

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 1182

INTRODUCER: Senator Harrell

SUBJECT: Medicaid Coverage of Continuous Glucose Monitors

DATE: March 31, 2025

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Morgan	Brown	HP	Pre-meeting
2.			AHS	
3.			FP	

I. Summary:

SB 1182 creates undesignated sections of the Laws of Florida, to require the Florida Agency for Health Care Administration (AHCA) to seek federal approval as needed to provide coverage of continuous glucose monitors (CGMs) and related supplies as a durable medical equipment (DME) benefit for Medicaid recipients.

The bill provides requirements related to reimbursement and claims submission. The bill also does not prevent the AHCA from providing additional coverage of CGMs as a Medicaid pharmacy benefit.

The bill takes effect upon becoming law.

II. Present Situation:

What Is Diabetes?

Diabetes is a chronic health condition that affects how the human body turns food into energy.¹

The human digestive system breaks down carbohydrates consumed as food into glucose² and releases it into the bloodstream, which increases the blood's glucose level. Such an increase in blood glucose should signal the pancreas³ to release the hormone insulin, which acts as a catalyst

¹ U.S. Centers for Disease Control and Prevention, *Diabetes Basics*, available at https://www.cdc.gov/diabetes/about/?CDC_AAref_Val=https://www.cdc.gov/diabetes/basics/diabetes.html (last visited Mar. 28, 2025).

² Glucose is the simplest type of carbohydrate (chemical formula C₆H₁₂O₆), and all carbohydrates consumed as food must be broken down into glucose before the body can metabolize them.

³ The pancreas is an organ located in the abdomen. It plays an essential role in converting food into fuel. The pancreas has two main functions: an exocrine function that helps in digestion and an endocrine function that regulates blood glucose. *See*: <https://columbiasurgery.org/pancreas/pancreas-and-its-functions> (last visited Mar. 15, 2025).

to allow the body's cells to metabolize the glucose and convert it to energy, or to convert the glucose into forms suitable for short-term or long-term storage.⁴

With diabetes, depending on the type of diabetes, the pancreas either does not make any insulin or does not make enough insulin, or the body cannot use insulin as well as it should. When there is not enough insulin or cells stop responding to insulin, blood glucose levels elevate and stay elevated for extended periods. Over time, that can cause serious health problems, such as heart disease, vision loss, kidney disease, vascular disease, and other maladies. Such outcomes are often known as long-term complications of diabetes.⁵

According to the American Diabetes Association, approximately 2.1 million adults in Florida, or 11.4 percent of the adult population, have diabetes.⁶

Types of Diabetes

There are three main types of diabetes: Type 1, Type 2, and gestational diabetes.⁷

Type 1 Diabetes

Type 1 diabetes is thought to be caused by an autoimmune reaction in which the body's immune system attacks and destroys the cells in the pancreas that normally produce insulin. Approximately five percent⁸ of people with diabetes have Type 1. Symptoms of Type 1 often develop quickly. It is usually diagnosed in children, teens, and young adults (which has led the condition to sometimes be referred to as "juvenile diabetes"). An individual with Type 1 diabetes must take insulin, usually through subcutaneous injections, on a regular basis to survive, usually one or more times per day. Currently, Type 1 diabetes can neither be prevented nor cured.⁹

Type 2 Diabetes

With Type 2 diabetes, the body does not use insulin well and cannot keep blood glucose at normal levels.¹⁰ About 90 to 95 percent of people with diabetes have Type 2. It develops over many years and is usually diagnosed in overweight, middle-aged adults; however, manifestations in children, teens, and young adults have increased annually in recent years. Type 2 diabetes can often be prevented or delayed, or even eliminated altogether, with healthy lifestyle changes, such

⁴ U.S. Department of Health & Human Services, National Institutes of Health, National Library of Medicine, National Center for Biotechnology Information, *Physiology, Carbohydrates* (May 12, 2023), available at <https://www.ncbi.nlm.nih.gov/books/NBK459280/#:~:text=As%20carbohydrates%20are%20consumed%2C%20the,liver%20to%20release%20stored%20glucose>. (last visited Mar. 28, 2025).

