

118TH CONGRESS
2D SESSION

S. 5502

To ensure continued access to diabetes technology upon Medicare enrollment,
and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 12, 2024

Mrs. SHAHEEN (for herself and Ms. COLLINS) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To ensure continued access to diabetes technology upon
Medicare enrollment, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Diabetes Interventions
5 Addressing Barriers to Enrollment, Technology, and Edu-
6 cation Services (DIABETES) Act” or the “Diabetes Act”.

7 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

8 (a) FINDINGS.—Congress finds the following:

9 (1) According to the Centers for Disease Con-
10 trol and Prevention, in 2021, an estimated

1 38,400,000 Americans, or 11.6 percent of the entire
2 United States population, have diabetes.

3 (2) The total number of individuals with diabe-
4 tes is projected to increase to an estimated
5 54,900,000 individuals by 2030.

6 (3) Diabetes disproportionately impacts the
7 Medicare population, as the Centers for Medicare &
8 Medicaid Services found in 2022, and 26 percent of
9 Medicare beneficiaries have diabetes.

10 (4) Both type 1 and 2 diabetes can significantly
11 harm long-term health and is associated with numer-
12 ous comorbidities such as cancer, heart disease,
13 chronic kidney disease, blindness, and amputations.

14 (5) The direct and indirect cost of diabetes is
15 significant as the American Diabetes Association
16 found that the total annual cost of diabetes in 2022
17 was \$412,900,000,000, \$306,600,000,000 of which
18 is attributable to direct medical costs.

19 (6) The American Diabetes Association and the
20 American Association of Clinical Endocrinology have
21 set forth clinical guidelines that include the use of
22 continuous glucose monitors, insulin pumps, auto-
23 mated insulin delivery systems, and diabetes self-
24 management training for individuals with diabetes.

1 (7) An automated insulin delivery system con-
 2 sists of a continuous glucose monitor, an insulin
 3 pump, and an algorithm or software.

4 (8) The algorithm or software is a critical com-
 5 ponent of an automated insulin delivery system as it
 6 continuously learns the user’s behavior and physio-
 7 logical responses and automatically administers the
 8 appropriate amount of insulin.

9 (9) Medicare currently fails to separately reim-
 10 burse for the essential algorithms and software that
 11 drive automated insulin delivery (AID) systems,
 12 which may stifle future innovation and maintenance,
 13 and impede beneficiary access.

14 (10) Medicare has an existing pathway to sepa-
 15 rately reimburse for the algorithm or software in an
 16 automated insulin delivery system, the Medicare du-
 17 rable medical equipment benefit.

18 (b) SENSE OF CONGRESS.—It is the sense of Con-
 19 gress that the Secretary of Health and Human Services
 20 should commit to take administrative action to—

21 (1) recognize that the algorithm or software in
 22 an automated insulin delivery system is a “reason-
 23 able and necessary” item “for the diagnosis or treat-
 24 ment of illness or injury or to improve the func-
 25 tioning of a malformed body member” consistent

1 with Medicare coverage requirements under section
 2 1862(a)(1)(A) of the Social Security Act;

3 (2) ensure the algorithm or software in an auto-
 4 mated insulin delivery system is treated as a sepa-
 5 rately payable supply to durable medical equipment;
 6 and

7 (3) when applicable, recognize the algorithm or
 8 software in an automated insulin delivery system as
 9 “medical supplies associated with the injection of in-
 10 sulin” consistent with section 1860D–2(e)(1) of the
 11 Social Security Act.

12 **SEC. 3. CONTINUED ACCESS TO DIABETES RELATED TECH-**
 13 **NOLOGIES.**

14 (a) IN GENERAL.—Section 1861(ww) of the Social
 15 Security Act (42 U.S.C. 1395x(ww)) is amended—

16 (1) in paragraph (1)—

17 (A) by striking “and” after “upon the
 18 agreement with the individual,”; and

19 (B) by inserting “and ensuring care con-
 20 tinuity for individuals using diabetes technology
 21 covered under part B as described in paragraph
 22 (5),” after “(as defined in paragraph (4)),”;
 23 and

24 (2) by adding at the end the following new
 25 paragraph:

1 “(5)(A) Subject to subparagraphs (B) and (C) of this
2 paragraph, during the first 12 months of an individual’s
3 enrollment for benefits under part B, a provider (as de-
4 fined in subparagraph (E)) may certify to the Secretary
5 that an individual is using 1 or multiple diabetes tech-
6 nologies covered under part B (as defined in subparagraph
7 (D)).

