## S. 814

To amend title XVIII of the Social Security Act to improve access to diabetes outpatient self-management training services, and for other purposes.

## IN THE SENATE OF THE UNITED STATES

March 14, 2019

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 amend title XVIII of the Social Security Act to improve access to diabetes outpatient self-management training services, 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 "Expanding Access to
- 5 Diabetes Self-Management Training Act of 2019".
- 6 SEC. 2. IMPROVING ACCESS TO DIABETES OUTPATIENT
- 7 SELF-MANAGEMENT TRAINING SERVICES.
- 8 (a) IN GENERAL.—Section 1861(qq) of the Social Se-
- 9 curity Act (42 U.S.C. 1395x(qq)) is amended—
- 10 (1) in paragraph (1)—

1	(A) by striking "the Secretary determines
2	appropriate" and inserting "specified in para-
3	graph (3)";
4	(B) by inserting "or qualified nonphysician
5	practitioner" after "only if the physician"; and
6	(C) by inserting "(or other physician or
7	qualified nonphysician practitioner furnishing
8	items or services to such individual, in coordina-
9	tion with the physician or qualified nonphysi-
10	cian practitioner managing such individual's di-
11	abetic condition)" after "managing the individ-
12	ual's diabetic condition";
13	(2) in paragraph (2)(B), by striking "para-
14	graph" and inserting "subparagraph"; and
15	(3) by adding at the end the following new
16	paragraphs:
17	"(3) For purposes of paragraph (1), the times speci-
18	fied in this paragraph are the following:
19	"(A) An initial 10 hours of educational and
20	training services described in paragraph (1), to re-
21	main available until used.
22	"(B) Six additional hours (or a greater number
23	of hours if determined appropriate by the Secretary)
24	of such services during the year in which the indi-
25	vidual exhausts the initial hours described in sub-

paragraph (A), provided that the physician or qualified nonphysician practitioner who is managing the individual's diabetic condition (or other physician or qualified nonphysician practitioner furnishing items or services to such individual, in coordination with the physician or qualified nonphysician practitioner managing such individual's diabetic condition) certifies the medical necessity of such additional hours.

"(C) Six additional hours (or a greater number of hours if determined appropriate by the Secretary) of such services per year for each year beginning after the year in which the individual exhausts the initial hours described in subparagraph (A), provided that the physician or qualified nonphysician practitioner who is managing the individual's diabetic condition (or other physician or qualified nonphysician practitioner furnishing items or services to such individual, in coordination with the physician or qualified nonphysician practitioner managing such individual's diabetic condition) certifies the medical necessity of such additional hours.

"(D) For a year in which the individual has received additional hours described in subparagraph (B) or (C) and exhausted such hours, an additional number of hours determined appropriate by the phy-

1 sician or qualified nonphysician practitioner who is 2 managing the individual's diabetic condition (or other physician or qualified nonphysician practi-3 tioner furnishing items or services to such individual, in coordination with the physician or quali-5 6 fied nonphysician practitioner managing such indi-7 vidual's diabetic condition), provided that the physi-8 cian or qualified nonphysician practitioner who is 9 managing the individual's diabetic condition (or 10 other physician or qualified nonphysician practi-11 tioner furnishing items or services to such indi-12 vidual, in coordination with the physician or quali-13 fied nonphysician practitioner managing such indi-14 vidual's diabetic condition) certifies that— 15

- "(i) there has been a change in the individual's diagnosis, medical condition, or treatment regimen;
- "(ii) the individual is not meeting appropriate clinical outcomes (as determined by such physician or qualified nonphysician practitioner) for such condition; or
- "(iii) the individual meets other criteria that necessitates such additional number of hours, as determined by the Secretary.

