

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 Appropriations Committee on Health and Human Services

BILL: CS/SB 988

INTRODUCER: Health Policy Committee and Senator Burton

SUBJECT: Medicaid Coverage of Continuous Glucose Monitors

DATE: April 11, 2023 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Brown</u>	<u>Brown</u>	<u>HP</u>	Fav/CS
2.	<u>Barr</u>	<u>Money</u>	<u>AHS</u>	Favorable
3.	_____	_____	<u>FP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 988 creates s. 409.9063, F.S., requiring the Agency for Health Care Administration (AHCA) to provide coverage for continuous glucose monitors (CGM) under the Medicaid pharmacy benefit to treat Medicaid recipients diagnosed with diabetes who meet certain criteria and requirements, subject to the availability of funds and any limitations or directions provided in the General Appropriations Act (GAA).

The bill requires the AHCA to seek federal approval, if needed, to implement the bill, and to include the bill's impact in Medicaid managed care plan capitation rates that are scheduled to take effect October 1, 2023.

This bill has a significant negative fiscal impact on the Agency for Health Care Administration and the Florida Medicaid program. *See* Section V of this analysis.

The bill takes effect on October 1, 2023.

II. Present Situation:

What Is Diabetes?

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

The human digestive system breaks down carbohydrates consumed as food into glucose¹ and releases it into the bloodstream, which increases the blood's glucose level. Such an increase in blood glucose should signal the pancreas to release the hormone insulin, which acts as a catalyst 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.

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.

Approximately 2,164,009 people in Florida have diabetes, according to the American Diabetes Association.

Types of Diabetes

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

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 5 to 10 percent of the people with diabetes have Type 1. Symptoms of Type 1 often develop quickly. It is usually diagnosed in children, teens, and young adults. Someone with Type 1 diabetes must take insulin, usually through subcutaneous injection, on a regular basis to survive, usually one or more times per day. Currently, Type 1 diabetes can neither be prevented nor cured.²

Type 2 Diabetes

With Type 2 diabetes, the body does not use insulin well and cannot keep blood glucose at normal levels. 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, although it can sometimes manifest in adolescents and young adults. Type 2 diabetes can often be prevented or delayed, or even eliminated altogether, with healthy lifestyle changes, such as losing weight, eating healthy food, and exercising regularly.³ Type 2 diabetes is usually treated with oral medications but can require insulin injections in some cases.

¹ 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.

² Centers for Disease Control and Prevention, *What Is Diabetes?*, available at: <https://www.cdc.gov/diabetes/basics/diabetes.html> (last visited March 9, 2023).

³ *Id.*

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.⁴

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.

A widely accepted “normal” level of blood glucose is 100 milligrams of glucose per deciliter (mg/dL) of whole blood, although normal levels may vary. A normal fasting blood glucose level for someone without diabetes is 70 to 99 mg/dL.⁵

Testing blood glucose levels is key to managing diabetes. Years of elevated blood glucose levels 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 can lead to unconsciousness, brain damage, or death.

Blood Glucose Meters

Blood glucose meters are small devices used to measure a person’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.⁶ After the reading, the used test strip must be discarded and a new one inserted in order to conduct a subsequent test.

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 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

⁴ *Id.*

⁵ Cleveland Clinic, *Blood Glucose (Sugar) Test*, available at: <https://my.clevelandclinic.org/health/diagnostics/12363-blood-glucose-test> (last visited March 9, 2023).

⁶ DiaTribe Learn: Making Sense of Diabetes, *Blood Glucose Meters and Strips*, available at: <https://diatribe.org/blood-glucose-meters-and-strips> (last visited March 9, 2023).

informed decisions throughout the day about how to balance food intake, physical activity, and medicines.⁷

CGMs are approved in the U.S. for adults and children with a health care practitioner's prescription. 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.⁸

CGMs are always on and recording glucose levels. Many CGMs have special features that work with information from glucose readings, such as:⁹

- 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:

- 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 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.

Over time, good management of glucose levels greatly helps people with diabetes stay healthy and prevent costly and potentially disabling complications of the disease.¹⁰

The Florida Medicaid Program

Florida Medicaid is the health care safety net for low-income Floridians. The national Medicaid

⁷ 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 March 9, 2023).

