FLORIDA HOUSE OF REPRESENTATIVES
BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.

BILL #: CS/HB 1465	**COMPANION BILL:** SB 1182 (Harrell)
TITLE: Continuous Glucose Monitors	**LINKED BILLS:** None
SPONSOR(S): Franklin	**RELATED BILLS:** None

Committee References

Health Care Facilities & Systems
15 Y, 0 N, As CS
➤
Health Care Budget
15 Y, 0 N
➤
Health & Human Services

SUMMARY

Effect of the Bill:

The bill requires the Agency for Health Care Administration (AHCA) to seek federal approval through a Medicaid waiver or state plan amendment to cover continuous glucose monitors (CGMs) and related supplies as a durable medical equipment (DME) benefit. The bill directs AHCA to seek such federal approval within 30 days of the bill becoming a law. This coverage would be in addition to coverage currently provided under the pharmacy benefit, as directed by the Legislature in 2023.

The bill also requires licensed DME providers to submit claims for CGMs and related supplies through an active Medicare Healthcare Common Procedure Coding System, and prohibits AHCA from requiring DME providers to use National Drug Code numbers when submitting claims.

Fiscal or Economic Impact:

The bill will have a significant, negative fiscal impact on state government.
(See Fiscal Impact on State Government Section)

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ANALYSIS

EFFECT OF THE BILL:

Prior to 2023, the Florida Medicaid program covered continuous glucose monitors (CGMs) as a durable medical equipment (DME) benefit. In 2023, the Legislature directed the Agency for Health Care Administration (AHCA) to cover CGMs as a pharmacy benefit, which AHCA began doing in October of 2024.

The bill requires AHCA to seek federal approval through a Medicaid waiver or state plan amendment to cover continuous glucose monitors (CGMs) and related supplies as a DME benefit. AHCA must seek such federal approval within 30 days of the bill becoming a law. (Section 1) This coverage would be in addition to coverage currently provided under the pharmacy benefit, as directed by the Legislature in 2023.

The bill requires licensed DME providers to submit claims for CGMs and related supplies through an active Medicare Healthcare Common Procedure Coding System in order to receive reimbursement.[1] The bill prohibits AHCA from requiring DME providers to use National Drug Code (NDC) Numbers when submitting claims. Currently, AHCA uses the NDC numbers to collect manufacturer rebates on CGMs and related supplies. (Section 1)

The bill provides an effective date of July 1, 2025. (Section 2)

[1] The Healthcare Common Procedure Coding System, produced by the Centers for Medicare and Medicaid Services (CMS), is a collection of standardized codes that represent medical procedures, supplies, products and services. The codes are used to facilitate the processing of health insurance claims by Medicare and other insurers. *See* Unified Medical Language System, *HCPCS – Healthcare Common Procedure Coding System*, National Library of Medicine, available at https://www.nlm.nih.gov/research/umls/sourcereleasedocs/current/HCPCS (last visited April 4, 2025). *See also* Federal CMS, *Healthcare Common Procedure Coding System (HCPCS)*, available at https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system (last visited April 4, 2025).

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

The bill is expected to have a significant negative fiscal impact on state government. AHCA estimates the bill will result in the loss of $10 million annually as a result of the loss of diabetic product related rebate revenues, which are only available for CGMs when covered as a pharmacy benefit.[2] The loss of rebates is expected as a result of:[3]

- Allowing all CGM products, including those not on the Preferred Product List (PPL), to be available through the DME benefit. AHCA's participation in pooled rebate negotiation is limited to collecting rebates for products listed on the PPL, which means that any product not provided by a pharmacy would not be eligible for a rebate.
- Prohibiting 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.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Diabetes

Diabetes occurs when blood glucose, also called blood sugar, is too high. Blood glucose is the body's main source of energy and comes mainly from one's diet. Insulin, a hormone made by the pancreas, helps the glucose in the blood get into the cells to be used for energy. Another hormone, glucagon, works with insulin to control blood glucose levels. There are two primary types of diabetes- type 1 and type 2.

Type 1 Diabetes

In most people with type 1 diabetes, the body's immune system, which normally fights infection, attacks and destroys the cells in the pancreas that make insulin.[4] As a result, the pancreas stops making insulin. Without insulin, glucose cannot get into the cells and blood glucose rises above normal.[5] People with type 1 diabetes need to take insulin every day to stay alive.