8 “(B) During the initial preventive physical examina-
9 tion or other covered service as determined appropriate by
10 the Secretary during the period described in subparagraph
11 (A), the provider may make a determination of the individ-
12 ual’s use of diabetes technology covered under part B. In
13 the case where the provider makes such determination, the
14 provider shall submit a certification to the Secretary as
15 required under subparagraph (C).

16 “(C) Not later than January 1, 2026, the Secretary
17 shall—

18 “(i) issue a finalized certification form, devel-
19 oped pursuant to public notice and opportunity for
20 comment, for use under this paragraph;

21 “(ii) issue guidance and instructions to medi-
22 care administrative contractors (as defined in section
23 1874A(3)), that require the relevant medicare ad-
24 ministrative contractors to only assess whether the
25 certification form is included in the individual’s med-

1 ical records when making a determination of wheth-
 2 er coverage of the diabetes technology covered under
 3 part B is reasonable and necessary as described in
 4 section 1862(a)(1)(A);

5 “(iii) develop a process through notice and com-
 6 ment rulemaking for considering whether an individ-
 7 ual’s diabetes technology that is not covered under
 8 part B at the time of the certification described in
 9 subparagraph (A) should be a covered benefit under
 10 existing statutory authority; and

11 “(iv) issue appropriate guidance to relevant
 12 audit and oversight entities to ensure those entities
 13 do not inappropriately cause disruptions in access to
 14 diabetes technology covered under part B.

15 “(D) For purposes of this paragraph, the term ‘dia-
 16 betes technology covered under part B’ means, with re-
 17 spect to an individual, any device, related supplies, and
 18 software or algorithm that, at the time the certification
 19 described in subparagraph (C) is made with respect to the
 20 individual, is covered under part B for an individual that
 21 has diabetes under the applicable ICD–10 code list as de-
 22 termined by the Secretary.

23 “(E) For purposes of this paragraph, the term ‘pro-
 24 vider’ means a physician (as defined in section 1861(r)),
 25 nurse practitioner, clinical nurse specialist, physician as-

1 sistant, (as those terms are defined in section
 2 1861(aa)(5)), or certified nurse-midwife (as defined in sec-
 3 tion 1861(gg)(2)), or other provider of services or supplier
 4 as determined appropriate by the Secretary.”.

5 (b) EFFECTIVE DATE.—The amendments made by
 6 this section shall apply to items and services furnished on
 7 or after January 1, 2026.

8 **SEC. 4. EXPANDING ACCESS TO DIABETES OUTPATIENT**
 9 **SELF-MANAGEMENT TRAINING SERVICES.**

10 (a) IN GENERAL.—Section 1861(qq) of the Social Se-
 11 curity Act (42 U.S.C. 1395x(qq)) is amended—

12 (1) in paragraph (1)—

13 (A) by inserting “and consistent with para-
 14 graph (2)(C)” after “as the Secretary deter-
 15 mines appropriate”;

16 (B) by inserting “or qualified non-physi-
 17 cian practitioner” after “only if the physician”;
 18 and

19 (C) by inserting “(or other physician or
 20 qualified non-physician practitioner furnishing
 21 items or services to such individual, in coordina-
 22 tion with the physician or qualified non-physi-
 23 cian practitioner managing such individual’s di-
 24 abetic condition)” after “managing the individ-
 25 ual’s diabetic condition”; and

1 (2) in paragraph (2)—

2 (A) in subparagraph (A), by striking
3 “and” at the end;

4 (B) in subparagraph (B)—

5 (i) by striking “paragraph” and in-
6 serting “subparagraph”; and

7 (ii) by striking the period at the end
8 and inserting “; and”; and

9 (C) by adding the following new subpara-
10 graph:

11 “(C) the times determined appropriate by the
12 Secretary shall in no way limit the quantity or dura-
13 tion of educational and training services furnished
14 by a certified provider to an individual with diabetes
15 if such service is deemed medically necessary by a
16 physician or qualified non-physician practitioner.”.

17 (b) EFFECTIVE DATE.—The amendments made by
18 this section shall apply to items and services furnished on
19 or after January 1, 2026.