⁵ *Supra* note 1.

⁶ American Diabetes Association, *The Burden of Diabetes in Florida*, available at https://diabetes.org/sites/default/files/2024-03/adv_2024_state_fact_florida.pdf (last visited Mar. 28, 2025).

⁷ *Supra* note 1.

⁸ American Diabetes Association, *Statistics About Diabetes*, available at <https://diabetes.org/about-diabetes/statistics/about-diabetes> (last visited Mar. 28, 2025).

⁹ *Supra* note 1.

¹⁰ *Id.*

as losing weight, eating healthy food, and exercising regularly. Type 2 diabetes is usually treated with oral medications but can require insulin injections in some cases.¹¹

Gestational Diabetes

Gestational diabetes develops in pregnant women who have never had diabetes. In pregnant women with gestational diabetes, the baby could be at higher risk for health problems.

Gestational diabetes usually goes away after the baby is born; however, it correlates to a higher risk for Type 2 diabetes later in life. A baby delivered by a woman with gestational diabetes is more likely to become obese as a child or teen and to develop Type 2 diabetes later in life.¹²

Managing Diabetes

In order for Type 1 or Type 2 diabetics to avoid long-term complications, or for a pregnant woman with gestational diabetes to mitigate the effects of that condition, blood glucose levels must be managed to stay as close to normal ranges as possible.

The expected values for normal fasting blood glucose concentration are between 70 and 100 milligrams of glucose per deciliter (mg/dL) of whole blood, although normal levels may vary.¹³

Testing blood glucose levels is key to managing diabetes. Years of elevated blood glucose levels (hyperglycemia) can lead to diabetes' costly and disabling long-term complications, while levels that are too low (hypoglycemia) can be dangerous in an immediate sense and, in severe episodes, can lead to disorientation, unconsciousness, seizure, brain damage, or death.¹⁴

Blood Glucose Meters

Blood glucose meters are small devices used to measure an individual's blood glucose level at a specific point in time. To use a meter, a person inserts a test strip into the metering device, pricks one of his or her fingers with a lancing device (lancet) to draw a drop of blood, and then puts the blood drop onto the test strip, which causes a chemical reaction based on the presence of glucose in the blood. That chemical reaction can be detected and measured by the meter, which then displays a blood glucose reading, usually within a few seconds. After the reading, the used test strip must be discarded and a new one inserted to conduct a subsequent test.¹⁵

Continuous Glucose Monitors

Continuous glucose monitoring makes use of a specialized device to automatically track blood glucose levels throughout the day and night. Using a continuous glucose monitor (CGM) allows

¹¹ U.S. Centers for Disease Control and Prevention, *Type 2 Diabetes*, available at <https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html> (last visited Mar. 28, 2025).

¹² *Supra* note 1.

¹³ World Health Organization, *Mean fasting blood glucose*, available at <https://www.who.int/data/gho/indicator-metadata-registry/imrdetails/2380#:~:text=The%20expected%20values%20for%20normal,and%20monitoring%20glycemia%20are%20recommended.> (last visited Mar. 28, 2025).

¹⁴ Mayo Clinic, *Diabetic Coma*, available at <https://www.mayoclinic.org/diseases-conditions/diabetic-coma/symptoms-causes/syc-20371475> (last visited Mar. 28, 2025).

