

## HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

**BILL #:** CS/HB 967 Medicaid Coverage of Continuous Glucose Monitors

**SPONSOR(S):** Healthcare Regulation Subcommittee, Bell and others

**TIED BILLS:**           **IDEN./SIM. BILLS:** CS/SB 988

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**FINAL HOUSE FLOOR ACTION:** 116 Y's      0 N's            **GOVERNOR'S ACTION:** Approved

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### SUMMARY ANALYSIS

CS/HB 967 passed the House on April 26, 2023 and subsequently passed the Senate on May 2, 2023.

Diabetes occurs when blood glucose, or 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.

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.

The bill requires the Agency for Health Care Administration, subject to funding and any limitations or directives in the General Appropriations Act, to cover CGMs, and necessary repairs and replacement parts, under the Medicaid pharmacy benefit for Medicaid recipients 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 CGM to assist the recipient and practitioner in managing the recipient's diabetes.

The bill would have an indeterminate, but likely significant, negative fiscal impact on state government and no fiscal impact on local government.

The bill was approved by the Governor on June 22, 2023, ch. 2023-283, L.O.F., and will become effective on October 1, 2023.

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF CHANGES:

#### **Background**

#### **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.<sup>1</sup> As a result, the pancreas stops making insulin. Without insulin, glucose cannot get into the cells and blood glucose rises above normal.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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

- Increased thirst and urination
- Increased hunger
- Blurred vision
- Fatigue
- Unexplained weight loss<sup>5</sup>

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.<sup>6</sup> Without enough insulin, the body begins to break down fat as fuel.<sup>7</sup> This causes a buildup of acids in the bloodstream called ketones; if left untreated, the buildup can lead to diabetic ketoacidosis.<sup>8</sup> Some symptoms of DKA include:

- Breath that smells fruity
- Dry or flushed skin
- Nausea or vomiting
- Stomach pain

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<sup>1</sup> 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 on April 5, 2023).

<sup>2</sup> Id.

<sup>3</sup> Id.

<sup>4</sup> 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](http://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf) (last visited April 5, 2023).

<sup>5</sup> Supra, FN 1.

<sup>6</sup> 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 on April 5, 2023).

<sup>7</sup> Id.

<sup>8</sup> Id.

- Trouble breathing
- Trouble paying attention or feeling confused<sup>9</sup>

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.<sup>10</sup>

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.<sup>11</sup> Few people with type 1 diabetes take pramlintide, however. Another diabetes medicine, metformin, may help decrease the amount of insulin necessary.<sup>12</sup> 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.<sup>13</sup>

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

- Heart disease
- Stroke
- Kidney disease
- Eye problems
- Dental disease
- Nerve damage
- Foot problems
- Depression
- Sleep apnea<sup>14</sup>

## Type 2 Diabetes

Type 2 diabetes, the most common type of diabetes, occurs when blood glucose is too high.<sup>15</sup> 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.<sup>16</sup> However, type 2 diabetes occurs most often in middle-aged and older people.<sup>17</sup> A person is more likely to develop type 2 diabetes if he or she is aged 45 or older, has a family history of diabetes, or is overweight or has obesity.<sup>18</sup> Diabetes is more common in people who are African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander.<sup>19</sup>

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<sup>9</sup> Id.

<sup>10</sup> Supra, FN 1.

<sup>11</sup> Id.

<sup>12</sup> Id.

<sup>13</sup> Id.

<sup>14</sup> Id.

<sup>15</sup> 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 on April 5, 2023).

<sup>16</sup> Id.

<sup>17</sup> Id.

<sup>18</sup> Id.

<sup>19</sup> Id.

