

119TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mrs. SHAHEEN introduced the following bill; which was read twice and
referred to the Committee on _____

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 (11) Including continuous glucose monitors, du-
19 rable insulin pumps, and related supplies into the
20 competitive bidding program further limits innova-
21 tion and access to diabetes technologies.

22 (12) The Centers for Medicare & Medicaid
23 Services’ final rule entitled “Medicare and Medicaid
24 Programs; Calendar Year 2026 Home Health Pro-
25 spective Payment System (HH PPS) Rate Update;

1 Requirements for the HH Quality Reporting Pro-
2 gram and the HH Value-Based Purchasing Ex-
3 panded Model; Durable Medical Equipment, Pros-
4 thetics, Orthotics, and Supplies (DMEPOS) Com-
5 petitive Bidding Program Updates; DMEPOS Ac-
6 creditation Requirements; Provider Enrollment; and
7 Other Medicare and Medicaid Policies” (90 Fed.
8 Reg. 55342 (December 2, 2025)), which reclassifies
9 continuous glucose monitors and durable insulin
10 pumps as items requiring frequent and substantial
11 servicing when they are phased into the competitive
12 bidding program, will have numerous unintended
13 consequences that may prevent Medicare bene-
14 ficiaries from accessing the continuous glucose mon-
15 itor or durable insulin pump they need to survive.

16 (b) SENSE OF CONGRESS REGARDING AUTOMATED
17 INSULIN DELIVERY SYSTEMS.—It is the sense of Con-
18 gress that the Secretary of Health and Human Services
19 should commit to take administrative action to—

20 (1) recognize that the algorithm or software in
21 an automated insulin delivery system is a “reason-
22 able and necessary” item “for the diagnosis or treat-
23 ment of illness or injury or to improve the func-
24 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(w) of the Social
15 Security Act (42 U.S.C. 1395x(w)) 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, 2027, 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(a)(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, 2027.

8 **SEC. 4. IMPROVING 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 striking “the Secretary determines
14 appropriate” and inserting “specified in para-
15 graph (3)”; and

16 (B) by striking “the physician who is man-
17 aging the individual’s diabetic condition” and
18 inserting “a physician or qualified nonphysician
19 practitioner”;

20 (2) in paragraph (2)(B), by striking “para-
21 graph” and inserting “subparagraph”; and

22 (3) by adding at the end the following new
23 paragraph:

1 “(3) For purposes of paragraph (1) and subject to
2 subparagraph (B), the times specified in this paragraph
3 are the following:

4 “(A) An initial 10 hours of individual or group
5 educational and training services to remain available
6 until used.

7 “(B) An additional 2 hours of individual or
8 group educational and training services each year,
9 beginning with the year in which the initial 10 hours
10 described in subparagraph (A) are completed.

11 “(4) The Secretary shall not limit the quantity or du-
12 ration of educational and training services furnished by
13 a certified provider to an individual with diabetes if such
14 services are deemed medically necessary by a physician or
15 qualified non-physician practitioner.”.

16 (b) MEDICAL NUTRITION THERAPY SERVICES.—Sec-
17 tion 1861(s)(2)(V) of the Social Security Act (42 U.S.C.
18 1395x(s)(2)(V)) is amended—

19 (1) by striking clause (i);

20 (2) by redesignating clauses (ii) and (iii) as
21 clauses (i) and (ii), respectively; and

22 (3) in clause (ii), as so redesignated, by striking
23 “after consideration of” and inserting “consistent
24 with”.

1 (c) COST-SHARING.—Section 1833 of the Social Se-
2 curity Act (42 U.S.C. 1395l) is amended—

3 (1) in subsection (a)(1)—

4 (A) by striking “and (HH)” and inserting
5 “(HH)”; and

6 (B) by inserting the following before the
7 semicolon at the end: “and (II) with respect to
8 diabetes outpatient self-management training
9 services (as defined in section 1861(qq)), the
10 amount paid shall be 100 percent of the lesser
11 of the actual charge for the services or the
12 amount determined under the fee schedule that
13 applies to such services under this part;”; and
14 (2) in subsection (b), in the first sentence—

15 (A) by striking “, and (13)” and inserting
16 “(13)”; and

17 (B) by striking “1861(n)..”and inserting
18 “1861(n), and (14) such deductible shall not
19 apply with respect to diabetes outpatient self-
20 management training services (as defined in
21 section 1861(qq))”.