Type 1 diabetes typically occurs in children and young adults, although it can appear at any age.[6] Having a parent or sibling with the disease may increase the chance of developing type 1 diabetes. In the United States, about 5 percent of people with diabetes have type 1.[7]

Symptoms of type 1 diabetes are serious and usually happen quickly, over a few days to weeks, and can include:[8]

- Increased thirst and urination;
- Increased hunger;
- Blurred vision;
- Fatigue; and
- Unexplained weight loss

Sometimes the first symptoms of type 1 diabetes are signs of a life-threatening condition called diabetic ketoacidosis (DKA). The condition develops when the body cannot produce enough insulin.[9] Without enough

[2] AHCA, Agency Analysis of HB 1465 (March 18, 2025)
[3] *Id.*
[4] U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, *Type 1 Diabetes*, available at https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-1-diabetes/ (last visited April 4, 2025).
[5] *Id.*
[6] *Id.*
[7] Centers for Disease Control and Prevention, *National diabetes statistics report, 2017*, available at www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf (last visited April 4, 2025).
[8] *Supra* note 4.

insulin, the body begins to break down fat as fuel.[10] This causes a buildup of acids in the bloodstream called ketones; if left untreated, the buildup can lead to diabetic ketoacidosis.[11] Some symptoms of DKA include:[12]

- Breath that smells fruity;
- Dry or flushed skin;
- Nausea or vomiting;
- Stomach pain;
- Trouble breathing; and
- Trouble paying attention or feeling confused.

Type 1 diabetics must take insulin because the body no longer makes it on its own. Different types of insulin start to work at different speeds, and the effects of each last a different length of time. Insulin can be taken in several ways; common options include a needle and syringe, insulin pen, or insulin pump.[13]

Some people who have trouble reaching their blood glucose targets with insulin alone also might need to take another type of diabetes medicine that works with insulin, such as pramlintide. Pramlintide, given by injection, helps keep blood glucose levels from going too high after eating.[14] Few people with type 1 diabetes take pramlintide, however. Another diabetes medicine, metformin, may help decrease the amount of insulin necessary.[15] Researchers are also studying other diabetes pills that people with type 1 diabetes might take along with insulin.

Hypoglycemia, or low blood sugar, can occur if insulin is taken, but the dose does not account for food eaten or physical activity.[16]

Over time, high blood glucose leads to problems such as:[17]

- Heart disease;
- Stroke;
- Kidney disease;
- Eye problems;
- Dental disease;
- Nerve damage;
- Foot problems;
- Depression; and
- Sleep apnea.

Type 2 Diabetes

Type 2 diabetes, the most common type of diabetes, occurs when blood glucose is too high.[18] In type 2 diabetes, the body does not make enough insulin or does not use insulin well enough. Too much glucose then stays in the blood, and not enough reaches the cells.

Type 2 diabetes can develop at any age, even during childhood.[19] However, type 2 diabetes occurs most often in middle-aged and older people.[20] A person is more likely to develop type 2 diabetes if he or she is aged 45 or older,

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[9] Mayo Clinic, Patient Care & Health Information, Disease & Conditions, *Diabetic Ketoacidosis*, available at https://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/symptoms-causes/syc-20371551 (last visited April 4, 2025).
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Supra* note 4.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, *Type 2 Diabetes*, https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-2-diabetes (last visited April 4, 2025).

has a family history of diabetes, or is overweight or has obesity.[21] Diabetes is more common in people who are African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander.[22]

Physical inactivity and certain health problems such as high blood pressure affects a person's chances of developing type 2 diabetes. A person is also more likely to develop type 2 diabetes if they have prediabetes or had gestational diabetes when they were pregnant.[23] Symptoms of type 2 diabetes include:[24]

- Increased thirst and urination;
- Increased hunger;
- Feeling tired;
- Blurred vision;
- Numbness or tingling in the feet or hands;
- Sores that do not heal; and
- Unexplained weight loss.