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.<sup>20</sup> Symptoms of type 2 diabetes include:

- Increased thirst and urination
- Increased hunger
- Feeling tired
- Blurred vision
- Numbness or tingling in the feet or hands
- Sores that do not heal
- Unexplained weight loss<sup>21</sup>

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.<sup>22</sup>

Type 2 diabetes is caused by several factors, including:

- Overweight and obesity
- Not being physically active
- Insulin resistance
- Genes<sup>23</sup>

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

- Heart disease and stroke
- Nerve damage
- Kidney disease
- Foot problems
- Eye disease
- Gum disease and other dental problems
- Sexual and bladder problems<sup>24</sup>

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.<sup>25</sup> Diabetes is also linked to other health problems such as sleep apnea, depression, some types of cancer, and dementia.<sup>26</sup>

The following chart shows the number of people in the U.S. with diabetes more than doubled from 1990 to 2019, increasing 115 percent.<sup>27</sup>

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<sup>20</sup> Id.

<sup>21</sup> Id.

<sup>22</sup> Id.

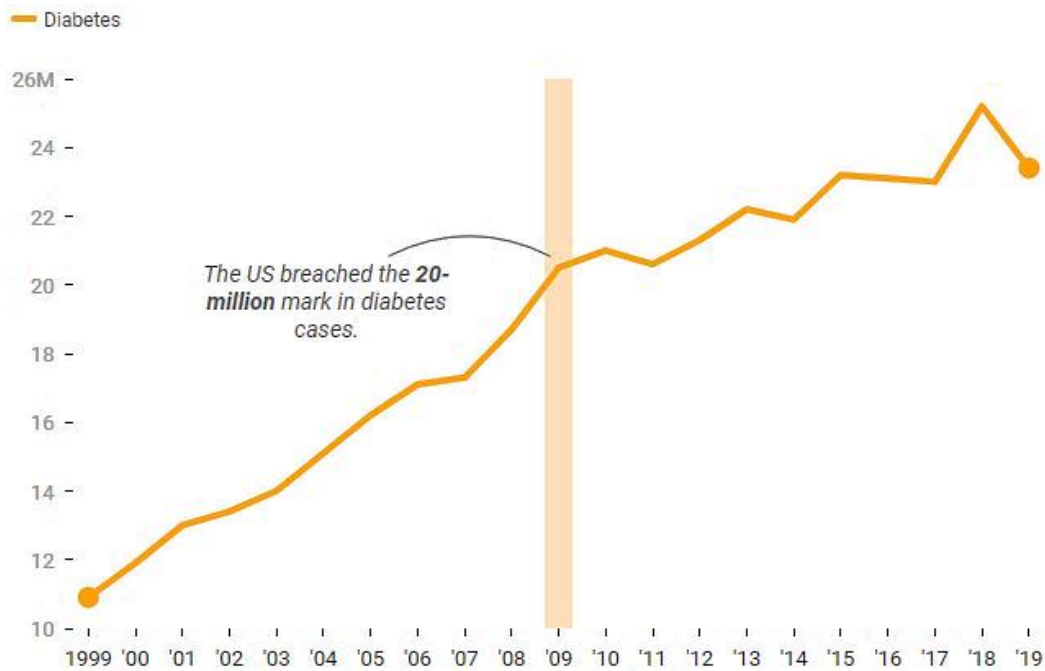
<sup>23</sup> Id.

<sup>24</sup> Id.

<sup>25</sup> 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 on April 5, 2023).

<sup>26</sup> Supra, FN 15.

<sup>27</sup> 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 on April 5, 2023).



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).<sup>28</sup>

Diabetes is the eighth leading cause of death in the United States.<sup>29</sup> Below is a snapshot of diabetes prevalence and health care costs in the U.S.<sup>30</sup>