22 (d) APPLICATION.—The amendments made by this
23 section shall apply with respect to items and services fur-
24 nished on or after January 1, 2027.

1 **SEC. 5. CMI TESTING OF PROVIDING VIRTUAL DIABETES**
2 **OUTPATIENT SELF-MANAGEMENT TRAINING**
3 **SERVICES.**

4 Section 1115A of the Social Security Act (42 U.S.C.
5 1315a) is amended—

6 (1) in subsection (b)(2)(A), by adding at the
7 end the following new sentence: “The models se-
8 lected under this subparagraph shall include the
9 testing of the model described in subsection (h).”;
10 and

11 (2) by adding at the end the following new sub-
12 section:

13 “(h) **TESTING OF PROVIDING VIRTUAL DIABETES**
14 **OUTPATIENT SELF-MANAGEMENT TRAINING SERV-**
15 **ICES.—**

16 “(1) **ESTABLISHMENT.—**Not later than Janu-
17 ary 1, 2027, the Secretary shall implement a model
18 to test the impact of providing coverage under title
19 XVIII for virtual diabetes outpatient self-manage-
20 ment training services furnished to applicable bene-
21 ficiaries with respect to improved health outcomes
22 for such applicable beneficiaries and reduced expend-
23 itures under such title XVIII.

24 “(2) **MODEL DESIGN.—**

25 “(A) **IN GENERAL.—**The Secretary shall
26 design the model under this subsection in such

1 a manner to allow for the evaluation of demo-
2 graphic characteristics of applicable bene-
3 ficiaries participating in such model and the ex-
4 tent to which such model accomplishes the fol-
5 lowing purposes:

6 “(i) Improvement in health outcomes
7 with respect to the diabetic conditions, in-
8 cluding by reducing A1c levels.

9 “(ii) Reduced hospitalizations due to
10 diabetic-related complications.

11 “(iii) Increased utilization of diabetes
12 outpatient self-management training serv-
13 ices as evidenced by, for example, Medicare
14 beneficiary participation and utilization of
15 covered hours during the first year and
16 subsequent years or use of diabetes out-
17 patient self-management training services
18 in rural and underserved communities.

19 “(iv) Improved medication adherence.

20 “(v) Reduced expenditures under this
21 title attributable to the model.

22 “(B) CONSULTATION.—In designing the
23 model under this subsection, the Secretary
24 shall, not later than 3 months after the date of
25 the enactment of this subsection, consult with

1 stakeholders in the field of diabetes care and
2 education, clinicians in the primary care com-
3 munity, experts in digital health, and bene-
4 ficiary groups.

5 “(3) DEFINITIONS.—In this subsection:

6 “(A) APPLICABLE BENEFICIARY.—The
7 term ‘applicable beneficiary’ means an indi-
8 vidual with diabetes as described in section
9 1861(qq).

10 “(B) QUALIFIED WEB-BASED PROGRAM.—
11 The term ‘qualified web-based program’ means
12 a web-based program—

13 “(i) designed to furnish educational
14 and training services to an individual with
15 diabetes to ensure therapy compliance with
16 respect to the individual’s diabetic condi-
17 tion or to provide the individual with nec-
18 essary skills and knowledge (including
19 skills related to the self-administration of
20 injectable drugs) to participate in the indi-
21 vidual’s management of such condition;
22 and

23 “(ii) that meets the quality standards
24 described in section 1861(qq)(2)(B).

1 “(C) VIRTUAL DIABETES OUTPATIENT
2 SELF-MANAGEMENT TRAINING SERVICES.—The
3 term ‘virtual diabetes outpatient self-manage-
4 ment training services’ means any diabetes out-
5 patient self-management training services (as
6 defined in section 1861(qq)) furnished by a
7 qualified web-based program for synchronous or
8 asynchronous diabetes outpatient self-manage-
9 ment training services.”.

