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114TH CONGRESS
1ST SESSION

S. 804

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

IN THE SENATE OF THE UNITED STATES

MARCH 19, 2015

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare CGM Access Act of 2015''.

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

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

(1) in subsection (s)(2)—

(A) in subparagraph (EE), by striking ''and'' at the end;

(B) in subparagraph (FF), by adding ''and''; and

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

''(GG) continuous glucose monitoring devices (as defined in subsection (iii)(1)) furnished to a CGM qualified individual (as defined in subsection (iii)(2));''; and

(2) by adding at the end the following new subsection:

''Continuous Glucose Monitoring Device; CGM Qualified Individual

''(iii)(1)(A) The term 'continuous glucose monitoring device' means a class III medical device approved by the Food and Drug Administration that continuously senses or continuously monitors and trends glucose levels in body fluid.

''(B) Such term applies to such medical device—

''(i) as a stand-alone product;

''(ii) when integrated with an insulin pump; or

''(iii) as an integral component of any other medical device cleared or approved by the Food and

Drug Administration, such as artificial pancreas device systems.

''(C) With respect to a continuous glucose monitoring device that is described in clause (ii) or (iii) of subparagraph (B), the Secretary shall treat an insulin pump or other medical device that has a continuous glucose monitoring device as an integrated or integral component as a single medical device.

''(D) Such term includes components, accessories, and supplies that are necessary and related to the operation of the class III medical device, such as sensors, transmitters, receivers, and requisite software.

''(2) The term 'CGM qualified individual' means any of the following:

''(A) An individual with Type I diabetes—

''(i) who is following an intensive insulin treatment regimen that consists of 3 or more insulin injections per day or the use of a subcutaneous insulin infusion pump;

''(ii) subject to paragraph (3), whose attending physician certifies that the individual's condition cannot be safely and effectively managed with self-monitoring of blood glucose; and

''(iii) who—

"(I) has been unable to achieve optimum glycemic control in accordance with evidence-based guidelines; or

"(II) has experienced hypoglycemia unawareness or frequent hypoglycemic episodes.

"(B) An individual not described in subparagraph (A) who meets such other medical criteria as the Secretary may specify for the furnishing of a continuous glucose monitoring device based on available medical evidence and taking into account any anticipated pathway to the development of artificial pancreas device systems.

"(C) An individual with diabetes who has been regularly using a continuous glucose monitoring device before becoming entitled to, or enrolling in, part A, or enrolling in part B, or both.

"(3) For purposes of a certification by an attending physician described in paragraph (2)(A)(ii), such certification shall not be required more frequently than once every 3 years.".

(b) PAYMENT.—

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

(A) by striking ''and'' before ''(Z)''; and

(B) by inserting before the semicolon at the end the following: '', and (AA) with respect to continuous glucose monitoring devices under section 1861(s)(2)(GG)), the amount paid shall be an amount equal to 80 percent of the amount determined under the fee schedule established under section 1834(r)''.

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

''(r) FEE SCHEDULE FOR CONTINUOUS GLUCOSE MONITORING DEVICES.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—With respect to continuous glucose monitoring devices (as defined in section 1861(iii)(1)) furnished during a year, the amount of payment under this part for such devices shall be determined under a fee schedule established by the Secretary in accordance with this subsection.

''(B) CLARIFICATION OF APPLICATION OF FEE SCHEDULE TO DEVICES HAVING CGM AS AN INTEGRAL COMPONENT.—Payment shall be cal-

culated and made under the fee schedule established under this subsection for any insulin pump or other medical device that has a continuous glucose monitoring device as an integrated or integral component.

''(2) INITIAL PAYMENT RATE.—

''(A) IN GENERAL.—With respect to each distinct type of continuous glucose monitoring device, the Secretary shall establish an initial payment rate under the fee schedule established under this subsection for the first year, which may be a partial year, during which payment may be made for such continuous glucose monitoring device under this part.

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

''(i) reflect market rates for such device; and

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

''(C) ACCOUNTING FOR DIFFERENCES IN FUNCTIONALITIES AMONG VARIOUS CGM DEVICES.—For purposes of the initial payment rates established under subparagraph (A), the

Secretary shall establish a new HCPCS code for each distinct type of class III medical device cleared or approved by the Food and Drug Administration that includes a continuous glucose monitoring device, such as a medical device described in clause (ii) or (iii) of section 1861(iii)(1)(B). Such HCPCS codes shall distinguish among the different functionalities of such devices in a manner that reflects the classifications of the Food and Drug Administration in clearing or approving such devices.

''(3) UPDATES TO PAYMENT RATES.—With respect to each year beginning after the year, or partial year, referred to in paragraph (2)(A) during which an initial payment rate is established for a distinct continuous glucose monitoring device, the Secretary shall provide for annual updates to the payment rate under the fee schedule established under this subsection for each such device for the preceding year by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

''(4) ADJUSTMENT FOR GEOGRAPHIC VARIATIONS.—The Secretary shall provide for adjust-

ments to the payment rates under the fee schedule established under this subsection to take into account geographic variations in the prices of continuous glucose monitoring devices.''.

(c) ENSURING BENEFICIARY ACCESS TO APPROPRIATE COMPONENTS.—Section 1847(a) of the Social Security Act (42 U.S.C. 1395w–3(a)) is amended by adding at the end the following new paragraph:

''(8) ENSURING BENEFICIARY ACCESS TO APPROPRIATE COMPONENTS.—

''(A) IN GENERAL.—In carrying out the programs under this section with respect to glucose meters required for continuous glucose monitoring devices (as defined in section 1861(iii)(1)) that are furnished to CGM qualified individuals (as defined in section 1861(iii)(2)), the Secretary shall ensure that such CGM qualified individuals are furnished the brand of diabetic testing supplies (as defined in subparagraph (B)) that function with such continuous glucose monitoring devices, such as in the case where there is only one brand of glucose meter that is compatible with a particular continuous glucose monitoring device.

''(B) DEFINITION.—In this paragraph, the term 'diabetic testing supplies' means glucose meters and diabetic testing strips.''.

(d) EFFECTIVE DATE; RULEMAKING.—

(1) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2016.

(2) RULEMAKING.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this paragraph referred to as the ''Secretary'') shall implement the amendments made by this section through notice and comment rulemaking.

(B) CONSULTATION.—As part of the rulemaking process under subparagraph (A), the Secretary shall consult with national organizations representing individuals with diabetes, physicians with relevant clinical expertise in endocrinology, and other relevant stakeholders to develop clinical criteria for the determination of whether an individual qualifies as having Type I diabetes under section 1861(iii)(2)(A) of the Social Security Act, as added by subsection (a)(2). Not later than 60 days after the date of enactment of this Act, the Secretary shall con-

vene a meeting of those stakeholders to develop consensus recommendations for such clinical criteria. The Secretary shall take such recommendations into account in implementing the amendments made by this section.

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