¹⁵ DiaTribe Learn: Making Sense of Diabetes, *Blood Glucose Meters: Uses, Types, and More* (Jul. 22, 2024), available at <https://diatribe.org/diabetes-technology/blood-glucose-meters> (last visited Mar. 28, 2025).

a diabetic to monitor glucose levels any time at a glance and to review how glucose levels have changed over a few minutes, hours, or days, to see trends, without drawing blood by pricking a finger. Seeing glucose levels in real-time and over periods of time can help diabetics make more informed decisions throughout the day about how to balance food intake, physical activity, and medicines.¹⁶

CGMs are approved in the U.S. for adults and children with a health care practitioner's prescription, although at least one such device is now available over-the-counter.¹⁷ A CGM works through a tiny sensor inserted under the skin, usually via a small plastic disk or pod adhered to the abdomen or the backside of the upper arm. The sensor measures interstitial glucose level, which is the glucose found in the fluid between the cells. The sensor tests glucose every minute or every few minutes. A transmitter within the sensor wirelessly sends the information to a monitor, which can be a dedicated device or, in some cases, an app on a smartphone.¹⁸

CGMs are always on and recording glucose levels. Many CGMs have special features that work with information from glucose readings, such as:¹⁹

- An alarm can sound when the glucose level goes too low or too high.
- Data can be entered manually, regarding meals, physical activity, and medicines, so that such pertinent information can be recorded alongside glucose levels.
- Some models can send information in real-time to a second person's smartphone, such as a parent or caregiver. For example, if a child's glucose drops dangerously low overnight, the CGM could be set to wake a parent in the next room.
- CGM data can be stored on the Internet and made accessible to a diabetic's treating health care practitioner, who can use the data to help monitor and manage the diabetic's treatment.

Benefits of a CGM

Compared with a standard blood glucose meter, using a CGM system can help a diabetic to:²⁰

- Better manage blood glucose levels every day.
- Have fewer emergencies relating to hypoglycemia.
- Need fewer finger sticks, which helps because the pain and bruising from repeated finger sticks can discourage the use of a blood glucose meter.

A graphic on the CGM screen shows whether the blood glucose level is rising or dropping, and how quickly it may be rising or dropping, allowing the diabetic to make better decisions about

¹⁶ U.S. Department of Health & Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, *Continuous Glucose Monitoring*, available at: <https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring> (last visited Mar. 28, 2025).

¹⁷ U.S. Food and Drug Administration, *FDA Clears First Over-the-Counter Continuous Glucose Monitor*, available at: <https://www.fda.gov/news-events/press-announcements/fda-clears-first-over-counter-continuous-glucose-monitor> (last visited Mar. 29, 2025).

¹⁸ *Supra* note 16.

¹⁹ *Id.*

²⁰ *Id.*

his or her behavior in the short-term regarding the need for insulin, food, or whether exercise is a good or bad idea for that point in time.²¹

Over time, good management of glucose levels greatly helps individuals with diabetes stay healthy and prevent costly and potentially disabling complications of the disease.²²

The Florida Agency for Health Care Administration

The Florida Agency for Health Care Administration (AHCA) is created under s. 20.42, F.S., to be the chief health policy and planning entity for the state, responsible for health facility licensure, inspection, and regulatory enforcement,²³ as well as the administration of Florida's Medicaid program.²⁴

The Florida Medicaid Program

The Medicaid program is a voluntary, federal-state program that finances health coverage for individuals, including eligible low-income adults, children, pregnant women, elderly adults, and persons with disabilities.²⁵ The federal Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services is responsible for administering the Medicaid program at the federal level. Florida Medicaid is the health care safety net for low-income Floridians and is financed through state and federal funds.²⁶

The AHCA is responsible for establishing and maintaining a Medicaid state plan approved by the CMS, as well as maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed under the Florida Statutes,²⁷ the General Appropriations Act (GAA), and other legislation accompanying the GAA.

A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs. The state plan establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements. State Medicaid programs may request from the CMS a formal waiver of the requirements codified in the federal Social Security Act. Federal waivers give states flexibility not afforded through their Medicaid state plan.²⁸

²¹ *Id.*

²² *Id.*

²³ Florida Agency for Health Care Administration, *Health Quality Assurance*, available at <https://ahca.myflorida.com/health-quality-assurance> (last visited Mar. 28, 2025).

