

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

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.

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 “Ensuring Patient Ac-
5 cess to Critical Breakthrough Products Act of 2020”.

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

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

1 **“SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES.**

2 “(a) BREAKTHROUGH DEVICES.—

3 “(1) IN GENERAL.—For purposes of this sec-
4 tion, the term ‘breakthrough device’ means a med-
5 ical device that is a device (as defined in section 201
6 of the Federal Food, Drug, and Cosmetic Act) and
7 that is—

8 “(A) provided with review priority by the
9 Secretary under subsection (d)(5) of section
10 515 of such Act; and

11 “(B) approved or cleared pursuant to sec-
12 tion 510(k), 513(f), or 515 of such Act for use
13 in treating an indication on or after July 1,
14 2019.

15 Such term also includes a breakthrough device that
16 is a specified breakthrough device (as defined in sub-
17 section (e)(1)(B)) approved or cleared pursuant to
18 section 510(k), 513(f), or 515 of such Act for use
19 in treating an indication on or after December 1,
20 2018.

21 “(2) LIMITATION ON NUMBER OF 510(k) DE-
22 VICES.—With respect to a 5-year period, in no case
23 may more than five medical devices described in
24 paragraph (1) that are classified under section
25 510(k) of the Federal Food, Drug, and Cosmetic

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

3 “(b) COVERAGE.—

4 “(1) TRANSITIONAL COVERAGE.—

5 “(A) IN GENERAL.—During the transi-
6 tional coverage period (as defined in subpara-
7 graph (B)) a breakthrough device shall be—

8 “(i) deemed to be reasonable and nec-
9 essary for purposes of section
10 1862(a)(1)(A);

11 “(ii) deemed to be a medical or other
12 health service for purposes of section
13 1861(s);

14 “(iii) deemed to be approved for an
15 additional payment under section
16 1886(d)(5)(K) (other than with respect to
17 the cost criterion under clause (ii)(I) of
18 such section);

19 “(iv) deemed to be approved for pass-
20 through payment under section 1833(t)(6)
21 and section 1833(i) (other than with re-
22 spect to the cost criterion under section
23 1833(t)(6)(A)(iv)); and

24 “(v) insofar as such breakthrough de-
25 vice may be furnished in a setting for

1 which payment is made under an applica-
2 ble payment system described in subpara-
3 graphs (D) through (L) of subsection
4 (c)(4), deemed eligible for an additional
5 payment or payment adjustment, as the
6 case may be, pursuant to subsection (d)(3)
7 when furnished in a setting for which pay-
8 ment is made under such an applicable
9 payment system during such transitional
10 coverage period.

11 “(B) TRANSITIONAL COVERAGE PERIOD
12 DEFINED.—As used in this section, the term
13 ‘transitional coverage period’ means, with re-
14 spect to a breakthrough device, the period
15 that—

16 “(i) begins on the date of the approval
17 under section 515 of the Federal Food,
18 Drug, and Cosmetic Act or of the clear-
19 ance under section 510(k) of such Act, as
20 applicable, of such device by the Secretary
21 for the indication described in subsection
22 (a)(1); and

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

1 (c)(2), updates the relevant applicable pay-
2 ment system (as defined in subsection
3 (c)(4)) to recognize the unique temporary
4 or permanent code or codes assigned under
5 subsection (c)(1) to such breakthrough de-
6 vice, except as provided in subsections
7 (d)(1)(B) and (d)(2)(B).

8 “(C) DATA USED TO MEET THE NTAP AND
9 PASS-THROUGH COST CRITERIA.—In deter-
10 mining whether a breakthrough device qualifies
11 for an additional payment under section
12 1886(d)(5)(K) or for pass-through payment
13 under section 1833(t)(6) or section 1833(i), the
14 Secretary shall use the most recently available
15 data and information on the costs of such
16 breakthrough device, which may include list
17 prices and invoice prices charged for such
18 breakthrough device.

19 “(2) PROCESS FOR REGULAR COVERAGE.—For
20 purposes of the application of section 1862(a)(1)(A)
21 to a breakthrough device furnished after the transi-
22 tional coverage period (as defined in paragraph
23 (1)(B)) for such device, the Secretary shall establish
24 a process for the coverage of such breakthrough de-
25 vices under this title after such period as follows:

1 “(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—
2

3 “(i) IN GENERAL.—With respect to a
4 breakthrough device, not later than 1 year
5 after the date of the approval of such de-
6 vice under section 515 of the Federal
7 Food, Drug, and Cosmetic Act or of the
8 clearance of such device under section
9 510(k) of such Act, as applicable, the Sec-
10 retary shall identify whether any additional
11 data or evidence is required with respect to
12 any indications for such device for pur-
13 poses of the application of such section
14 1862(a)(1)(A) to such device for such indi-
15 cations.

