy and can be re-ordered for up to one year; and

(3) Is renewable annually if an individual still meets eligibility requirements.

(b) To ensure that insulin is affordable and accessible to Georgia residents in need of insulin each manufacturer shall, in addition to the program, establish at least one alternative plan, such as a cost-sharing assistance plan or a mechanism for providing an emergency or urgent supply of insulin.

(c) Each manufacturer shall:

(1) Provide information about its program and any alternative plans to the department;

(2) Post information and a hotline for the program and any alternative plans on its website; and

(3) Provide for dedicated personnel to promptly respond to individuals, pharmacies, healthcare providers, and the department regarding the program and any alternative plans.

49-4-203.

(a) To be deemed eligible to participate in a manufacturer's program, an individual shall:

(1) Provide proper identification that indicates the individual is a resident of this state. If the individual is under the age of 18, such individual's parent or legal guardian shall provide proper identification that indicates residency of this state;

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

(3) Not be enrolled in medical assistance;

(4) Not be eligible to receive healthcare through a federally funded program or receive prescription drug benefits through the Department of Veteran Affairs; provided, however, that an individual who is enrolled in Medicare Part D is eligible for a manufacturer's patient assistance program if such individual has spent $1,000.00 or more on prescription drugs in the current calendar year; and

(5) Not be enrolled in prescription drug coverage through an individual or group health plan that limits the total amount of cost-sharing for a 90 day supply of insulin, including co-payments, deductibles, or coinsurance to $75.00 or less, regardless of the type or amount of insulin needed.

(b) An individual shall apply directly to the manufacturer to participate in the program. Upon receipt of an application for the program, the manufacturer shall process the application and determine eligibility of the individual. The manufacturer shall notify the applicant within ten business days of receipt of the application. When additional information is required, the manufacturer shall notify the applicant within five business days of receipt of the application as to what additional information is required. Within three business days of receipt of the requested additional information, the manufacturer shall determine eligibility of the individual and shall notify the applicant of such determination.

(c) When the individual is determined to be eligible, the manufacturer shall provide such individual with an eligibility statement. An individual's eligibility is valid for twelve months and is renewable upon a redetermination of eligibility.

(d) When the individual is determined to be ineligible, the manufacturer shall include in its notification the reasons for such determination. The individual may appeal the determination as provided for in Code Section 49-4-205.

(e) The manufacturer shall provide to any applicant deemed ineligible information about any alternative plans available to such individual.

49-4-204.

(a) An eligible individual shall submit to a pharmacy the eligibility statement provided by the manufacturer.

(b) Upon receipt of an individual's eligibility statement, 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 pharmacy's name and shipping address, necessary contact information, and any specific days or times when deliveries are not accepted by such pharmacy.

(c) Upon receipt of an order and necessary information as provided for in subsection (b) of this Code section, 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.

(d) Except as authorized under subsection (e) of this Code section, the pharmacy shall provide the insulin to the individual at no charge to such individual. The pharmacy shall not provide insulin received from the manufacturer to any individual other than the individual associated with the specific order. The pharmacy shall not seek reimbursement for the insulin received from the manufacturer or from any third-party payer.

(e) The pharmacy may collect a co-payment from the individual to cover the pharmacy's costs for processing and dispensing the insulin in an amount not to exceed $50.00 for each 90 day supply of insulin sent to and dispensed from the pharmacy for an order or for a re-order.

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

(g) Notwithstanding subsection (c) of this Code section, a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option.

49-4-205.

(a) When an individual disagrees with a manufacturer's determination of ineligibility, such individual may contact the department to request a review of such determination. Such review shall be completed by a panel composed of three members of the department. The individual requesting the review shall submit to the department with the request for review all documents submitted by the individual to the manufacturer, which the department shall provide to the panel. The panel shall render a decision within ten business days of receipt of all the necessary documents from the individual. The decision of the panel shall be final.

(b) If the panel determines that the individual is eligible, the manufacturer shall provide the individual with an eligibility statement.

49-4-206.

(a) The department, in coordination with the manufacturer, shall develop an information sheet that shall include, but shall not be limited to:

(1) A description of the program, including how to access it and information about any alternative plans;

(2) Information on applying for medical assistance;

(3) Information on applying for a qualified health plan offered through the exchange as defined in Code Section 33-23-201; and

(4) Information on accessing healthcare providers who participate in prescription drug discount programs, including providers who are authorized to participate in the 340B program under section 340B of the federal Public Health Service Act, 42 U.S.C. Section 256b, as amended.