²⁴ Section 409.902, F.S.

²⁵ Medicaid.gov, *Medicaid*, available at <https://www.medicaid.gov/medicaid> (last visited Mar. 28, 2025).

²⁶ Section 20.42, F.S.

²⁷ See parts III and IV of ch. 409, F.S., available at

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0409/0409.html (last visited Mar. 28, 2025).

²⁸ Florida Agency for Health Care Administration, *2025 Agency Legislative Bill Analysis: SB 1182* (Feb. 28, 2025) (on file with the Senate Committee on Health Policy).

Approximately 72.5 percent of Florida Medicaid recipients receive services through a Medicaid managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program while the remainder receive services that are paid for on a fee-for-service (FFS) basis.^{29, 30} The SMMC program has three components: Managed Medical Assistance (MMA), Long-Term Care (LTC), and the Prepaid Dental Health Program (Prepaid Dental).³¹ Florida's SMMC program benefits are authorized through federal waivers and are specifically required by the Florida Legislature in ss. 409.973 and 409.98, F.S.³²

Medicaid Coverage of Prescribed Drugs

Medicaid managed care plans are required to provide all prescription drugs listed on the AHCA's Florida Medicaid Prescribed Drug List (PDL). As such, the AHCA's contracts with the managed care plans prevent them from implementing their own plan-specific formularies or PDLs and require the plans to provide a link to the AHCA's Medicaid PDL on their websites.³³

Medicaid covers all U.S. Food and Drug Administration (FDA) approved prescription medications. Section 409.91195, F.S., outlines the development and management of the PDL. The AHCA uses clinical factors and its negotiations with drug manufacturers for monetary rebates when determining drugs to include on the PDL. State-negotiated supplemental rebates, along with federally required rebates, frequently result in discounted prescription cost for brand name drugs, potentially resulting in a cost to the state lower than that of its generic equivalent.³⁴

Drugs not included on the PDL must be authorized by the AHCA's pharmacy benefit manager (PBM) prior to being dispensed. Additionally, the CMS allows states to cover non-pharmaceutical products under the pharmacy benefit if that product is FDA-approved and has been assigned a National Drug Code (NDC).^{35, 36}

²⁹ The other 27.5 percent of recipients receive Medicaid services through the fee-for-service (FFS) delivery model, where providers contract directly with the AHCA to render services, billing and receiving reimbursement directly from the AHCA; Florida Agency for Health Care Administration, *Senate Bill 306* (Feb. 7, 2025) (on file with Senate Committee on Health Policy).

³⁰ Florida Agency for Health Care Administration, *Florida Statewide Medicaid Enrollment Report As of February 28, 2025 (including Medikids Population)*, available at https://ahca.myflorida.com/content/download/26230/file/ENR_202502.xls (last visited Mar. 28, 2025).

³¹ Florida Agency for Health Care Administration, *Statewide Medicaid Managed Care*, available at <https://ahca.myflorida.com/medicaid/statewide-medicare-managed-care> (last visited Mar. 28, 2025).

³² *Supra* note 28.

³³ Florida Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis: SB 988* (on file with the Senate Committee on Health Policy).

³⁴ *Id.*

³⁵ *Id.*

³⁶ Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs; U.S. Food & Drug Administration, *National Drug Code Database Background Information*, available at <https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information> (last visited Mar. 28, 2025).

Medicaid Coverage of Durable Medical Equipment

Florida Medicaid reimburses for durable medical equipment (DME) and medical supplies appropriate for use in the recipient's home. DME may be rented, purchased, or rented-to-purchase. Examples of reimbursable equipment and supplies include:³⁷

- Augmentative and assistive communication devices;
- Commodes;
- Enteral nutrition supplements;
- Hospital type beds and accessories;
- Mobility aids, including canes, crutches, walkers, and wheelchairs;
- Orthopedic footwear;
- Orthotic and prosthetic devices;
- Ostomy and urological supplies;
- Respiratory equipment and supplies, including nebulizers and oxygen; and
- Suction pumps.