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1	"(4) For purposes of this section, the term 'qualified
2	nonphysician practitioner' means a physician assistant,
3	nurse practitioner, or clinical nurse specialist (as defined
4	in section 1861(aa)(5)).".
5	(b) Medical Nutrition Therapy Services.—Sec-
6	tion 1861(s)(2)(V) of the Social Security Act (42 U.S.C.
7	1395x(s)(2)(V)) is amended—
8	(1) by striking clause (i);
9	(2) by redesignating clauses (ii) and (iii) as
10	clauses (i) and (ii), respectively; and
11	(3) in clause (ii), as so redesignated, by striking
12	"after consideration of" and inserting "consistent
13	with".
<ul><li>13</li><li>14</li></ul>	with".  (c) Cost-Sharing.—Section 1833 of the Social Se-
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14 15	(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—
<ul><li>14</li><li>15</li><li>16</li></ul>	(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—  (1) in subsection (a)(1)—
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	<ul> <li>(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—</li> <li>(1) in subsection (a)(1)—</li> <li>(A) by striking "and (CC)" and inserting</li> </ul>
14 15 16 17 18	(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—  (1) in subsection (a)(1)—  (A) by striking "and (CC)" and inserting "(CC)"; and
14 15 16 17 18 19	<ul> <li>(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—</li> <li>(1) in subsection (a)(1)— <ul> <li>(A) by striking "and (CC)" and inserting</li> <li>"(CC)"; and</li> <li>(B) by striking the semicolon at the end</li> </ul> </li> </ul>
<ul><li>14</li><li>15</li><li>16</li><li>17</li><li>18</li><li>19</li><li>20</li></ul>	(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—  (1) in subsection (a)(1)—  (A) by striking "and (CC)" and inserting "(CC)"; and  (B) by striking the semicolon at the end and inserting ", and (DD) with respect to dia-
14 15 16 17 18 19 20 21	(c) Cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—  (1) in subsection (a)(1)—  (A) by striking "and (CC)" and inserting "(CC)"; and  (B) by striking the semicolon at the end and inserting ", and (DD) with respect to diabetes outpatient self-management training serv-

- 1 amount determined under the fee schedule that 2 applies to such services under this part;"; and 3 (2) in subsection (b), in the first sentence— 4 (A) by striking "and (10)" and inserting "(10)"; and 5 (B) by striking "1861(hhh)(1))." and in-6 7 serting "1861(hhh)(1)), and (11) such deduct-8 ible shall not apply with respect to diabetes out-9 patient self-management training services (as 10 defined in section 1861(qq))." 11 (d) REVISION OF MANUAL.—Not later than 180 days 12 after the date of the enactment of this Act, the Secretary 13 of Health and Human Services shall revise the Medicare Benefit Policy Manual to ensure that diabetes outpatient 14 15 self-management training services (as defined in section 1861(qq) of the Social Security Act (42) U.S.C. 16 1395x(qq)), as amended by subsection (a)) may be fur-17 18 nished by an entity that is a hospital outpatient depart-19 ment at alternate, nonhospital sites (including community-20 based locations). 21 (e) APPLICATION.—The amendments made by this
- 22 section shall apply with respect to items and services fur-
- nished on or after January 1, 2020.

1	SEC. 3. VIRTUAL DIABETES OUTPATIENT SELF-MANAGE-
2	MENT TRAINING SERVICES DEMONSTRATION
3	PROGRAM.
4	(a) In General.—Beginning not later than January
5	1, 2020, the Secretary of Health and Human Services (in
6	this section referred to as the "Secretary") shall select an
7	appropriate number of applicable beneficiaries to partici-
8	pate in a 2-year demonstration program to test the impact
9	of furnishing diabetes outpatient self-management train-
10	ing services through a qualified online platform with re-
11	spect to cost and clinical outcomes for such applicable
12	beneficiaries. Under such program, diabetes outpatient
13	self-management training services furnished through a
14	qualified online platform to an applicable beneficiary shall
15	be covered under title XVIII of the Social Security Act,
16	and payment for such services shall be made in the same
17	manner as payment is made under such title for such serv-
18	ices furnished in an outpatient setting.
19	(b) Definitions.—In this section:
20	(1) APPLICABLE BENEFICIARY.—The term "ap-
21	plicable beneficiary" means an individual—
22	(A) who is enrolled under part B of title
23	XVIII of the Social Security Act;
24	(B) who has a diagnosis of diabetes; and
25	(C) who agrees to take part in the dem-
26	onstration program described in subsection (a).