20 **SEC. 5. PROVIDING INSULIN PUMP TRAINING AND EDU-**
21 **CATION.**

22 (a) IN GENERAL.—Not later than January 1, 2026,
23 the Secretary of Health and Human Services (in this sec-
24 tion referred to as the “Secretary”) shall establish new
25 Healthcare Common Procedure Coding System codes

1 under the fee schedule established under section 1848(b)
 2 of the Social Security Act (42 U.S.C. 1395w-4(b)) that
 3 describe hook-up, calibration, and patient training with re-
 4 spect to an insulin pump similar to Current Procedural
 5 Terminology codes 95249 and 95250 (and any succeeding
 6 codes). The Secretary shall ensure the newly established
 7 codes sufficiently describe patient education and training
 8 as well as insulin pump placement services for technologies
 9 covered under section 1834 of the Social Security Act (42
 10 U.S.C. 1395m) and part D of title XVIII of the Social
 11 Security Act (42 U.S.C. 1395w-101 et seq.).

12 (b) EDUCATION AND OUTREACH.—The Secretary
 13 shall use existing communications and mechanisms to pro-
 14 vide education and outreach to stakeholders with respect
 15 to the ability of health professionals to bill the newly es-
 16 tablished codes described in subsection (a).

17 **SEC. 6. NATIONAL COVERAGE DETERMINATION ON INSU-**
 18 **LIN PUMPS.**

19 Not later than 180 days after the date of enactment
 20 of this Act, the Secretary of Health and Human Services
 21 shall issue a proposed national coverage determination (as
 22 defined in section 1869(f)(1)(B) of the Social Security Act
 23 (42 U.S.C. 1395ff(f)(1)(B)) for infusion pumps, contin-
 24 uous subcutaneous insulin infusion (CSII), number

1 280.14 pursuant to section 1862(l) of the Social Security
2 Act (42 U.S.C. 1395y(l)).

3 **SEC. 7. REPORT ON ENROLLEE ACCESS TO DIABETES-RE-**
4 **LATED SERVICES AND TECHNOLOGIES IN**
5 **FEDERAL HEALTH CARE PROGRAMS.**

6 (a) IN GENERAL.—Not later than 1 year after the
7 date of enactment of this Act, the Comptroller General
8 of the United States, in collaboration with the Secretary
9 of Health and Human Services, shall submit to the Com-
10 mittee on Finance and the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate and the Com-
12 mittee on Energy and Commerce and the Committee on
13 Ways and Means of the House of Representatives, a report
14 that assesses the barriers individuals face in accessing dia-
15 betes technologies and diabetes self-management edu-
16 cation and support services across Federal health care
17 programs. The report shall specifically review barriers,
18 which include prior authorization practices, the use of pre-
19 ferred formularies, coverage intensity limitations, and
20 other utilization management techniques, to accessing dia-
21 betes technologies and diabetes self-management edu-
22 cation and support services faced by individuals enrolled
23 in a Federal health care program, and whether any Fed-
24 eral law, regulation, or policy adversely affects access to
25 those covered services or limits the ability of individuals

1 with diabetes to receive services that align with standards
2 of care.

3 (b) DEFINITIONS.—In this section:

4 (1) DIABETES TECHNOLOGIES.—The term “di-
5 abetes technologies” means items described in sec-
6 tion 1861(ww)(5)(D) of the Social Security Act, as
7 added by section 3, and any device, related supplies,
8 and software or algorithm that monitors or manages
9 an individual’s diabetes that is medically necessary
10 for the individual’s diagnosis of diabetes, regardless
11 of whether the device, related supplies, and software
12 or algorithm is covered under part B of title XVIII
13 of the Social Security Act. Such term includes glu-
14 cose monitors, insulin delivery technologies, related
15 supplies, and software or algorithms.

16 (2) DIABETES SELF-MANAGEMENT EDUCATION
17 AND SUPPORT SERVICES.—The term “diabetes self-
18 management education and support services” means
19 services described in section 1861(qq) of the Social
20 Security Act (42 U.S.C. 1395x(qq)).

21 (3) FEDERAL HEALTH CARE PROGRAM.—The
22 term “Federal health care program” means any plan
23 or program that provides health benefits, whether
24 through insurance or otherwise, that is directly
25 funded in whole or in part, by the United States

1 Government, including a Federal health care pro-
2 gram (as defined in section 1128B(f) of the Social
3 Security Act (42 U.S.C. 1320a–7b(f))) and a health
4 benefits plan under chapter 89 of title 5, United
5 States Code.

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