10 **SEC. 6. PROVIDING INSULIN PUMP TRAINING AND EDU-**
11 **CATION.**

12 (a) IN GENERAL.—Not later than January 1, 2027,
13 the Secretary of Health and Human Services (in this sec-
14 tion referred to as the “Secretary”) shall establish new
15 Healthcare Common Procedure Coding System codes
16 under the fee schedule established under section 1848(b)
17 of the Social Security Act (42 U.S.C. 1395w–4(b)) that
18 describe hook-up, calibration, and patient training with re-
19 spect to an insulin pump similar to Current Procedural
20 Terminology codes 95249 and 95250 (and any succeeding
21 codes). The Secretary shall ensure the newly established
22 codes sufficiently describe patient education and training
23 as well as insulin pump placement services for technologies
24 covered under section 1834 of the Social Security Act (42

1 U.S.C. 1395m) and part D of title XVIII of the Social
2 Security Act (42 U.S.C. 1395w–101 et seq.).

3 (b) EDUCATION AND OUTREACH.—The Secretary
4 shall use existing communications and mechanisms to pro-
5 vide education and outreach to stakeholders with respect
6 to the ability of health professionals to bill the newly es-
7 tablished codes described in subsection (a).

8 **SEC. 7. NATIONAL COVERAGE DETERMINATION ON INSU-**
9 **LIN PUMPS.**

10 Not later than 180 days after the date of enactment
11 of this Act, the Secretary of Health and Human Services
12 shall issue a proposed national coverage determination (as
13 defined in section 1869(f)(1)(B) of the Social Security Act
14 (42 U.S.C. 1395ff(f)(1)(B)) for infusion pumps, contin-
15 uous subcutaneous insulin infusion (CSII), number
16 280.14 pursuant to section 1862(l) of the Social Security
17 Act (42 U.S.C. 1395y(l)).

18 **SEC. 8. REPORT ON ENROLLEE ACCESS TO DIABETES-RE-**
19 **LATED SERVICES AND TECHNOLOGIES IN**
20 **FEDERAL HEALTH CARE PROGRAMS.**

21 (a) IN GENERAL.—Not later than 1 year after the
22 date of enactment of this Act, the Comptroller General
23 of the United States, in collaboration with the Secretary
24 of Health and Human Services, shall submit to the Com-
25 mittee on Finance and the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the Com-
2 mittee on Energy and Commerce and the Committee on
3 Ways and Means of the House of Representatives, a report
4 that assesses the barriers individuals face in accessing dia-
5 betes technologies and diabetes self-management edu-
6 cation and support services across Federal health care
7 programs. The report shall specifically review barriers,
8 which include prior authorization practices, the use of pre-
9 ferred formularies, coverage intensity limitations, and
10 other utilization management techniques, to accessing dia-
11 betes technologies and diabetes self-management edu-
12 cation and support services faced by individuals enrolled
13 in a Federal health care program, and whether any Fed-
14 eral law, regulation, or policy adversely affects access to
15 those covered services or limits the ability of individuals
16 with diabetes to receive services that align with standards
17 of care.

18 (b) DEFINITIONS.—In this section:

19 (1) DIABETES TECHNOLOGIES.—The term “di-
20 abetes technologies” means items described in sec-
21 tion 1861(w)(5)(D) of the Social Security Act, as
22 added by section 3, and any device, related supplies,
23 and software or algorithm that monitors or manages
24 an individual’s diabetes that is medically necessary
25 for the individual’s diagnosis of diabetes, regardless

1 of whether the device, related supplies, and software
2 or algorithm is covered under part B of title XVIII
3 of the Social Security Act. Such term includes glu-
4 cose monitors, insulin delivery technologies, related
5 supplies, and software or algorithms.

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

11 (3) FEDERAL HEALTH CARE PROGRAM.—The
12 term “Federal health care program” means any plan
13 or program that provides health benefits, whether
14 through insurance or otherwise, that is directly
15 funded in whole or in part, by the United States
16 Government, including a Federal health care pro-
17 gram (as defined in section 1128B(f) of the Social
18 Security Act (42 U.S.C. 1320a–7b(f))) and a health
19 benefits plan under chapter 89 of title 5, United
20 States Code.

21 **SEC. 9. ENSURING ACCESS TO DIABETES-RELATED TECH-**
22 **NOLOGIES.**

23 Section 1847(a)(2) of the Social Security Act (42
24 1395w–3(a)(2)) is amended by adding at the end the fol-
25 lowing new subparagraph:

1 “(E) CERTAIN DIABETIC-RELATED
2 ITEMS.—Continuous glucose monitors and insu-
3 lin pumps that are covered as durable medical
4 equipment under section 1861(n) furnished on
5 or after January 1, 2031.”.