

114TH CONGRESS
1ST SESSION

H. R. 1427

To amend title XVIII of the Social Security Act to specify coverage of continuous glucose monitoring devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 2015

Mr. REED (for himself, Ms. DEGETTE, and Mr. WHITFIELD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to specify coverage of continuous glucose monitoring devices, 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 “Medicare CGM Access
5 Act of 2015”.

1 **SEC. 2. MEDICARE COVERAGE OF CONTINUOUS GLUCOSE**
2 **MONITORING DEVICES.**

3 (a) IN GENERAL.—Section 1861 of the Social Secu-
4 rity Act (42 U.S.C. 1395x) is amended—

5 (1) in subsection (s)(2)—

6 (A) in subparagraph (EE), by striking
7 “and” at the end;

8 (B) in subparagraph (FF), by adding
9 “and”; and

10 (C) by adding at the end the following new
11 subparagraph:

12 “(GG) continuous glucose monitoring devices
13 (as defined in subsection (iii)(1)) furnished to a
14 CGM qualified individual (as defined in subsection
15 (iii)(2));” and

16 (2) by adding at the end the following new sub-
17 section:

18 “Continuous Glucose Monitoring Device; CGM Qualified
19 Individual

20 “(iii)(1)(A) The term ‘continuous glucose monitoring
21 device’ means a class III medical device approved by the
22 Food and Drug Administration that continuously senses
23 or continuously monitors and trends glucose levels in body
24 fluid.

25 “(B) Such term applies to such medical device—

26 “(i) as a stand-alone product;

1 “(ii) when integrated with an insulin pump; or

2 “(iii) as an integral component of any other
3 medical device cleared or approved by the Food and
4 Drug Administration, such as artificial pancreas de-
5 vice systems.

6 “(C) With respect to a continuous glucose monitoring
7 device that is described in clause (ii) or (iii) of subpara-
8 graph (B), the Secretary shall treat an insulin pump or
9 other medical device that has a continuous glucose moni-
10 toring device as an integrated or integral component as
11 a single medical device.

12 “(D) Such term includes components, accessories,
13 and supplies that are necessary and related to the oper-
14 ation of the class III medical device, such as sensors,
15 transmitters, receivers, and requisite software.

16 “(2) The term ‘CGM qualified individual’ means any
17 of the following:

18 “(A) An individual with Type I diabetes—

19 “(i) who is following an intensive insulin
20 treatment regimen that consists of 3 or more
21 insulin injections per day or the use of a sub-
22 cutaneous insulin infusion pump;

23 “(ii) subject to paragraph (3), whose at-
24 tending physician certifies that the individual’s

1 condition cannot be safely and effectively man-
2 aged with self-monitoring of blood glucose; and

3 “(iii) who—

4 “(I) has been unable to achieve opti-
5 mum glycemic control in accordance with
6 evidence-based guidelines; or

7 “(II) has experienced hypoglycemia
8 unawareness or frequent hypoglycemic epi-
9 sodes.

10 “(B) An individual not described in subpara-
11 graph (A) who meets such other medical criteria as
12 the Secretary may specify for the furnishing of a
13 continuous glucose monitoring device based on avail-
14 able medical evidence and taking into account any
15 anticipated pathway to the development of artificial
16 pancreas device systems.

17 “(C) An individual with diabetes who has been
18 regularly using a continuous glucose monitoring de-
19 vice before becoming entitled to, or enrolling in, part
20 A, or enrolling in part B, or both.

21 “(3) For purposes of a certification by an attending
22 physician described in paragraph (2)(A)(ii), such certifi-
23 cation shall not be required more frequently than once
24 every 3 years.”.

25 (b) PAYMENT.—

1 (1) IN GENERAL.—Section 1833(a)(1) of the
2 Social Security Act (42 U.S.C. 1395l(a)(1)) is
3 amended—

4 (A) by striking “and” before “(Z)”; and

5 (B) by inserting before the semicolon at
6 the end the following: “, and (AA) with respect
7 to continuous glucose monitoring devices under
8 section 1861(s)(2)(GG)), the amount paid shall
9 be an amount equal to 80 percent of the
10 amount determined under the fee schedule es-
11 tablished under section 1834(r)”.

12 (2) CONFORMING AMENDMENT.—Section 1834
13 of the Social Security Act (42 U.S.C. 1395m) is
14 amended by adding at the end the following new
15 subsection:

16 “(r) FEE SCHEDULE FOR CONTINUOUS GLUCOSE
17 MONITORING DEVICES.—

18 “(1) ESTABLISHMENT.—

19 “(A) IN GENERAL.—With respect to con-
20 tinuous glucose monitoring devices (as defined
21 in section 1861(iii)(1)) furnished during a year,
22 the amount of payment under this part for such
23 devices shall be determined under a fee schedule
24 established by the Secretary in accordance with
25 this subsection.

