II

116TH CONGRESS
2D SESSION

S. 3914

To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 8, 2020

Ms. MCSALLY 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 ensure prompt coverage of breakthrough devices under the Medicare program, 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 ''Ensuring Patient Access to Critical Breakthrough Products Act of 2020''.

SEC. 2. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.) is amended by adding at the end the following new section:

"SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES.

"(a) BREAKTHROUGH DEVICES.—

"(1) IN GENERAL.—For purposes of this section, the term 'breakthrough device' means a medical device that is a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) and that is—

"(A) provided with review priority by the Secretary under subsection (d)(5) of section 515 of such Act; and

"(B) approved or cleared pursuant to section 510(k), 513(f), or 515 of such Act for use in treating an indication on or after July 1, 2019.

Such term also includes a breakthrough device that is a specified breakthrough device (as defined in subsection (e)(1)(B)) approved or cleared pursuant to section 510(k), 513(f), or 515 of such Act for use in treating an indication on or after December 1, 2018.

"(2) LIMITATION ON NUMBER OF 510(k) DEVICES.—With respect to a 5-year period, in no case may more than five medical devices described in paragraph (1) that are classified under section 510(k) of the Federal Food, Drug, and Cosmetic

Act be covered and paid for under this title by reason of this section during each such 5-year period.

''(b) COVERAGE.—

''(1) TRANSITIONAL COVERAGE.—

''(A) IN GENERAL.—During the transitional coverage period (as defined in subparagraph (B)) a breakthrough device shall be—

''(i) deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

''(ii) deemed to be a medical or other health service for purposes of section 1861(s);

''(iii) deemed to be approved for an additional payment under section 1886(d)(5)(K) (other than with respect to the cost criterion under clause (ii)(I) of such section);

''(iv) deemed to be approved for pass-through payment under section 1833(t)(6) and section 1833(i) (other than with respect to the cost criterion under section 1833(t)(6)(A)(iv)); and

''(v) insofar as such breakthrough device may be furnished in a setting for

which payment is made under an applicable payment system described in subparagraphs (D) through (L) of subsection (c)(4), deemed eligible for an additional payment or payment adjustment, as the case may be, pursuant to subsection (d)(3) when furnished in a setting for which payment is made under such an applicable payment system during such transitional coverage period.

''(B) TRANSITIONAL COVERAGE PERIOD DEFINED.—As used in this section, the term 'transitional coverage period' means, with respect to a breakthrough device, the period that—

''(i) begins on the date of the approval under section 515 of the Federal Food, Drug, and Cosmetic Act or of the clearance under section 510(k) of such Act, as applicable, of such device by the Secretary for the indication described in subsection (a)(1); and

''(ii) ends on the last day of the 3-year period that begins on the date that the Secretary, pursuant to subsection

(c)(2), updates the relevant applicable payment system (as defined in subsection (c)(4)) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device, except as provided in subsections (d)(1)(B) and (d)(2)(B).

''(C) DATA USED TO MEET THE NTAP AND PASS-THROUGH COST CRITERIA.—In determining whether a breakthrough device qualifies for an additional payment under section 1886(d)(5)(K) or for pass-through payment under section 1833(t)(6) or section 1833(i), the Secretary shall use the most recently available data and information on the costs of such breakthrough device, which may include list prices and invoice prices charged for such breakthrough device.

''(2) PROCESS FOR REGULAR COVERAGE.—For purposes of the application of section 1862(a)(1)(A) to a breakthrough device furnished after the transitional coverage period (as defined in paragraph (1)(B)) for such device, the Secretary shall establish a process for the coverage of such breakthrough devices under this title after such period as follows:

"(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—

"(i) IN GENERAL.—With respect to a breakthrough device, not later than 1 year after the date of the approval of such device under section 515 of the Federal Food, Drug, and Cosmetic Act or of the clearance of such device under section 510(k) of such Act, as applicable, the Secretary shall identify whether any additional data or evidence is required with respect to any indications for such device for purposes of the application of such section 1862(a)(1)(A) to such device for such indications.