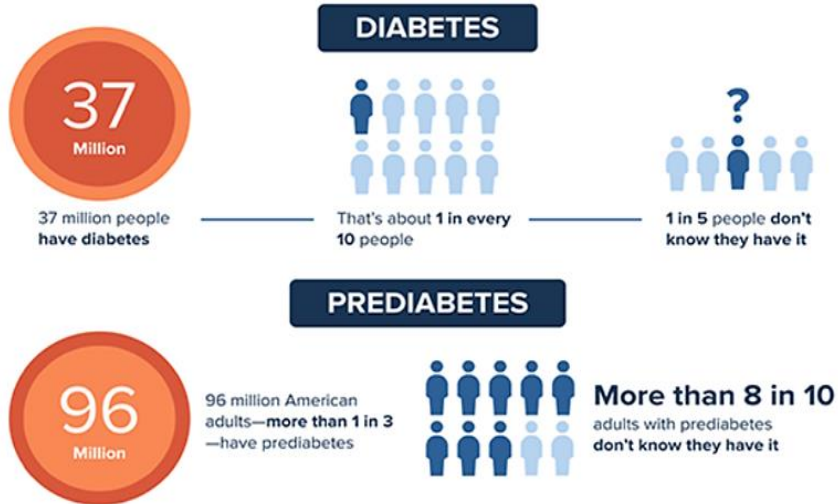
<sup>28</sup> International Diabetes Federation, *IDF Diabetes Atlas: 10<sup>th</sup> Edition*, available at <https://diabetesatlas.org/atlas/tenth-edition> (last visited on April 5, 2023).

<sup>29</sup> 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 on April 5, 2023).

<sup>30</sup> Centers for Disease Control and Prevention, *A Snapshot: Diabetes in the United States*, available at <https://www.cdc.gov/diabetes/library/socialmedia/infographics/diabetes.html> (last visited on April 5, 2023).