The DME service benefit is one of the minimum covered services for all MMA and LTC plans serving Medicaid enrollees; however, all Medicaid recipients³⁸ may receive medically necessary DME and medical supplies services in accordance with coverage and limitations requirements³⁹ established by the AHCA.⁴⁰

Medicaid Coverage of Diabetic Equipment and Supplies

Beginning October 1, 2024, the AHCA transitioned coverage of diabetic equipment and supplies from the DME benefit to be reimbursed through the pharmacy point-of-sale. This transition was authorized under HB 967 (2023), prioritizing both Medicaid recipients and taxpayer dollars as it allowed recipients to acquire diabetic supplies conveniently at a pharmacy and the AHCA to collect rebates for CGMs provided by the pharmacy, which the AHCA was unable to do prior to October 1, 2024.⁴¹

In order to collect rebates on CGMs and other diabetic supply products, the AHCA entered into a collaborative, multi-state agreement (pool) with the state's contracted pharmacy benefit manager (PBM) and 10 other states, allowing for more rebate negotiation using the state's collective power to reduce costs for CGM products. The AHCA also established a Medicaid Preferred Product List (PPL) that listed the items negotiated through the pool. Products not included on the PPL must be authorized by the AHCA's PBM prior to dispensing.⁴²

³⁷ Florida Agency for Health Care Administration, *Durable Medical Equipment (DME) and Medical Supplies*, available at <https://ahca.myflorida.com/medicaid/medicaid-policy-quality-and-operations/medicaid-policy-and-quality/medicaid-policy/medical-and-behavioral-health-coverage-policy/specialized-health-services/durable-medical-equipment-dme-and-medical-supplies> (last visited Mar. 28, 2025).

³⁸ Section 409.906(10), F.S.

³⁹ Florida Agency for Health Care Administration, *Adopted Rules – Service Specific Policies*, available at <https://ahca.myflorida.com/medicaid/rules/adopted-rules-service-specific-policies> (last visited Mar. 28, 2025); see rules 59G-4.072, 59G-4.073, 59G-4.074, 59G-4.075, 59G-4.076, and 59G-4.077, F.A.C.

⁴⁰ *Supra* note 37.

⁴¹ *Supra* note 28.

⁴² *Id.*

Medicaid managed care plans are required to provide all CGMs and related products listed on the AHCA's PPL. As such, the plans cannot implement their own plan-specific formularies or PPLs and are required to provide a link to the AHCA's Medicaid PPL on their website. This allows the AHCA to collect rebates on both FFS and managed care claims. Both clinical factors and drug manufacturers' rebate offers are considered when determining products to include on the PPL.⁴³

In 2021, Florida Medicaid spent nearly \$40 million on diabetic supplies. Nearly half the expense was for glucose test strips, totaling \$19 million for SMMC diabetic enrollees and \$500,000 for FFS recipients. Additional diabetic supplies (e.g., glucose sensors, transmitters, insulin pumps,⁴⁴ needles, lancets, CGMs, syringes, glucose meters, alcohol swabs) accounted for the remaining approximately \$19 million in SMMC diabetic enrollee expenses.⁴⁵

Though most CGMs are covered only by pharmacies, the AHCA still allows CGMs and other diabetic supplies to be provided through the DME benefit under certain circumstances. In an effort to achieve the most patient-centric approach and promote a simplified patient experience, the AHCA has ensured recipients filling a traditional insulin pump are still able to receive their CGM products through a DME provider. To receive an insulin pump from a DME provider, recipients must present a prescription for the insulin pump to the DME provider. Once the prescription is provided, the insulin pump associated with Healthcare Common Procedure Coding System (HCPCS) code⁴⁶ E0784 and all related supplies, including the associated CGM, will be covered. If a recipient is not eligible to receive an insulin pump from a DME provider, they must get their CGM product(s) at the pharmacy.⁴⁷