"(ii) NON-DUPLICATION OF DATA REQUESTS.—In carrying out clause (i) with respect to a breakthrough device, the Secretary shall ensure that data or evidence identified—

"(I) does not duplicate data required to be collected by the Food and Drug Administration with respect to such breakthrough device;

"(II) minimizes the administrative burdens of data collection and reporting on providers of services, suppliers, and manufacturers of breakthrough devices; and

"(III) is not otherwise unnecessary or redundant.

"(B) PROPOSAL FOR COVERAGE AFTER THE TRANSITIONAL COVERAGE PERIOD.—Not later than 2 years after the date of the approval or clearance of a breakthrough device by the Food and Drug Administration, the Secretary shall develop a proposal for coverage under this title of such breakthrough device for such indications as the Secretary determines to be appropriate, based on the data and evidence collected under subparagraph (A), for such devices furnished after the transitional coverage period under paragraph (1) for such device. If the Secretary does not, on a date that is before the end of such 2-year period, take action to modify the indications for which coverage of a breakthrough device may be provided under this title after such period, for purposes of section 1862(a)(1)(A) coverage under this title of such

breakthrough device shall be made for all indications for which such device is approved under section 515 of the Federal Food, Drug, and Cosmetic Act or cleared under section 510(k) of such Act.

''(3) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(A) affect the ability of the manufacturer of a breakthrough device to seek approval for pass-through payment status under section 1833(t)(6) or to seek approval for an additional payment under section 1886(d)(5)(K) insofar as such breakthrough device does not qualify for transitional coverage under paragraph (1); or

''(B) affect the application and approval process for pass-through payment status under section 1833(t)(6) or for an additional payment under section 1886(d)(5)(K) in the case of a medical device that is not approved by the Food and Drug Administration as a breakthrough device.

''(c) CODING.—

''(1) PROMPT ASSIGNMENT.—Not later than three months after the date of approval or clearance

of a breakthrough device by the Food and Drug Administration, subject to subsection (b)(1)(B), the Secretary shall assign a unique temporary or permanent code or codes for purposes of coverage and payment for such breakthrough device under the applicable payment systems (described in paragraph (4)).

''(2) UPDATES.—

''(A) IPPS.—The Secretary shall provide for semiannual updates under the applicable payment system described in paragraph (4)(A) (relating to the inpatient hospital prospective payment system) to recognize the code or codes assigned under paragraph (1).

''(B) OPPS.—The Secretary shall provide for quarterly updates under the applicable payment system described in paragraph (4)(B) (relating to the outpatient hospital prospective payment system) to recognize the code or codes assigned under paragraph (1).

''(C) OTHER PAYMENT SYSTEMS.—The Secretary shall provide for semiannual or quarterly updates, as the case may be, under the applicable payment systems described in subparagraphs (C) through (L) of paragraph (4) to rec-

ognize the code or codes assigned under paragraph (1).

''(3) TRANSPARENCY.—The process for the assignment of a code or codes under this subsection shall provide for public notice and a meaningful opportunity for public comment from affected parties.

''(4) APPLICABLE PAYMENT SYSTEMS DESCRIBED.—For purposes of this subsection, the term 'applicable payment systems' means—

''(A) with respect to inpatient hospital services, the prospective payment system for inpatient hospital services established under section 1886(d);

''(B) with respect to outpatient hospital services, the prospective payment system for covered OPD services established under section 1833(t);

''(C) with respect to ambulatory surgical center services, the fee schedule for such services established under section 1833(i);

''(D) with respect to physicians' services, the physician fee schedules established under section 1848;

"(E) with respect to covered items of durable medical equipment, the applicable fee schedules established under section 1834;

"(F) with respect to diagnostic laboratory tests, the payment amounts under section 1834A and the fee schedules establish under section 1848, as the case may be;

"(G) with respect to renal dialysis services furnished by a provider of services or a renal dialysis facility, the single payment system established under section 1881(b)(14);

"(H) with respect to inpatient hospital services furnished by rehabilitation facilities, the prospective payment system established under section 1886(j);

"(I) with respect to inpatient hospital services furnished by long-term care hospitals, the prospective payment system under section 1886(m);

"(J) with respect to inpatient hospital services furnished by psychiatric hospitals and psychiatric units, the prospective payment system under section 1886(s);

''(K) with respect to home health services, the prospective payment system under section 1895; and

''(L) with respect to items and services, or a provider of services or supplier, not described in subparagraphs (A) through (K), the payment system established under this title for such items and services when furnished by such provider of services or supplier.

