

## ***Diabetes Interventions Addressing Barriers to Enrollment, Technology, and Education Services (DIABETES) Act***

- According to the CDC, 38.4 million Americans have diabetes, representing 11.6 percent of the U.S. population.<sup>1</sup>
- Many individuals with diabetes rely on life-sustaining diabetes technologies, such as continuous glucose monitors (CGMs) and insulin delivery devices, to monitor and control their diabetes.
- Likewise, individuals with diabetes use and benefit from diabetes self-management training (DSMT), which teaches individuals how to use diabetes technologies and administer medications and supports lifestyle changes to improve diabetes management.
- These interventions are highly effective and part of the standard of care for all people with diabetes.<sup>2</sup>
- People with diabetes often encounter obstacles in accessing care, especially through federal health care programs.
  - Individuals aging into Medicare experience disruptions in care as they are forced to “re-prove” that they have diabetes. This creates an unnecessary and dangerous disruption in care. Further, Medicare beneficiaries face outdated coverage policies that can force them to switch therapies even if they had safely used and benefited from their current therapy for years prior to enrolling in Medicare.
  - Under Medicare Advantage and Medicaid managed care plans, some enrollees do not have access to the diabetes technology that would be most effective for them due to the structure and nature of these plans.
  - In all circumstances, these disruptions break the continuity of care, prevent individuals from accessing the diabetes care that works best for them, and inappropriately interfere with medical determinations made jointly by the prescribing providers and the individual with diabetes. In the worst cases, disruption in access to devices like insulin pumps and CGMs may lead to life-threatening scenarios like severe hypoglycemic events.
  - Medicare places strict and arbitrary limits on the number hours of DSMT available, while also unnecessarily limiting the type of providers who can refer for the service.
- In addition to individuals facing challenges in accessing the care they need, antiquated Medicare fee-for-service payment methodologies have not kept pace with advances in technology and threaten to undermine future innovation.
  - In particular, the FDA recognizes algorithms that drive automated insulin delivery (AID) systems as independent from the continuous glucose monitors and insulin pumps that they connect to,<sup>3</sup> yet CMS has failed to establish a reimbursement pathway to ensure beneficiary access.
  - Without separate and adequate reimbursement for the software or algorithm in an AID system, innovators may be unable to invest in developing cutting-edge AID technologies, thereby reducing patient access to an essential life-sustaining technology.
- All these obstacles to care disrupt care continuity and add undue burdens on people living with diabetes.

***The DIABETES Act (S. 5502, 118<sup>th</sup>), \* introduced by Diabetes Caucus Co-Chairs Senators Shaheen and Collins, addresses these issues with common sense solutions to ensure that Medicare beneficiaries can access necessary diabetes care.***

\*Introduction in the Senate and House for the 119<sup>th</sup> Congress is pending.

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<sup>1</sup> *National Diabetes Statistics Report*, Centers for Disease Control and Prevention (May 15, 2024), <https://www.cdc.gov/diabetes/php/data-research/index.html>.

<sup>2</sup> American Diabetes Association Professional Practice Committee, *Standards of Care in Diabetes—2025*, 48 Diabetes Care S146-S166, [https://diabetesjournals.org/care/issue/48/Supplement\\_1](https://diabetesjournals.org/care/issue/48/Supplement_1).

<sup>3</sup> 21 CFR 862.1356.

## ***DIABETES Act – Section-by-Section Summary***

### **Section 3 – Continuing Access to Diabetes Technologies Upon Medicare Enrollment**

During the first 12 months of an individual's enrollment in Medicare Part B, a provider may certify to the HHS Secretary that an individual is using one or multiple diabetes technologies (e.g., CGMs, insulin delivery technology). Medicare Administrative Contractors must provide continued coverage of these technologies solely based on the certification in the beneficiary's medical record. Continued coverage of these technologies beyond the initial coverage determination would be assessed consistent with existing requirements for ongoing coverage.

For the purposes of this Section, the term "diabetes technologies" means a device, related supplies, and software, that at the time of certification, is covered under Medicare Part B for individuals with diabetes. The HHS Secretary must develop the certification form following public notice and comment and in conjunction with diabetes stakeholders. Additionally, the HHS Secretary must develop a process, through public notice and comment, for continued coverage of an individual's diabetes-related technology if it is not currently covered by Medicare Part B (e.g., Part D-covered insulin pumps). Finally, the HHS Secretary must issue guidance to audit and oversight entities regarding the certification form to ensure these entities do not hinder access to diabetes technologies.

### **Section 4 – Expanding Access to Diabetes Self-Management Training**

Allows a wider range of physicians and qualified non-physician providers to certify whether an individual needs DSMT. Currently, only providers who are "managing the patient's diabetic condition" can certify whether an individual needs DSMT, leaving many physicians and qualified nonphysician providers unable to appropriately refer their patients. Additionally, the bill ensures continued access to DSMT services deemed medically necessary by a physician or a qualified nonphysician provider.

### **Section 5 – Insulin Pump Training and Education**

Requires the HHS Secretary to create new Healthcare Common Procedure Coding System (HCPCS) codes to describe patient education, training, and device set up for insulin pumps. The new HCPCS codes must be similar to existing Current Procedural Terminology (CPT) codes for education, training, and device set up for CGMs.

### **Section 6 – National Coverage Determination Decision**

Directs the HHS Secretary to, within 180 days, issue a proposed National Coverage Determination for infusion pumps – continuous subcutaneous insulin infusion (CSII).

### **Section 7 – Government Accountability Office Report**

Directs the Government Accountability Office to submit a report to Congress that assesses barriers individuals face in accessing diabetes technologies and diabetes self-management education and support services in federal health care programs, including, but not limited to, those in public-private programs such as Medicare Advantage and Medicaid managed care plans. The report must include an assessment of utilization management techniques (e.g., prior authorization, formularies, preferred products) and the impact on individual access to services and technologies that are covered under Medicare.

### **For more information, contact:**

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