16 “(ii) NON-DUPLICATION OF DATA RE-
17 QUESTS.—In carrying out clause (i) with
18 respect to a breakthrough device, the Sec-
19 retary shall ensure that data or evidence
20 identified—

21 “(I) does not duplicate data re-
22 quired to be collected by the Food and
23 Drug Administration with respect to
24 such breakthrough device;

1 “(II) minimizes the administra-
2 tive burdens of data collection and re-
3 porting on providers of services, sup-
4 pliers, and manufacturers of break-
5 through devices; and

6 “(III) is not otherwise unneces-
7 sary or redundant.

8 “(B) PROPOSAL FOR COVERAGE AFTER
9 THE TRANSITIONAL COVERAGE PERIOD.—Not
10 later than 2 years after the date of the approval
11 or clearance of a breakthrough device by the
12 Food and Drug Administration, the Secretary
13 shall develop a proposal for coverage under this
14 title of such breakthrough device for such indi-
15 cations as the Secretary determines to be ap-
16 propriate, based on the data and evidence col-
17 lected under subparagraph (A), for such devices
18 furnished after the transitional coverage period
19 under paragraph (1) for such device. If the Sec-
20 retary does not, on a date that is before the end
21 of such 2-year period, take action to modify the
22 indications for which coverage of a break-
23 through device may be provided under this title
24 after such period, for purposes of section
25 1862(a)(1)(A) coverage under this title of such

1 breakthrough device shall be made for all indi-
2 cations for which such device is approved under
3 section 515 of the Federal Food, Drug, and
4 Cosmetic Act or cleared under section 510(k) of
5 such Act.

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

8 “(A) affect the ability of the manufacturer
9 of a breakthrough device to seek approval for
10 pass-through payment status under section
11 1833(t)(6) or to seek approval for an additional
12 payment under section 1886(d)(5)(K) insofar
13 as such breakthrough device does not qualify
14 for transitional coverage under paragraph (1);
15 or

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

23 “(c) CODING.—

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

1 of a breakthrough device by the Food and Drug Ad-
2 ministration, subject to subsection (b)(1)(B), the
3 Secretary shall assign a unique temporary or perma-
4 nent code or codes for purposes of coverage and pay-
5 ment for such breakthrough device under the appli-
6 cable payment systems (described in paragraph (4)).

7 “(2) UPDATES.—

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

14 “(B) OPPI.—The Secretary shall provide
15 for quarterly updates under the applicable pay-
16 ment system described in paragraph (4)(B) (re-
17 lating to the outpatient hospital prospective
18 payment system) to recognize the code or codes
19 assigned under paragraph (1).

20 “(C) OTHER PAYMENT SYSTEMS.—The
21 Secretary shall provide for semiannual or quar-
22 terly updates, as the case may be, under the ap-
23 plicable payment systems described in subpara-
24 graphs (C) through (L) of paragraph (4) to rec-

1 ognize the code or codes assigned under para-
2 graph (1).

3 “(3) TRANSPARENCY.—The process for the as-
4 signment of a code or codes under this subsection
5 shall provide for public notice and a meaningful op-
6 portunity for public comment from affected parties.

7 “(4) APPLICABLE PAYMENT SYSTEMS DE-
8 SCRIBED.—For purposes of this subsection, the term
9 ‘applicable payment systems’ means—

10 “(A) with respect to inpatient hospital
11 services, the prospective payment system for in-
12 patient hospital services established under sec-
13 tion 1886(d);

14 “(B) with respect to outpatient hospital
15 services, the prospective payment system for
16 covered OPD services established under section
17 1833(t);

18 “(C) with respect to ambulatory surgical
19 center services, the fee schedule for such serv-
20 ices established under section 1833(i);

21 “(D) with respect to physicians’ services,
22 the physician fee schedules established under
23 section 1848;

1 “(E) with respect to covered items of dura-
2 ble medical equipment, the applicable fee sched-
3 ules established under section 1834;

4 “(F) with respect to diagnostic laboratory
5 tests, the payment amounts under section
6 1834A and the fee schedules establish under
7 section 1848, as the case may be;