''(d) PAYMENT.—

''(1) INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM: DEEMED ELIGIBILITY FOR BREAKTHROUGH PAYMENT.—The Secretary shall deem each breakthrough device as approved for an additional payment under section 1886(d)(5)(K) for the 3-year period that begins—

''(A) except as provided in subparagraph (B), on the date that the Secretary, pursuant to subsection (c)(2)(A), updates the payment system under section 1886(d) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device; or

''(B) in the case of a device that has not received approval or clearance as a break-

through device by the Food and Drug Administration before such payment system is updated under subsection (c)(2)(A) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such device, on the date of such approval or clearance.

Nothing in this paragraph shall be construed to affect the authority of the Secretary to use claims data to establish new diagnosis or procedure codes for breakthrough devices or to identify appropriate diagnosis-related groups for the assignment of breakthrough devices under annual rulemaking to carry out section 1886(d)(5)(K).

''(2) OUTPATIENT PROSPECTIVE PAYMENT SYSTEM: DEEMED ELIGIBILITY FOR PASS-THROUGH PAYMENT.—The Secretary shall deem each breakthrough device as approved for pass-through payment under section 1833(t)(6) (including for purposes of section 1833(i)(2)(D)) during the 3-year period that begins—

''(A) except as provided in subparagraph (B), on the date that the Secretary, pursuant to subsection (c)(2)(B), updates the payment system under section 1833(t) to recognize the unique temporary or permanent code or codes

assigned under subsection (c)(1) to such breakthrough device; or

"(B) in the case of a device that has not received approval or clearance as a breakthrough device by the Food and Drug Administration before such payment system is updated under subsection (c)(2)(B) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such device, on the date of such approval or clearance.

Nothing in this paragraph shall be construed to affect the authority of the Secretary to use claims data to establish new ambulatory payment classification groups for breakthrough devices or to revise such groups to take into account breakthrough devices under annual rulemaking to carry out section 1833(t).

"(3) OTHER PAYMENT SYSTEMS.—

"(A) IN GENERAL.—In the case of a breakthrough device that is furnished and for which payment may be made under the payment system established under section 1834, 1834A, 1848, 1881(b)(14), 1886(j), 1886(m), 1886(s), or 1895, or any other provision of this title (other than sections 1833(i), 1833(t), and

1886(d)), the Secretary shall provide for an additional payment for such breakthrough device under such applicable payment system or an adjustment to such applicable payment system, as the case may be. The payment basis for such additional payment or adjustment, as the case may be, shall equal an amount that the Secretary determines covers the costs of such breakthrough device.

''(B) COST INFORMATION.—In determining the costs of a breakthrough device for purposes of determining an additional payment or payment adjustment under subparagraph (A), the Secretary shall use the most recently available data and information on the costs of such breakthrough device, which may include list prices and invoice prices charged for such breakthrough device.

''(C) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to affect the authority of the Secretary to use claims data to establish new or modify existing ambulatory payment classification groups, diagnosis-related groups, level II HCPCS codes, or such other groups or codes as the Secretary may es-

tablish under the annual rulemaking authority under the provisions referred to in subparagraph (A).

"(D) CLINICAL DIAGNOSTIC LABORATORY TESTS.—An additional payment or payment adjustment under subparagraph (A) for a breakthrough device under the applicable payment system established in section 1834A may be in the form of an increase to the amount determined for the breakthrough device using crosswalking under section 1834A(c)(1)(A), an extension of the initial period of payment applicable to advance diagnostic laboratory tests under section 1834A(d)(1)(A), and in such other form or manner as the Secretary determines reflects the costs for such breakthrough device under the relevant provisions of section 1834A.

"(4) PAYMENT FOR BREAKTHROUGH DEVICES AFTER THE TRANSITIONAL COVERAGE PERIOD.—Payment for a breakthrough device that is furnished after the conclusion of the transitional coverage period under subsection (b)(1) for such device shall be made pursuant to the applicable payment system involved, taking into account the additional evidence and data collected under subsection (b)(2).