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

program is a partnership of federal and state governments established to provide coverage for health services for eligible persons. Florida's program is financed through state and federal funds.¹¹

The Agency for Health Care Administration (AHCA) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act (SSA). This authority includes establishing and maintaining a Medicaid state plan approved by the Centers for Medicare & Medicaid Services (CMS) and maintaining any Medicaid waivers needed to operate the Florida Medicaid program as directed under the Florida Statutes,¹² 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 CMS a formal waiver of the requirements codified in the SSA. Federal waivers give states flexibility not afforded through their Medicaid state plan.

In Florida, a large majority of Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program.¹³ Other recipients who are not eligible for managed care, are not subject to mandatory managed care enrollment, or are not yet enrolled in a plan, are provided services directly from health care practitioners or facilities, and in those cases, providers are paid on a fee-for-service (FFS) basis.

SMMC has three components:

- Managed Medical Assistance (MMA), under which the AHCA makes payments for primary and acute medical treatments and related services using a managed care model;
- Long-term Care Managed Care (LTCMC), under which the AHCA makes payments for long-term care, including home and community-based services, using a managed care model; and
- The Medicaid Prepaid Dental Health Program (Prepaid Dental), under which the AHCA makes payments for dental services for children and adults using a managed care model.

SMMC benefits are authorized through federal waivers and are specifically required by the Florida Legislature in ss. 409.973 and 409.98, F.S. SMMC benefits cover primary, acute, preventive, behavioral health, prescribed drugs, long-term care, and dental services.

¹¹ Section 20.42, F.S.

¹² 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=0400-0499/0409/0409ContentsIndex.html (last visited March 9, 2023).

¹³ As of January 31, 2023, Florida Medicaid's total enrollment comprised 5,696,638 persons. Eighty-seven percent were enrolled in a Medicaid managed care plan. See:

https://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/docs/ENR_202301.xls (last visited March 9, 2023).

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, AHCA's contracts with the managed care plans prevent them implementing their own plan-specific formularies or PDLs and require them to provide a link to the AHCA's Medicaid PDL on their websites.¹⁴

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.¹⁵

Drugs not included on the PDL must be authorized by the AHCA's pharmacy benefit manager (PBM) for Medicaid FFS or a managed care plan prior to being dispensed. Additionally, 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).¹⁶

Medicaid Coverage of Diabetes Equipment and Supplies

Florida Medicaid FFS recipients presently acquire diabetic supplies from a durable medical equipment (DME) provider. DME providers are reimbursed according to an AHCA fee schedule containing fixed payment amounts for all products falling under the same billable codes. Currently, Florida Medicaid covers CGM for recipients younger than 21 years of age; however, the managed care plans can be less restrictive, and some have already elected to cover CGM for adults as an expanded benefit or to provide CGM as a pharmacy benefit.¹⁷

In 2021, Florida Medicaid spent nearly \$40 million on diabetic supplies, including expenditures in the FFS delivery system and SMMC. 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, such as glucose sensors, transmitters, insulin pumps, needles, lancets, CGM, syringes, glucose meters, and alcohol swabs, accounted for the approximate \$19 million in SMMC diabetic enrollee expenses.¹⁸

Currently, more than 20 other states cover diabetic supplies for both Type 1 and Type 2 diabetes through the pharmacy benefit, thereby collecting rebates from manufacturers of equipment and supplies. Diabetic supplies in these arrangements include CGMs, test strips, lancets, meters, transmitters, and sensors.¹⁹

¹⁴ Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis: SB 988*, on files with the Senate Committee on Health Policy.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

Diabetes and Medicaid

Approximately 14 percent of Medicaid enrollees nationwide have diabetes. Within the Medicaid population, health care costs for people with diabetes are 1.5 to 4.4 times higher than for those without diabetes. Studies show CGM use is associated with reductions in rates of acute diabetes-related events and rates of hospitalization in people with Type 2 diabetes being treated with insulin.²⁰

III. Effect of Proposed Changes:

Section 1 creates s. 409.9063, F.S. The bill defines “continuous glucose monitor” (GCM) to mean an instrument or a device designed for the purpose of aiding in the treatment of diabetes by measuring glucose levels on demand or at set intervals through a small, electronic sensor that slightly penetrates a person’s skin when applied and that is designed to remain in place and active for at least seven days.