# DIABETES IN THE U.S

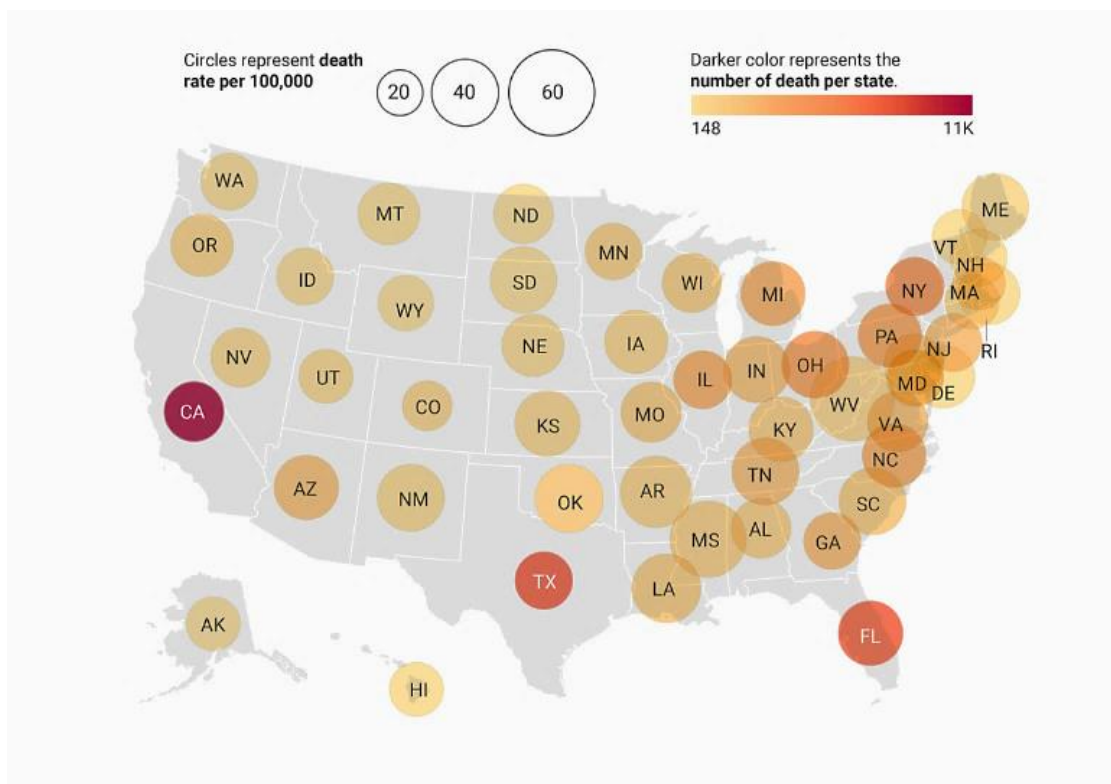
## A SNAPSHOT

The following map shows the number of diabetes deaths in the United States, by state.<sup>31</sup> 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.<sup>32</sup>

<sup>31</sup> Supra, FN 27.

<sup>32</sup> Id.



## 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.<sup>33</sup> 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.<sup>34</sup>

A CGM works through a tiny sensor inserted under the skin, usually on the belly or arm.<sup>35</sup> The sensor measures the interstitial glucose level, which is the glucose found in the fluid between the cells.<sup>36</sup> 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.<sup>37</sup> Some CGMs send information directly to a smartphone or tablet.

CGMs are always on and recording glucose levels, regardless of activity level.<sup>38</sup> Many CGMs have special features that work with information from the glucose readings, such as:

- 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.<sup>39</sup>

<sup>33</sup> 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 on April 5, 2023).

<sup>34</sup> Id.

<sup>35</sup> Id.

<sup>36</sup> Id.

<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>39</sup> Id.

Currently, one CGM model is approved for treatment decisions, the Dexcom G5 Mobile, which means changes can be made to a diabetes care plan based on CGM results alone.<sup>40</sup>

Twice a day, a diabetic may need to check the CGM itself by testing a drop of blood on a standard glucose meter.<sup>41</sup> 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.<sup>42</sup>

Most people who use CGMs have type 1 diabetes. Research is underway to learn how CGMs might help people with type 2 diabetes.<sup>43</sup>

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:

- Is on intensive insulin therapy, also called tight blood sugar control.
- Has hypoglycemia unawareness.
- Often has high or low blood glucose.<sup>44</sup>

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.<sup>45</sup>

People with type 1 and type 2 diabetes who use a CGM have fewer instances of hypoglycemia and a lower A1C.<sup>46</sup>

There are three manufacturers of CGMs with models on the market: Medtronic, Libre, and Dexcom.

## Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), which makes eligibility determinations.

The state uses a comprehensive managed care delivery model for primary and acute care services provided to most Medicaid enrollees, the Statewide Medicaid Managed Care (SMMC) program.<sup>47</sup> The SMMC program provides acute health care services through managed care plans contracted with AHCA in the 11 regions across the state. Specialty plans are also available to serve distinct populations, such as the Children's Medical Services Network for children with special health care needs, or those in the child welfare system. Medicaid recipients with HIV/AIDS, serious mental illness, dual enrollment with Medicare, chronic obstructive pulmonary disease, congestive heart failure, or cardiovascular disease may also select from specialized plans.

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<sup>40</sup> Id.

<sup>41</sup> Id.

<sup>42</sup> Id.

<sup>43</sup> Id.

<sup>44</sup> Id.

<sup>45</sup> 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 on April 5, 2023).

<sup>46</sup> 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 on April 5, 2023).

<sup>47</sup> S. 409.964, F.S.



## Medicaid Coverage for Continuous Glucose Monitors

### Florida

Florida Medicaid fee-for-service (FFS) recipients acquire diabetic supplies from a durable medical equipment (DME) provider.<sup>48</sup> DME providers are reimbursed according to a promulgated fee schedule containing fixed payment amounts for all products falling under the same billable codes. Currently, Florida Medicaid covers CGMs for recipients ages 0-20 years only; however, in managed care the plans can be less restrictive, and some have already elected to cover CGMs for adults as an expanded benefit, and/or to provide CGMs as a pharmacy benefit. The companies that cover diabetic supplies under the pharmacy benefit include:

- United
- Aetna
- Humana
- Molina
- Simply
- Sunshine Health
- Community Care Plan (CCP)
- Florida Community Care (FCC)
- AmeriHealth Caritas
- Children's Medical Services (CMS)<sup>49</sup>

In 2021, Florida Medicaid spent nearly \$40M on diabetic supplies for recipients, inclusive of expenditures for the FFS delivery system and SMMC. Nearly half the expense was for diabetic test strips, totaling \$19M for SMMC diabetic enrollees and \$500,000 for FFS recipients. Additional diabetic supplies, such as sensors, transmitters, pumps, needles, lancets, CGMs, syringes, glucose meters and alcohol swabs, accounted for the approximate \$19M in SMMC diabetic enrollee expenses.<sup>50</sup>

### Other States

More than 20 state Medicaid procedures cover diabetic supplies for both Type 1 and Type 2 diabetes through the pharmacy benefit and collect rebates.<sup>51</sup> Diabetic supplies in these arrangements include CGMs, test strips, lancets, meters, transmitters, and sensors. The map below shows which states provide Medicaid coverage for diabetic supplies.

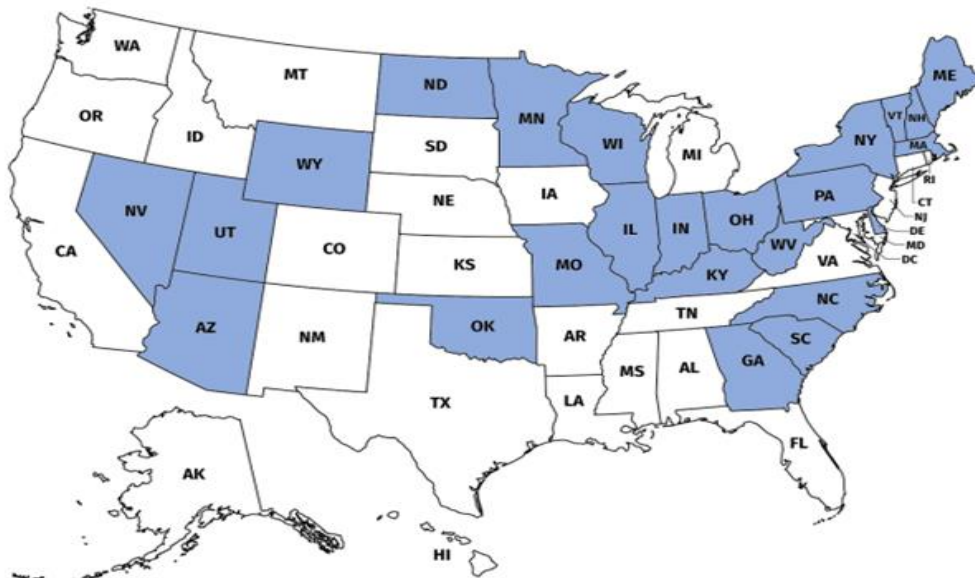
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<sup>48</sup> On March 30, 2023, AHCA issued a Florida Medicaid Health Care Alert advising all provider types that the Medicaid program will transfer diabetic coverage from the DME benefit to the pharmacy benefit. In the coming months, AHCA will begin rulemaking to update necessary coverage policies; amend the Florida Medicaid State Plan; and amend Statewide Medicaid Managed Care plan contracts to reflect the change in policy. Agency for Health Care Administration, Florida Medicaid, Florida Medicaid Health Care Alert, *Florida Medicaid Transfer of Diabetic Supply Coverage from the Durable Medical Equipment Benefit to the Pharmacy Benefit*, March 30, 2023. Also, on March 2, 2023, the Centers for Medicare and Medicaid Services announced that Medicare will cover CGMs for an expanded group of people with type 2 diabetes. Up until now, Medicare only covered CGMs for people with type 2 diabetes who were on at least three shots of insulin per day. Beginning April 16, 2023, the expanded policy now includes people who are taking any type of insulin as well as people with non-insulin-treated diabetes who have a history of recurrent level 2 hypoglycemia, or who have had at least one level 3 hypoglycemic event. The diaTribe Foundation, *Medicare to Expand CGM Coverage for People with Type 2 Diabetes*, March 3, 2023, available at <https://diatribe.org/medicare-expands-cgm-continuous-glucose-monitor-coverage-type-2-diabetes#:~:text=Medicare%20will%20begin%20covering%20continuous%20glucose%20monitors%20%28CGMs%29,coverage%20to%20more%20people%20with%20type%20%20diabetes> (last visited on April 5, 2023).