''(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH DEVICES.—

''(1) COVERAGE OF SPECIFIED BREAKTHROUGH DEVICES.—

''(A) IN GENERAL.—Subject to the succeeding provisions of this subsection and notwithstanding any other provision of law, the Secretary shall provide for coverage and payment pursuant to this section of a specified breakthrough device (as defined in subparagraph (B)).

''(B) SPECIFIED BREAKTHROUGH DEVICE DEFINED.—In this section, the term 'specified breakthrough device' means a breakthrough device with respect to which no Medicare benefit category exists.

''(2) PERIOD OF TRANSITIONAL COVERAGE.—

''(A) IN GENERAL.—Subject to subparagraph (C), the provisions of subsection (b)(1) (relating to the transitional coverage period and payment for breakthrough devices, including the use of the most recently available data and information on costs) shall apply to a specified breakthrough device in the same manner as such provisions apply to a breakthrough device.

The Secretary may use methodologies under existing payment systems established under this title, may provide for appropriate adjustments to such methodologies, or may establish a new payment methodology under this title, to provide for payment for a specified breakthrough device to ensure the payment basis for such payment covers costs of the specified breakthrough device.

''(B) REPORT.—

''(i) IN GENERAL.—With respect to each specified breakthrough device, the Secretary shall submit to Congress a report on the coverage of and payment for such specified breakthrough device under this section that includes the following information:

''(I) The manner in which coverage is provided and payment is made for the specified breakthrough device, including how such device was classified (such as an item of durable medical equipment or otherwise) and the payment methodology the Sec-

retary applied with respect to such device.

''(II) The impact of the availability of the specified breakthrough device to Medicare beneficiaries, including impacts on the quality of patient care, patient outcomes, and patient experience.

''(III) The impact of the availability of the specified breakthrough device to Medicare beneficiaries on program expenditures under this title.

''(IV) Such other information as the Secretary determines to be appropriate.

''(ii) DEADLINE.—

''(I) IN GENERAL.—Except as provided in subclause (II), the Secretary shall submit a report required under this subparagraph no later than the end of the transitional period of coverage and payment applicable to such specified breakthrough device.

''(II) EXTENSION TO GENERATE ADDITIONAL DATA.—If the Secretary

determines that additional data or evidence is required to complete a report required under this subparagraph with respect to a specified breakthrough device, the deadline under this clause may be extended for an additional two years.

''(C) ADDITIONAL PERIOD OF TRANSITIONAL COVERAGE TO DEVELOP ADDITIONAL DATA.—Insofar as the Secretary determines that additional data or evidence is required to complete a report required under subparagraph (B) with respect to a specified breakthrough device, the transitional coverage period of coverage and payment for such device shall be extended by the lesser of—

''(i) two years; or

''(ii) the amount of additional time required for the submission of the report with respect to such device.

''(3) COVERAGE AND PAYMENT AFTER THE TRANSITIONAL PERIOD.—The Secretary may continue to provide for coverage of and payment for a specified breakthrough device after the end of the transitional period of coverage and payment for

breakthrough devices through the national coverage determination process if the Secretary determines that the specified breakthrough device—

"(A) improves the quality of care and patient outcomes;

"(B) improves the delivery of care; or

"(C) reduces spending under this title without reducing the quality of care.".

(b) STUDY OF LIMIT ON 510(k) BREAKTHROUGH DEVICES.—

(1) STUDY.—The Secretary of Health and Human Services shall conduct a study on the effect of the limit under section 1899C(a)(2) of the Social Security Act, as added by subsection (a), on the number of devices cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) that are breakthrough devices for purposes of such section 1899C.

(2) MATTERS EXAMINED.—In conducting the study described in paragraph (1), the Secretary shall—

(A) determine the number of medical devices cleared under such section 510(k) during the 5-year period beginning on the date of the enactment of this Act;

(B) determine the number of such devices that were not included as breakthrough devices for purposes of such section 1899C by reason of the limitation under subsection (a)(2) of such section; and

(C) examine the impact of such limitation on access to such devices for individuals entitled to benefits under part A or enrolled in part B of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or both.