(b) The department shall post the information sheet provided for in subsection (a) of this Code section on its website.

49-4-207.

(a) The department, in coordination with the manufacturer, shall develop a survey to assess an eligible individual's satisfaction with the program and any alternative plans, including:

(1) Adequacy of information available and provided to individuals;

(2) Accessibility to insulin; and

(3) Individual's ability to access affordable insulin.

(b) The department, in coordination with the manufacturer, shall develop a survey to assess a pharmacy's satisfaction with the program and alternative plans, including:

(1) Ease in submitting claims and insulin product orders to the manufacturers; and

(2) Timeliness of receiving insulin re-orders or renewal orders from the manufacturers.

(c) The department shall post the surveys provided for in subsections (a) and (b) of this Code section on its website.

49-4-208.

(a) Any data collected, created, received, maintained, or disseminated by the department pursuant to this article related to an individual seeking access to the program or any alternative plans shall be kept confidential and shall be retained for no longer than ten years.

(b) Each pharmacy and manufacturer shall maintain the privacy of all data received from any individual applying for the manufacturer's program or any alternative plans and shall be prohibited from selling, sharing, or disseminating such data received unless required to do so under this article or when an individual has provided the manufacturer with signed authorization.

49-4-209.

(a) Any person who by means of a false statement, failure to disclose information, or impersonation, or by other fraudulent device, obtains, attempts to obtain, or retains for himself, herself, or any other person any medical assistance or other benefit or payment under this article to which such person is not entitled or in an amount greater than that to which such person is entitled shall be guilty of a misdemeanor. If the total amount of the value of the assistance so obtained exceeds $1,500.00, such person shall be guilty of a felony.

(b)(1) If a manufacturer fails to comply with the provisions of this article, the department may assess an administrative penalty of $200,000.00 per month of such noncompliance.

(2) Such penalty shall increase to $400,000.00 per month if the manufacturer continues to be in noncompliance after six months and shall increase to $600,000.00 per month if the manufacturer continues to be in noncompliance after one year.

(3) The penalty shall remain at $600,000.00 per month for as long as the manufacturer continues in noncompliance.

(c) An individual or entity that is aggrieved by the action of the department pursuant to subsections (a) or (b) of this Code section shall be entitled to a hearing conducted in accordance with Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.'

49-4-210.

(a) By February 15, 2024, and every February 15 thereafter, each manufacturer shall report to the department the following information for the preceding calendar year:

(1) A description of the program and any changes made to the program;

(2) The number of Georgia residents who accessed and received insulin through the program;

(3) The total value of the insulin, determined by the wholesale acquisition cost of the insulin, provided by the manufacturer through the program;

(4) A description of the alternative plans and any changes made to them;

(5) The number of Georgia residents who accessed and received insulin through the alternative plans;

(6) The total value of the insulin, determined by the wholesale acquisition cost of the insulin, provided by the manufacturer through the alternative plans;

(7) The number of individuals deemed ineligible for the program or the alternative plans and the reasons for their ineligibility;

(8) The number of appeals and the number of eligibility statuses that were sustained or reversed;

(9) The timeliness and adequacy of the manufacturers in responding to individuals applying for the program or the alternative plans and pharmacies requesting insulin through the program or the alternative plans;

(10) Any administrative penalties assessed under Code Section 49-4-209; and

(11) Any additional information deemed necessary by the department.

(b) By February 15, 2024, and every February 15 thereafter, a pharmacy that received any eligibility statements from individuals for the program or the alternative plans shall report to the department the following information for the preceding calendar year:

(1) The number of eligibility statements received;

(2) The amount of insulin dispensed through the program;

(3) The average and total amount of copayment collected from individuals;

(4) The timeliness and adequacy of manufacturers' responses; and

(5) Any additional information deemed necessary by the department.

(b) By March 15, 2025, and every March 15 thereafter, the department shall submit to the General Assembly a report regarding the implementation of the program under this article. Such report shall include the following information for the preceding year:

(1) The data collected under subsections (a) and (b) of this Code section;

(2) The results of the satisfaction surveys provided for in Code Section 49-4-207; and

(3) Any additional information deemed necessary by the department to assess the implementation and effectiveness of the program."

SECTION 2.

This Act shall become effective upon its approval by the Governor or upon its becoming law without such approval.

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.