1 “(B) CLARIFICATION OF APPLICATION OF
2 FEE SCHEDULE TO DEVICES HAVING CGM AS AN
3 INTEGRAL COMPONENT.—Payment shall be cal-
4 culated and made under the fee schedule estab-
5 lished under this subsection for any insulin
6 pump or other medical device that has a contin-
7 uous glucose monitoring device as an integrated
8 or integral component.

9 “(2) INITIAL PAYMENT RATE.—

10 “(A) IN GENERAL.—With respect to each
11 distinct type of continuous glucose monitoring
12 device, the Secretary shall establish an initial
13 payment rate under the fee schedule established
14 under this subsection for the first year, which
15 may be a partial year, during which payment
16 may be made for such continuous glucose moni-
17 toring device under this part.

18 “(B) DATA.—With respect to a continuous
19 glucose monitoring device, the initial payment
20 rate under subparagraph (A) shall—

21 “(i) reflect market rates for such de-
22 vice; and

23 “(ii) take into account the most recent
24 available data on prices for such device.

1 “(C) ACCOUNTING FOR DIFFERENCES IN
2 FUNCTIONALITIES AMONG VARIOUS CGM DE-
3 VICES.—For purposes of the initial payment
4 rates established under subparagraph (A), the
5 Secretary shall establish a new HCPCS code for
6 each distinct type of class III medical device
7 cleared or approved by the Food and Drug Ad-
8 ministration that includes a continuous glucose
9 monitoring device, such as a medical device de-
10 scribed in clause (ii) or (iii) of section
11 1861(iii)(1)(B). Such HCPCS codes shall dis-
12 tinguish among the different functionalities of
13 such devices in a manner that reflects the clas-
14 sifications of the Food and Drug Administra-
15 tion in clearing or approving such devices.

16 “(3) UPDATES TO PAYMENT RATES.—With re-
17 spect to each year beginning after the year, or par-
18 tial year, referred to in paragraph (2)(A) during
19 which an initial payment rate is established for a
20 distinct continuous glucose monitoring device, the
21 Secretary shall provide for annual updates to the
22 payment rate under the fee schedule established
23 under this subsection for each such device for the
24 preceding year by the percentage increase in the
25 consumer price index for all urban consumers

1 (United States city average) for the 12-month period
2 ending with June of the preceding year.

3 “(4) ADJUSTMENT FOR GEOGRAPHIC VARI-
4 ATIONS.—The Secretary shall provide for adjust-
5 ments to the payment rates under the fee schedule
6 established under this subsection to take into ac-
7 count geographic variations in the prices of contin-
8 uous glucose monitoring devices.”.

9 (c) ENSURING BENEFICIARY ACCESS TO APPRO-
10 PRIATE COMPONENTS.—Section 1847(a) of the Social Se-
11 curity Act (42 U.S.C. 1395w–3(a)) is amended by adding
12 at the end the following new paragraph:

13 “(8) ENSURING BENEFICIARY ACCESS TO AP-
14 PROPRIATE COMPONENTS.—

15 “(A) IN GENERAL.—In carrying out the
16 programs under this section with respect to glu-
17 cose meters required for continuous glucose
18 monitoring devices (as defined in section
19 1861(iii)(1)) that are furnished to CGM quali-
20 fied individuals (as defined in section
21 1861(iii)(2)), the Secretary shall ensure that
22 such CGM qualified individuals are furnished
23 the brand of diabetic testing supplies (as de-
24 fined in subparagraph (B)) that function with
25 such continuous glucose monitoring devices,

1 such as in the case where there is only one
2 brand of glucose meter that is compatible with
3 a particular continuous glucose monitoring de-
4 vice.

5 “(B) DEFINITION.—In this paragraph, the
6 term ‘diabetic testing supplies’ means glucose
7 meters and diabetic testing strips.”.

8 (d) EFFECTIVE DATE; RULEMAKING.—

9 (1) EFFECTIVE DATE.—The amendments made
10 by this section shall apply to items and services fur-
11 nished on or after January 1, 2016.

12 (2) RULEMAKING.—

13 (A) IN GENERAL.—The Secretary of
14 Health and Human Services (in this paragraph
15 referred to as the “Secretary”) shall implement
16 the amendments made by this section through
17 notice and comment rulemaking.

18 (B) CONSULTATION.—As part of the rule-
19 making process under subparagraph (A), the
20 Secretary shall consult with national organiza-
21 tions representing individuals with diabetes,
22 physicians with relevant clinical expertise in en-
23 docrinology, and other relevant stakeholders to
24 develop clinical criteria for the determination of
25 whether an individual qualifies as having Type

1 I diabetes under section 1861(iii)(2)(A) of the
2 Social Security Act, as added by subsection
3 (a)(2). Not later than 60 days after the date of
4 enactment of this Act, the Secretary shall con-
5 vene a meeting of those stakeholders to develop
6 consensus recommendations for such clinical
7 criteria. The Secretary shall take such rec-
8 ommendations into account in implementing the
9 amendments made by this section.

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