8 “(G) with respect to renal dialysis services
9 furnished by a provider of services or a renal
10 dialysis facility, the single payment system es-
11 tablished under section 1881(b)(14);

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

16 “(I) with respect to inpatient hospital serv-
17 ices furnished by long-term care hospitals, the
18 prospective payment system under section
19 1886(m);

20 “(J) with respect to inpatient hospital
21 services furnished by psychiatric hospitals and
22 psychiatric units, the prospective payment sys-
23 tem under section 1886(s);

1 “(K) with respect to home health services,
2 the prospective payment system under section
3 1895; and

4 “(L) with respect to items and services, or
5 a provider of services or supplier, not described
6 in subparagraphs (A) through (K), the payment
7 system established under this title for such
8 items and services when furnished by such pro-
9 vider of services or supplier.

10 “(d) PAYMENT.—

11 “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-
12 MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-
13 THROUGH PAYMENT.—The Secretary shall deem
14 each breakthrough device as approved for an addi-
15 tional payment under section 1886(d)(5)(K) for the
16 3-year period that begins—

17 “(A) except as provided in subparagraph
18 (B), on the date that the Secretary, pursuant to
19 subsection (c)(2)(A), updates the payment sys-
20 tem under section 1886(d) to recognize the
21 unique temporary or permanent code or codes
22 assigned under subsection (c)(1) to such break-
23 through device; or

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

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

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

14 “(2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
15 TEM: DEEMED ELIGIBILITY FOR PASS-THROUGH
16 PAYMENT.—The Secretary shall deem each break-
17 through device as approved for pass-through pay-
18 ment under section 1833(t)(6) (including for pur-
19 poses of section 1833(i)(2)(D)) during the 3-year pe-
20 riod that begins—

21 “(A) except as provided in subparagraph
22 (B), on the date that the Secretary, pursuant to
23 subsection (c)(2)(B), updates the payment sys-
24 tem under section 1833(t) to recognize the
25 unique temporary or permanent code or codes

1 assigned under subsection (c)(1) to such break-
2 through device; or

3 “(B) in the case of a device that has not
4 received approval or clearance as a break-
5 through device by the Food and Drug Adminis-
6 tration before such payment system is updated
7 under subsection (c)(2)(B) to recognize the
8 unique temporary or permanent code or codes
9 assigned under subsection (c)(1) to such device,
10 on the date of such approval or clearance.

11 Nothing in this paragraph shall be construed to af-
12 fect the authority of the Secretary to use claims
13 data to establish new ambulatory payment classifica-
14 tion groups for breakthrough devices or to revise
15 such groups to take into account breakthrough de-
16 vices under annual rulemaking to carry out section
17 1833(t).

18 “(3) OTHER PAYMENT SYSTEMS.—

19 “(A) IN GENERAL.—In the case of a
20 breakthrough device that is furnished and for
21 which payment may be made under the pay-
22 ment system established under section 1834,
23 1834A, 1848, 1881(b)(14), 1886(j), 1886(m),
24 1886(s), or 1895, or any other provision of this
25 title (other than sections 1833(i), 1833(t), and

1 1886(d)), the Secretary shall provide for an ad-
2 ditional payment for such breakthrough device
3 under such applicable payment system or an
4 adjustment to such applicable payment system,
5 as the case may be. The payment basis for such
6 additional payment or adjustment, as the case
7 may be, shall equal an amount that the Sec-
8 retary determines covers the costs of such
9 breakthrough device.

10 “(B) COST INFORMATION.—In determining
11 the costs of a breakthrough device for purposes
12 of determining an additional payment or pay-
13 ment adjustment under subparagraph (A), the
14 Secretary shall use the most recently available
15 data and information on the costs of such
16 breakthrough device, which may include list
17 prices and invoice prices charged for such
18 breakthrough device.

19 “(C) RULE OF CONSTRUCTION.—Nothing
20 in this paragraph shall be construed to affect
21 the authority of the Secretary to use claims
22 data to establish new or modify existing ambu-
23 latory payment classification groups, diagnosis-
24 related groups, level II HCPCS codes, or such
25 other groups or codes as the Secretary may es-

1 tablish under the annual rulemaking authority
2 under the provisions referred to in subpara-
3 graph (A).

4 “(D) CLINICAL DIAGNOSTIC LABORATORY
5 TESTS.—An additional payment or payment ad-
6 justment under subparagraph (A) for a break-
7 through device under the applicable payment
8 system established in section 1834A may be in
9 the form of an increase to the amount deter-
10 mined for the breakthrough device using cross-
11 walking under section 1834A(c)(1)(A), an ex-
12 tension of the initial period of payment applica-
13 ble to advance diagnostic laboratory tests under
14 section 1834A(d)(1)(A), and in such other form
15 or manner as the Secretary determines reflects
16 the costs for such breakthrough device under
17 the relevant provisions of section 1834A.