(3) REPORT.—Not later than 6 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under this subsection and shall include such recommendations for legislative or administrative changes as the Secretary determines to be appropriate.

(c) CLARIFICATION REGARDING CERTAIN PAYMENTS.—

(1) IPPS NEW TECHNOLOGY PAYMENT.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

''(x) During the period with respect to which a new medical service or technology is eligible for an additional

payment under this subsection by reason of this subparagraph, any local coverage determination (as defined in section 1869(f)(2)(B)) that would affect the coverage of, or the additional payment under this subsection for, such new medical service or technology shall have no force or effect in law or regulation.''.

(2) OPPS PASS-THROUGH PAYMENT.—Section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

''(K) PROHIBITION ON USE OF LOCAL COVERAGE DETERMINATIONS TO AFFECT COVERAGE OF AND PAYMENT FOR PASS-THROUGH PRODUCTS.—During the period with respect to which a drug, biological, or medical device is eligible for an additional payment under this paragraph, any local coverage determination (as defined in section 1869(f)(2)(B)) that would affect the coverage of, or the additional payment under this paragraph for, such drug, biological, or medical device shall have no force or effect in law or regulation.''.

(3) EFFECTIVE DATE.—This subsection, and the amendments made by this subsection, shall apply with respect to items and services furnished on or

after the date of the enactment of this Act, including any such item or service that is eligible on such date for an additional payment under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) by reason of paragraph (5)(K) of such section or under section 1833(t)(6) of such Act (42 U.S.C. 1395ww(t)(6)), or that would have been so eligible on such date but for a local coverage determination that limits or denies coverage of and such additional payment for the item or service.

(d) CONFORMING AMENDMENTS.—

(1) INPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)), as amended by subsection (c)(1), is amended by adding at the end the following new clause:

''(xi) Effective for discharges occurring on or after October 1, 2020, in the case of a new medical service or technology that is a breakthrough device (as defined in section 1899C(a)), the additional payment established for such breakthrough device under this subparagraph shall be made for the 3-year period applicable to such breakthrough device under section 1899C(d)(1). In determining the amount of the additional payment for a breakthrough device under this subparagraph during such 3-year period,

the Secretary shall apply section 412.88(b) of title 42, Code of Federal Regulations (or any successor regulation), as if the reference to '50 percent' in such section were a reference to '80 percent'.''.

(2) OUTPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C. 1395l(t)(6)(C)) is amended by adding at the end the following new clause:

''(iii) SPECIAL RULE FOR BREAKTHROUGH DEVICES.—Notwithstanding clause (i) or (ii), or any other provision of this paragraph to the contrary, in the case of a breakthrough device (as defined in section 1899C(a)) that is furnished on or after January 1, 2021, payment under this paragraph for such breakthrough device shall be made for the 3-year period applicable to such breakthrough device under section 1899C(d)(2). The provisions of this clause shall also apply for purposes of transitional pass-through payment under section 1833(i)(2)(D).''.

(3) COMPETITIVE BIDDING PROGRAM.—Section 1847(a) of such Act (42 U.S.C. 1395w–3(a)) is amended—

(A) in paragraph (2)(A)—

(i) by striking ''and excluding drugs'' and inserting ''excluding drugs''; and

(ii) by inserting before the period at the end the following: '', and excluding breakthrough devices (as defined in section 1899C(a))''; and

(B) in paragraph (7), by adding at the end the following new subparagraph:

''(C) BREAKTHROUGH DEVICES.—A breakthrough device described in paragraph (2)(A) that is furnished during the transitional coverage period (as defined in section 1899C(b)(1)(B)) applicable to such device under section 1899C.''.

(e) EFFECTIVE DATE.—This section, and the amendments made by this section, shall take effect on the date of the enactment of this Act and, unless otherwise specified in this section (or in an amendment made by this section), shall apply to breakthrough devices (as defined in section 1899C(a) of the Social Security Act, as added by subsection (a)), approved or cleared on or after July 1, 2019, or, in the case of a specified breakthrough device

(as defined in such section as so added), approved or cleared on or after December 1, 2018.

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