The bill requires the Agency for Health Care Administration (AHCA), subject to the availability of funds and subject to any limitations or directions provided in the General Appropriations Act, to provide coverage for a continuous glucose monitor under the Medicaid pharmacy benefit for the treatment of a Medicaid recipient if:

- The recipient has been diagnosed by his or her primary care physician, or another licensed health care practitioner authorized to make such diagnosis, with Type 1 diabetes, Type 2 diabetes, gestational diabetes, or any other type of diabetes that may be treated with insulin; and
- A health care practitioner with the applicable prescribing authority has prescribed insulin to treat the recipient’s diabetes and a continuous glucose monitor to assist the recipient and practitioner in managing the recipient’s diabetes.

The bill requires that CGM coverage include the cost of any necessary repairs or replacement parts.

To qualify for continued CGM coverage, the bill requires a Medicaid recipient to participate in follow-up care with his or her treating health care practitioner, in person or through telehealth, at least once every six months during the first 18 months after the CGM has first been prescribed to the patient under the bill, to facilitate an assessment of the efficacy of using the monitor for treatment of the recipient’s diabetes. After the first 18 months, such follow-up care must occur at least once every 12 months.

The bill requires the AHCA to seek federal approval, if needed, to implement the bill.

Section 2 requires the AHCA to include the rate impact of the bill in the Medicaid Managed Medical Assistance program and the Long-term Care Managed Care program rates, as applicable, that take effect on October 1, 2023.

²⁰ Center for Health Care Strategies, *Expanding Medicaid Access to Continuous Glucose Monitors*, January 2022, p. 3, available at: https://www.chcs.org/media/Expanding-Medicaid-Access-to-Continuous-Glucose-Monitors_011222.pdf (last visited March 9, 2023).

Section 3 provides an effective date of October 1, 2023.

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:

To the extent CS/SB 988 provides for Medicaid recipients with diabetes to better manage their conditions and stay healthier, the bill could allow such persons to avoid fiscal disadvantages associated with poor health or the inability to work due to disability caused by long-term complications of diabetes.

C. Government Sector Impact:

The Agency for Health Care Administration (AHCA) reports that the bill has a negative fiscal impact on state expenditures as it directs the agency to expand continuous glucose monitor (CGM) coverage to include adults.

The state currently does not cover CGMs for adults aged 21 or older. Thus, there are no Florida Medicaid fee for service claims data available for cost projections. However, in state fiscal year 2021-2022, there were 43,924 Medicaid recipients that required diabetic supplies. If five percent of that population were eligible and were prescribed a CGM under the bill, the overall increase in CGM expenditures in state fiscal year 2023-2024

would be approximately \$13,152,603, with \$5,329,435 being the general revenue impact.²¹

Participation %	Number of Potential Recipient Participation	Total Potential Expense	Potential Impact to General Revenue
1%	439	\$ 2,630,521	\$ 1,065,887
3%	1318	\$ 7,891,562	\$ 3,197,661
5%	2196	\$ 13,152,603	\$ 5,329,435
15%	6589	\$ 39,457,808	\$ 15,988,304
50%	21962	\$ 131,526,026	\$ 53,294,346

The projection above does not account for a potential reduction in Medicaid health care costs resulting from adult diabetics in the Medicaid program being better able to manage their conditions and stay healthier. It also does not provide an estimate or contemplate a potential dollar amount for the revenue the AHCA will receive by negotiating for rebates from CGM manufacturers in exchange for placement on the state Prescribed Drug List. Those mitigating effects on the bill’s fiscal impact are indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 409.9063 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 13, 2023:

The CS provides that a continuous glucose monitor must be designed to stay in place and remain active for at least seven days after being applied, as opposed to at least 10 days in the underlying bill.

²¹ Agency for Health Care Administration, 2023 Agency Legislative Bill Analysis: SB 988, on files with the Senate Committee on Health Policy.

B. Amendments:

None.

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