The Florida Medicaid Diabetic Supply Services Coverage Policy,⁴⁸ as well as the Diabetic Supply Criteria,⁴⁹ can be viewed on the AHCA's website.⁵⁰

III. Effect of Proposed Changes:

Section 1 creates a non-statutory section of the Laws of Florida to require the AHCA, within 30 days after this bill becomes a law, to seek federal approval through a Medicaid waiver or state plan amendment as needed to provide coverage of CGMs and related supplies as a DME benefit

⁴³ *Id.*

⁴⁴ An insulin pump is a device that delivers insulin continuously and on-demand, mimicking the pancreas. Pumps deliver insulin through a tiny catheter that goes in a fleshy area of the body; Cleveland Clinic, *Type 1 Diabetes*, available at <https://my.clevelandclinic.org/health/diseases/21500-type-1-diabetes#management-and-treatment> (last visited Mar. 29, 2025).

⁴⁵ *Supra* note 33.

⁴⁶ HCPCS codes are developed by the CMS and maintained by the American Medical Association. HCPCS codes are one of the primary medical languages used by health care providers to bill for procedures and services rendered; Centers for Medicare & Medicaid Services, *Healthcare Common Procedure Coding System (HCPCS)*, available at <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system> (last visited Mar. 28, 2025).

⁴⁷ *Supra* note 28.

⁴⁸ Florida Agency for Health Care Administration, *Florida Medicaid Diabetic Supply Services Coverage Policy* (Sep. 2024), available at https://ahca.myflorida.com/content/download/25105/file/59G-4.252%20Diabetic%20Supply%20Services%20Coverage%20Policy_FINAL.pdf (last visited Mar. 28, 2025).

⁴⁹ Florida Agency for Health Care Administration, *Diabetic Supply Criteria*, available at https://ahca.myflorida.com/content/download/25202/file/Diabetic_Supply_Criteria.pdf (last visited Mar. 29, 2025).

⁵⁰ Florida Agency for Health Care Administration, *Diabetic Supply Services*, available at <https://ahca.myflorida.com/medicaid/medicaid-policy-quality-and-operations/medicaid-policy-and-quality/medicaid-policy/pharmacy-policy/diabetic-supply-services> (last visited Mar. 29, 2025).

for Medicaid recipients. The bill requires that a licensed DME provider be reimbursed for CGMs and related supplies, provided the claim is submitted through an active Medicare HCPCS. Under the bill, the AHCA may not require such provider to use an NDC number as part of such claim submission.

The bill indicates that it does not preclude the AHCA from providing additional coverage of CGMs as a Medicaid pharmacy benefit.

The AHCA must begin implementation of the bill's provisions upon receiving any necessary federal approval.

Section 2 provides that the bill takes effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The AHCA anticipates a fiscal impact of approximately \$10 million dollars annually. This estimate was calculated using the potential loss of rebates through the pharmacy

benefit and the increased cost incurred from the utilization of non-preferred CGMs and related supplies provided through the DME benefit. The two primary inputs affecting loss of rebates are as follows:⁵¹

- The AHCA's participation in pooled rebate negotiation is limited to collecting rebates for products listed on the PPL. The bill would allow all CGM products, including those not included on the PPL, to be available through the DME benefit, which means that any product not provided by a pharmacy would not be eligible for a rebate.
- Rebate collection requires NDC reporting to capture the exact products that are dispensed, to accurately invoice manufacturers. This bill prohibits NDC reporting for products billed by a DME provider, which would prevent the state from collecting rebates on any products filled through the DME benefit.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill creates undesignated sections of the Laws of Florida.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

⁵¹ *Supra* note 28.