Symptoms of type 2 diabetes often develop slowly, usually over the course of several years, and can be so mild as to not be noticed. Many people have no symptoms. Some people do not find out they have the disease until they have diabetes-related health problems, such as blurred vision or heart disease.[25]

Type 2 diabetes is caused by several factors, including:[26]

- Overweight and obesity;
- Not being physically active;
- Insulin resistance; and
- Genes.

If not managed, diabetes can lead to problems such as:[27]

- Heart disease and stroke;
- Nerve damage;
- Kidney disease;
- Foot problems;
- Eye disease;
- Gum disease and other dental problems; and
- Sexual and bladder problems.

Many people with type 2 diabetes also have nonalcoholic fatty liver disease, a disease in which fat appears inside the liver that can, over time, affect liver function and cause liver injury.[28] Diabetes is also linked to other health problems such as sleep apnea, depression, some types of cancer, and dementia.[29]
The following chart shows that the number of people in the U.S. with diabetes more than doubled from 1990 to 2019, increasing 115 percent.[30]

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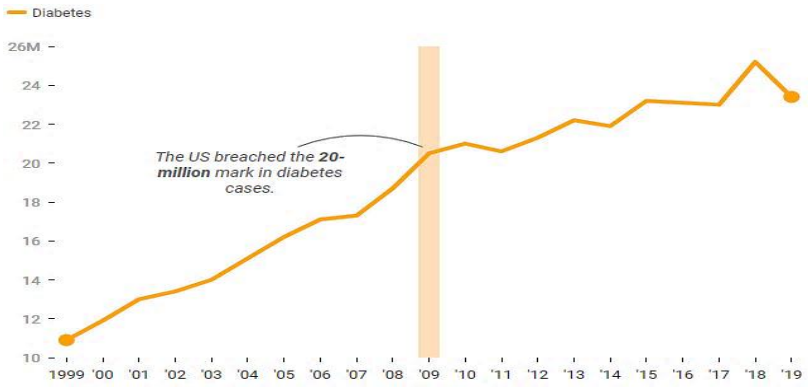
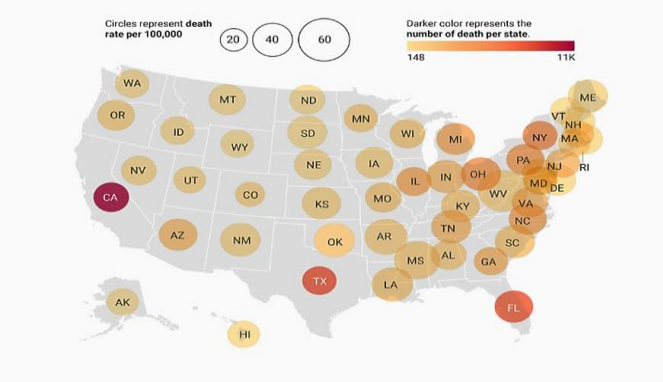
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] Id.
[26] *Id.*
[27] *Id.*
[28] Johns Hopkins Medicine, Health, Conditions and Diseases, *Nonalcoholic Fatty Liver Disease*, available at https://hopkinsmedicine.org/health/conditions-and-diseases/nonalcoholic-fatty-liver-disease (last visited April 4, 2025).
[29] *Supra* note 18.
[30] Center for the Advancement of Health, *Diabetes Statistics: Facts & Latest Data in the US (2023 Update)*, available at https://cfah.org/diabetes-statistics/ (last visited April 4, 2025).



The United States ranks fourth, globally, in the number of diabetes cases (32 million), behind China (141 million), India (74 million), and Pakistan (33 million).[31] Diabetes is the eighth leading cause of death in the United States.[32]

The following map shows the number of diabetes deaths in the United States, by state.[33] While the largest number of deaths are from California, with 11.4 percent of all diabetes deaths in the U.S., the highest diabetes rates, by population and incidence, are West Virginia, Mississippi, and Arkansas.[34]



Continuous Glucose Monitors

A continuous glucose monitor (CGM) automatically tracks blood glucose levels, allowing a person to see their glucose level anytime at a glance. It can also review how glucose changes over a few hours or days to see trends. Seeing glucose levels in real time can help a diabetic make more informed decisions throughout the day about how to balance food, physical activity, and medicines.[35]