18 “(4) PAYMENT FOR BREAKTHROUGH DEVICES
19 AFTER THE TRANSITIONAL COVERAGE PERIOD.—
20 Payment for a breakthrough device that is furnished
21 after the conclusion of the transitional coverage pe-
22 riod under subsection (b)(1) for such device shall be
23 made pursuant to the applicable payment system in-
24 volved, taking into account the additional evidence
25 and data collected under subsection (b)(2).

1 “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH
2 DEVICES.—

3 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH
4 DEVICES.—

5 “(A) IN GENERAL.—Subject to the suc-
6 ceeding provisions of this subsection and not-
7 withstanding any other provision of law, the
8 Secretary shall provide for coverage and pay-
9 ment pursuant to this section of a specified
10 breakthrough device (as defined in subpara-
11 graph (B)).

12 “(B) SPECIFIED BREAKTHROUGH DEVICE
13 DEFINED.—In this section, the term ‘specified
14 breakthrough device’ means a breakthrough de-
15 vice with respect to which no Medicare benefit
16 category exists.

17 “(2) PERIOD OF TRANSITIONAL COVERAGE.—

18 “(A) IN GENERAL.—Subject to subpara-
19 graph (C), the provisions of subsection (b)(1)
20 (relating to the transitional coverage period and
21 payment for breakthrough devices, including the
22 use of the most recently available data and in-
23 formation on costs) shall apply to a specified
24 breakthrough device in the same manner as
25 such provisions apply to a breakthrough device.

1 The Secretary may use methodologies under ex-
2 isting payment systems established under this
3 title, may provide for appropriate adjustments
4 to such methodologies, or may establish a new
5 payment methodology under this title, to pro-
6 vide for payment for a specified breakthrough
7 device to ensure the payment basis for such
8 payment covers costs of the specified break-
9 through device.

10 “(B) REPORT.—

11 “(i) IN GENERAL.—With respect to
12 each specified breakthrough device, the
13 Secretary shall submit to Congress a re-
14 port on the coverage of and payment for
15 such specified breakthrough device under
16 this section that includes the following in-
17 formation:

18 “(I) The manner in which cov-
19 erage is provided and payment is
20 made for the specified breakthrough
21 device, including how such device was
22 classified (such as an item of durable
23 medical equipment or otherwise) and
24 the payment methodology the Sec-

1 retary applied with respect to such de-
2 vice.

3 “(II) The impact of the avail-
4 ability of the specified breakthrough
5 device to Medicare beneficiaries, in-
6 cluding impacts on the quality of pa-
7 tient care, patient outcomes, and pa-
8 tient experience.

9 “(III) The impact of the avail-
10 ability of the specified breakthrough
11 device to Medicare beneficiaries on
12 program expenditures under this title.

13 “(IV) Such other information as
14 the Secretary determines to be appro-
15 priate.

16 “(ii) DEADLINE.—

17 “(I) IN GENERAL.—Except as
18 provided in subclause (II), the Sec-
19 retary shall submit a report required
20 under this subparagraph no later than
21 the end of the transitional period of
22 coverage and payment applicable to
23 such specified breakthrough device.

24 “(II) EXTENSION TO GENERATE
25 ADDITIONAL DATA.—If the Secretary

1 determines that additional data or evi-
2 dence is required to complete a report
3 required under this subparagraph
4 with respect to a specified break-
5 through device, the deadline under
6 this clause may be extended for an
7 additional two years.

8 “(C) ADDITIONAL PERIOD OF TRANSI-
9 TIONAL COVERAGE TO DEVELOP ADDITIONAL
10 DATA.—Insofar as the Secretary determines
11 that additional data or evidence is required to
12 complete a report required under subparagraph
13 (B) with respect to a specified breakthrough de-
14 vice, the transitional coverage period of cov-
15 erage and payment for such device shall be ex-
16 tended by the lesser of—

17 “(i) two years; or

18 “(ii) the amount of additional time re-
19 quired for the submission of the report
20 with respect to such device.