<sup>49</sup> Email from Patrick Steele, Legislative Affairs Director for AHCA, *Re: HB 967 bill analysis*, March 17, 2023, on file with the House Healthcare Regulation Subcommittee.

<sup>50</sup> Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis – HB 967, February 22, 2023*, pg. 3.

<sup>51</sup> Id.



### **Effect of Proposed Changes**

The bill requires AHCA, subject to funding and any limitations or directives in the General Appropriations Act (GAA), to cover CGMs under the Medicaid pharmacy benefit for Medicaid recipients 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 CGM to assist the recipient and practitioner in managing the recipient's diabetes.

The bill requires AHCA to cover necessary repairs and replacement parts for the CGM.

To receive continuing coverage for the CGM, the Medicaid recipient must get follow-up care, in person or through telehealth, once every six months for the first 18 months he or she has the CGM to assess the efficacy of using the CGM for treatment of their diabetes. After the first 18 months, such follow-up care must take place annually.

The bill directs AHCA to seek federal approval, if necessary, to implement the bill. Lastly, the bill directs AHCA to include the rate impact of CGM coverage in the Medicaid medical managed assistance and long-term care managed care programs' rates that take effect on October 1, 2023.

The bill provides an effective date of October 1, 2023.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

#### **1. Revenues:**

CGMs are currently reimbursed under a durable medical equipment (DME) benefit within in the SMMC program. On March 30, 2023, AHCA announced that it would be shifting diabetic supply coverage from the DME benefit to the pharmacy benefit.<sup>52</sup> Under the pharmacy benefit, the state may negotiate rebates for diabetic supplies, generating revenue and offsetting a portion of the cost of CGMs to the Medicaid program. It is unknown when AHCA will complete this transition; therefore, it is unknown when rebate revenues might be expected, or the amount of such negotiated rebates.

2. Expenditures:

The Medicaid program in Florida currently does not cover CGMs for adults over the age of 20. In federal fiscal year 2021-2022, 43,924 Medicaid recipients required diabetic supplies.<sup>53</sup> If five percent of that eligible population were prescribed a CGM, the increase in expenditures for state fiscal year 2023-2024 would be \$13.1 million, with a \$5.3 million impact to the General Revenue Fund.<sup>54</sup> The chart below contains estimated fiscal impacts based on select percentages of the eligible population being prescribed a CGM.<sup>55</sup>

Participation Rate (Eligible Recipients)	Participation Number (Eligible Recipients)	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

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

Neither the bill nor the General Appropriations Act appropriate funds to cover the cost of CGMs under the bill. Future expenditures related to CGMs and potential revenues from negotiated rebates would be considered by the Social Services Estimating Conference in the Medicaid Expenditures forecast.

<sup>52</sup> Agency for Health Care Administration, *Florida Medicaid Health Care Alert: "Florida Medicaid Transfer of Diabetic Supply Coverage from the Durable Medical Equipment Benefit to the Pharmacy Benefit"*, March 30, 2023.

<sup>53</sup> Agency for Health Care Administration, *2023 Agency Legislative Bill Analysis—HB 967*, pg. 5 (Feb. 22, 2023).

<sup>54</sup> Id.

<sup>55</sup> Id.