A CGM works through a tiny sensor inserted under the skin, usually on the belly or arm. The sensor measures the interstitial glucose level, which is the glucose found in the fluid between the cells. The sensor tests glucose every few minutes. A transmitter wirelessly sends the information to a monitor. The monitor may be part of an insulin pump or a separate device, which can be carried in a pocket or purse. Some CGMs send information directly to a smartphone or tablet.[36]

CGMs are always on and recording glucose levels, regardless of activity level. Many CGMs have special features that work with information from the glucose readings, such as:[37]

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[31] International Diabetes Federation, *IDF Diabetes Atlas: 10th Edition*, available at https://diabetesatlas.org/atlas/tenth-edition (last visited April 4, 2025).
[32] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Underlying Cause of Death, 2018-2021, Single Race Results*, January 17, 2023, available at https://wonder.cdc.gov/controller/datarequest/D158 (last visited April 4, 2025).
[33] Supra note 30.
[34] *Id.*
[35] U.S. Department of Health and 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 April 4, 2025).
[36] *Id.*
[37] *Id.*

- An alarm can sound when the glucose level goes too low or too high.
- A diabetic can track meals, physical activity, and medicines in a CGM device.
- Data can be downloaded to a computer or smart device to more easily see glucose trends. Some models can send information right away to a second person's smartphone. For example, if a child's glucose drops dangerously low overnight, the CGM could be set to wake a parent in the next room.

Twice a day, a diabetic may need to check the CGM itself by testing a drop of blood on a standard glucose meter. The glucose reading should be similar on both devices. The CGM sensor needs to be changed every 3 to 7 days, depending on the model.[38]

Currently, six CGM models are approved by the FDA for treatment decisions, which means changes can be made to a diabetes care plan based on CGM results alone.[39] CGMs are approved for use by adults and children with a doctor's prescription. Some models may be used for children as young as age 2. A physician may recommend a CGM if a person, including a child:[40]

- Is on intensive insulin therapy, also called tight blood sugar control.
- Has hypoglycemia unawareness.
- Often has high or low blood glucose.

Compared with a standard blood glucose meter, using a CGM system can better manage glucose levels every day, lead to fewer low blood glucose emergencies, and require fewer finger sticks. On average, CGMs cost between $1,000 and $1,400, but can cost thousands of dollars, depending on the model and features, and usually require an annually battery change, costing another $500.[41]

Most people who use CGMs have type 1 diabetes. Research is underway to learn how CGMs might help people with type 2 diabetes.[42] However, both people with type 1 and type 2 diabetes who use a CGM have fewer instances of hypoglycemia and a lower A1C.[43]

Medicaid Coverage for Continuous Glucose Monitors

The federal Centers for Medicare and Medicaid Services (CMS) allows states to cover non-pharmaceutical products provided by a pharmacy if that product is FDA-approved and has been assigned a National Drug Code (NDC).

Prior to 2024, Florida Medicaid covered CGMs as a DME benefit; however, some Medicaid managed care plans covered additional CGM access as a pharmacy benefit.[44] In 2023, the Legislature required the state Medicaid program to cover CGMs under the Medicaid pharmacy benefit instead of as durable medical equipment[45] (DME).[46] On October 1, 2024, AHCA transitioned the majority of CGM and related supply coverage to be reimbursed as a

[38] *Id.*
[39] Klonoff DC, Gabbay M, Moon SJ, Wilmot EG. *Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy of Continuous Glucose Monitoring.* J Diabetes Sci Technol (May 3, 2024), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11571640/#:~:text=Currently%2C%20the%20only%20CGMs%20which%20do%20meet,3%20Plus%2C%20Dexcom%20G6%2C%20and%20Dexcom%20G7.&text=By%20contrast%2C%20adjunctive%20CGM%20devices%20require%20confirmation,prior%20to%20making%20any%20relevant%20treatment%20decisions (last visited April 4, 2025).
[40] *Supra* note 35.
[41] CheckDiabetes, *Continuous Glucose Monitoring System and Devices*, Jan. 8, 2022, available at https://www.checkdiabetes.org/continuous-glucose-monitoring-system-and-devices/#:~:text=The%20cost%20of%20continuous%20glucose%20monitor%20varies%20depending,a%20battery%20usually%20cost%20around%20%24400%20to%20%24500 (last visited April 4, 2025).
[42] *Supra* note 35.
[43] American Diabetes Association, Get Involved–Advocacy Overview, *Continuous Glucose Monitors (CGMs) – Everything You Need to Know*, available at https://diabetes.org/get-involved/advocacy/continuous-glucose-monitors (last visited April 4, 2025).
[44] AHCA, Agency Analysis of 2023 HB 967, p. 3 (February 22, 2023).
[45] S. 409.815(2)(h), F.S. "Durable medical equipment" covered services include equipment and devices that are medically indicated to assist in the treatment of a medical condition and specifically prescribed as medically necessary.
[46] Chapter 2023-283, Laws of Fla.