- (2) QUALIFIED ONLINE PLATFORM.—The term "qualified online platform" means an online-based platform—
  - (A) designed to furnish educational and training services to an individual with diabetes to ensure therapy compliance with respect to the individual's diabetic condition or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the individual's management of such condition; and
  - (B) that meets the National Standards for Diabetes Self-Management Education and Support, as jointly published by the American Association of Diabetes Educators and the American Diabetes Association.
  - (3) DIABETES SELF-MANAGEMENT TRAINING SERVICES.—The term "diabetes outpatient self-management training services" has the meaning given such term in section 1861(qq) of the Social Security Act (42 U.S.C. 1395x(qq)) except that the requirement in paragraph (1) of such section with respect to such services being furnished in an outpatient setting shall not apply.

1	(c) EVALUATION.—The Secretary shall evaluate the
2	demonstration program described in subsection (a) based
3	on the following criteria:
4	(1) The improvement, if any, in health out-
5	comes with respect to the diabetic conditions of ap-
6	plicable beneficiaries participating in such program
7	as evidenced by—
8	(A) any improvement attributable to such
9	program in the knowledge of such beneficiaries
10	with respect to such conditions;
11	(B) any behavioral changes attributable to
12	such program;
13	(C) any clinical outcome improvements at-
14	tributable to such program;
15	(D) any quality of life improvements at-
16	tributable to such program; and
17	(E) the overall satisfaction of such bene-
18	ficiaries with such program.
19	(2) Reductions, if any, in expenditures under
20	title XVIII of the Social Security Act attributable to
21	such program.
22	(3) Other criteria determined appropriate by
23	the Secretary.
24	(d) Report.—Not later than 18 months after the
25	date of the completion of the demonstration program de-

- scribed in subsection (a), the Secretary shall submit to
   Congress a report containing—
- 3 (1) the results of the evaluation described in 4 subsection (c);
- 5 (2) an analysis of the demographic characteris-6 tics of applicable beneficiaries who participated in 7 such program; and
- (3) a recommendation on whether such programshould be continued or expanded.
- 10 (e) WAIVER AUTHORITY.—The Secretary may waive
- 11 such requirements of titles XI and XVIII of the Social
- 12 Security Act (42 U.S.C. 1301 et seq., 1395 et seq.) as
- 13 may be necessary to carry out the provisions of this sec-
- 14 tion.
- 15 (f) AUTHORITY TO EXPAND DEMONSTRATION PRO-
- 16 GRAM.—Notwithstanding subsection (a), taking into ac-
- 17 count the evaluation described in subsection (c), the Sec-
- 18 retary may, through rulemaking, expand the duration and
- 19 the scope of the demonstration program described in sub-
- 20 section (a), to the extent determined appropriate by the
- 21 Secretary, if—
- 22 (1) the Secretary determines that such expan-
- sion is expected to—

1	(A) reduce spending under title XVIII of
2	the Social Security Act without reducing quality
3	of care; or
4	(B) improve the quality of care for individ-
5	uals enrolled under part B of such title without
6	increasing spending under such title;
7	(2) the Chief Actuary of the Centers for Medi-
8	care & Medicaid Services certifies that such expan-
9	sion would reduce (or would not result in any in-
10	crease in) net program spending under such title;
11	and
12	(3) the Secretary determines that such expan-
13	sion would not deny or limit the coverage or provi-
14	sion of benefits under such title for individuals en-
15	rolled under part B of such title.