21 “(3) COVERAGE AND PAYMENT AFTER THE
22 TRANSITIONAL PERIOD.—The Secretary may con-
23 tinue to provide for coverage of and payment for a
24 specified breakthrough device after the end of the
25 transitional period of coverage and payment for

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

4 “(A) improves the quality of care and pa-
5 tient outcomes;

6 “(B) improves the delivery of care; or

7 “(C) reduces spending under this title
8 without reducing the quality of care.”.

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

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

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

22 (A) determine the number of medical de-
23 vices cleared under such section 510(k) during
24 the 5-year period beginning on the date of the
25 enactment of this Act;

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

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

11 (3) REPORT.—Not later than 6 years after the
12 date of the enactment of this Act, the Secretary
13 shall submit to Congress a report on the study con-
14 ducted under this subsection and shall include such
15 recommendations for legislative or administrative
16 changes as the Secretary determines to be appro-
17 priate.

18 (c) CLARIFICATION REGARDING CERTAIN PAY-
19 MENTS.—

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

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

1 payment under this subsection by reason of this subpara-
2 graph, any local coverage determination (as defined in sec-
3 tion 1869(f)(2)(B)) that would affect the coverage of, or
4 the additional payment under this subsection for, such
5 new medical service or technology shall have no force or
6 effect in law or regulation.”.

7 (2) OPPTS PASS-THROUGH PAYMENT.—Section
8 1833(t)(6) of the Social Security Act (42 U.S.C.
9 1395l(t)(6)) is amended by adding at the end the
10 following new subparagraph:

11 “(K) PROHIBITION ON USE OF LOCAL COV-
12 ERAGE DETERMINATIONS TO AFFECT COV-
13 ERAGE OF AND PAYMENT FOR PASS-THROUGH
14 PRODUCTS.—During the period with respect to
15 which a drug, biological, or medical device is eli-
16 gible for an additional payment under this
17 paragraph, any local coverage determination (as
18 defined in section 1869(f)(2)(B)) that would af-
19 fect the coverage of, or the additional payment
20 under this paragraph for, such drug, biological,
21 or medical device shall have no force or effect
22 in law or regulation.”.

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

1 after the date of the enactment of this Act, including
2 any such item or service that is eligible on such date
3 for an additional payment under section 1886(d) of
4 the Social Security Act (42 U.S.C. 1395ww(d)) by
5 reason of paragraph (5)(K) of such section or under
6 section 1833(t)(6) of such Act (42 U.S.C.
7 1395ww(t)(6)), or that would have been so eligible
8 on such date but for a local coverage determination
9 that limits or denies coverage of and such additional
10 payment for the item or service.

11 (d) CONFORMING AMENDMENTS.—

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

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

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

5 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
6 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
7 13951(t)(6)(C)) is amended by adding at the end the
8 following new clause:

9 “(iii) SPECIAL RULE FOR BREAK-
10 THROUGH DEVICES.—Notwithstanding
11 clause (i) or (ii), or any other provision of
12 this paragraph to the contrary, in the case
13 of a breakthrough device (as defined in
14 section 1899C(a)) that is furnished on or
15 after January 1, 2021, payment under this
16 paragraph for such breakthrough device
17 shall be made for the 3-year period appli-
18 cable to such breakthrough device under
19 section 1899C(d)(2). The provisions of this
20 clause shall also apply for purposes of
21 transitional pass-through payment under
22 section 1833(i)(2)(D).”

23 (3) COMPETITIVE BIDDING PROGRAM.—Section
24 1847(a) of such Act (42 U.S.C. 1395w-3(a)) is
25 amended—

1 (A) in paragraph (2)(A)—

2 (i) by striking “and excluding drugs”

3 and inserting “excluding drugs”; and

4 (ii) by inserting before the period at

5 the end the following: “, and excluding

6 breakthrough devices (as defined in section

7 1899C(a))”; and

8 (B) in paragraph (7), by adding at the end

9 the following new subparagraph:

10 “(C) BREAKTHROUGH DEVICES.—A break-

11 through device described in paragraph (2)(A)

12 that is furnished during the transitional cov-

13 erage period (as defined in section

14 1899C(b)(1)(B)) applicable to such device

15 under section 1899C.”.

16 (e) EFFECTIVE DATE.—This section, and the amend-

17 ments made by this section, shall take effect on the date

18 of the enactment of this Act and, unless otherwise speci-

19 fied in this section (or in an amendment made by this sec-

20 tion), shall apply to breakthrough devices (as defined in

21 section 1899C(a) of the Social Security Act, as added by

22 subsection (a)), approved or cleared on or after July 1,

23 2019, or, in the case of a specified breakthrough device

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

○