pharmacy benefit .[47] This allowed recipients to get their supplies at the pharmacy where they got their medications, and allowed AHCA to collect rebates for CGMs provided by the pharmacy, which AHCA wasn't able to do prior to October 1, 2024.[48]

In order to collect rebates on CGMs and other diabetic supply products, AHCA entered a collaborative, multi-state agreement (pool) with the state's contracted Pharmacy Benefit Manager (PBM) and 10 other states, which allows for more rebate negotiating power from the states as a collective in order to reduce the cost of CGM products. AHCA also established a Medicaid Preferred Product List (PPL) that listed the items negotiated through the pool.[49] Products not included on the PPL must be authorized by AHCA's PBM for Medicaid fee-for-service (FFS) or the Statewide Medicaid Managed Care program (SMMC) prior to dispensing.[50]

Medicaid plans are required to provide all CGMs and related products listed on AHCA's PPL and are prohibited from implementing their own plan-specific formularies or PPLs for DME.[51] This allows AHCA to collect rebates on both FFS and managed care claims. Both clinical factors and drug manufacturers' rebate offers are considered when determining drugs to include on the PPL.[52] State-negotiated supplemental rebates can result in discounted per-prescription cost for brand name devices and supplies, potentially resulting in a cost lower than those of competitors.[53]

Though most CGMs are covered only by pharmacies, AHCA still allows CGMs and other diabetic supplies to be provided through the DME benefit under certain circumstances.[54]

In 2021, diabetic supplies covered under the DME benefit, such as sensors, transmitters, pumps, needles, lancets, CGMs, syringes, glucose meters and alcohol swabs, accounted for approximately $21 million in Florida Medicaid expenditures.[55]

RECENT LEGISLATION:

YEAR	BILL #	HOUSE SPONSOR(S)	SENATE SPONSOR	OTHER INFORMATION
2023	967	Bell	Burton	

[47] Rule 59G-4.252, F.A.C., incorporates by reference the Florida Medicaid Diabetic Supply Services Coverage Policy (September 2024), available at https://flrules.org/Gateway/reference.asp?No=Ref-16935 (last visited April 4, 2025).
[48] *Supra* note 2.
[49] *Supra* note 47.
[50] *Id.* Agency for Health Care Administration, Florida Medicaid Diabetic Supply Services Policy, Diabetic Supply Preferred Product List, pp. 5-6, 59G-4.252 Diabetic Supply Services Coverage Policy.pdf (last visited April 4, 2025).
[51] *Id.*
[52] *Supra* note 2.
[53] *Id.*
[54] *Id.* 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 a Healthcare Common Procedure Coding System code of E0784 and all related supplies, including the associated CGM, would be covered. If a recipient is not eligible to receive an insulin pump from a DME provider, they must get their CGM products at the pharmacy with their medication.
[55] *Supra* note 2.

BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Health Care Facilities & Systems Subcommittee	15 Y, 0 N, As CS	3/27/2025	Calamas	Guzzo
THE CHANGES ADOPTED BY THE COMMITTEE:	• Directed AHCA to seek federal approval through a Medicaid waiver or a Medicaid state plan amendment to cover CGMs and related supplies as a DME benefit.			
Health Care Budget Subcommittee	15 Y, 0 N	4/15/2025	Clark	Smith
Health & Human Services Committee				

THIS BILL ANALYSIS HAS BEEN UPDATED TO INCORPORATE ALL OF THE CHANGES DESCRIBED ABOVE.
