

116TH CONGRESS
1ST SESSION

H. R. 5333

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 HOUSE OF REPRESENTATIVES

DECEMBER 6, 2019

Ms. DELBENE (for herself, Mrs. WALORSKI, Mr. CÁRDENAS, Mr. BILIRAKIS, Ms. SEWELL of Alabama, and Mr. MARSHALL) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, 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 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 2019”.

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

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

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

7 “(a) BREAKTHROUGH DEVICES.—

8 “(1) IN GENERAL.—For purposes of this sec-
9 tion, the term ‘breakthrough device’ means a med-
10 ical device that is a device (as defined in section 201
11 of the Federal Food, Drug, and Cosmetic Act) and
12 that is—

13 “(A) provided with review priority by the
14 Secretary under subsection (d)(5) of section
15 515 of such Act; and

16 “(B) approved or cleared pursuant to sec-
17 tion 510(k), 513(f), or 515 of such Act for use
18 in treating an indication on or after July 1,
19 2019.

20 Such term also includes a breakthrough device that
21 is a specified breakthrough device (as defined in sub-
22 section (e)(1)(B)) approved or cleared pursuant to
23 section 510(k), 513(f), or 515 of such Act for use
24 in treating an indication on or after December 1,
25 2018.

1 “(2) LIMITATION ON NUMBER OF 510(K) DE-
2 VICES.—With respect to a 5-year period, in no case
3 may more than five medical devices described in
4 paragraph (1) that are classified under section
5 510(k) of the Federal Food, Drug, and Cosmetic
6 Act be covered and paid for under this title by rea-
7 son of this section during each such 5-year period.

8 “(b) COVERAGE.—

9 “(1) TRANSITIONAL COVERAGE.—

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

13 “(i) deemed to be reasonable and nec-
14 essary for purposes of section
15 1862(a)(1)(A);

16 “(ii) deemed to be approved for an ad-
17 ditional payment under section
18 1886(d)(5)(K) (other than with respect to
19 the cost criterion under clause (ii)(I) of
20 such section);

21 “(iii) deemed to be approved for pass-
22 through payment under section 1833(t)(6)
23 and section 1833(i) (other than with re-
24 spect to the cost criterion under section
25 1833(t)(6)(A)(iv)); and

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

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

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

1 “(ii) ends on the last day of the 3-
2 year period that begins on the date that
3 the Secretary, pursuant to subsection
4 (c)(2), updates the relevant applicable pay-
5 ment system (as defined in subsection
6 (c)(4)) to recognize the unique temporary
7 or permanent code or codes assigned under
8 subsection (c)(1) to such breakthrough de-
9 vice, except as provided in subsections
10 (d)(1)(B) and (d)(2)(B).

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

22 “(2) PROCESS FOR REGULAR COVERAGE.—For
23 purposes of the application of section 1862(a)(1)(A)
24 to a breakthrough device furnished after the transi-
25 tional coverage period (as defined in paragraph

1 (1)(B)) for such device, the Secretary shall establish
2 a process for the coverage of such breakthrough de-
3 vices under this title after such period as follows:

4 “(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—
5 DENCE.—

6 “(i) IN GENERAL.—With respect to a
7 breakthrough device, not later than 1 year
8 after the date of the approval of such de-
9 vice under section 515 of the Federal
10 Food, Drug, and Cosmetic Act or of the
11 clearance of such device under section
12 510(k) of such Act, as applicable, the Sec-
13 retary shall identify whether any additional
14 data or evidence is required with respect to
15 any indications for such device for pur-
16 poses of the application of such section
17 1862(a)(1)(A) to such device for such indi-
18 cations.

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

24 “(I) does not duplicate data re-
25 quired to be collected by the Food and

1 Drug Administration with respect to
2 such breakthrough device;

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

8 “(III) is not otherwise unneces-
9 sary or redundant.

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

1 after such period, for purposes of section
2 1862(a)(1)(A) coverage under this title of such
3 breakthrough device shall be made for all indi-
4 cations for which such device is approved under
5 section 515 of the Federal Food, Drug, and
6 Cosmetic Act or cleared under section 510(k) of
7 such Act.

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

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

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

25 “(c) CODING.—

1 “(1) PROMPT ASSIGNMENT.—Not later than
2 three months after the date of approval or clearance
3 of a breakthrough device by the Food and Drug Ad-
4 ministration, subject to subparagraph (B), the Sec-
5 retary shall assign a unique temporary or permanent
6 code or codes for purposes of coverage and payment
7 for such breakthrough device under the applicable
8 payment systems (described in paragraph (4)).

9 “(2) UPDATES.—

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

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

22 “(C) OTHER PAYMENT SYSTEMS.—The
23 Secretary shall provide for semiannual or quar-
24 terly updates, as the case may be, under the ap-
25 plicable payment systems described in subpara-

1 graphs (C) through (L) of paragraph (4) to rec-
2 ognize the code or codes assigned under para-
3 graph (1).

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

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

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

15 “(B) with respect to outpatient hospital
16 services, the prospective payment system for
17 covered OPD services established under section
18 1833(t);

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

22 “(D) with respect to physicians’ services,
23 the physician fee schedules established under
24 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 inpatient hospital
9 services furnished by rehabilitation facilities,
10 the prospective payment system established
11 under section 1886(j);

12 “(H) with respect to inpatient hospital
13 services furnished by long-term care hospitals,
14 the prospective payment system under section
15 1886(m);

16 “(I) with respect to inpatient hospital serv-
17 ices furnished by psychiatric hospitals and psy-
18 chiatric units, the prospective payment system
19 under section 1886(s);

20 “(J) with respect to home health services,
21 the prospective payment system under section
22 1895; and

23 “(K) with respect to items and services, or
24 a provider of services or supplier, not described
25 in subparagraphs (A) through (I), the payment

1 system established under this title for such
2 items and services when furnished by such pro-
3 vider of services or supplier.

4 “(d) PAYMENT.—

5 “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-
6 MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-
7 THROUGH PAYMENT.—The Secretary shall deem
8 each breakthrough device as approved for an addi-
9 tional payment under section 1886(d)(5)(K) for the
10 3-year period that begins—

11 “(A) except as provided in subparagraph
12 (B), on the date that the Secretary, pursuant to
13 subsection (c)(2)(A), updates the payment sys-
14 tem under section 1886(d) to recognize the
15 unique temporary or permanent code or codes
16 assigned under subsection (c)(1) to such break-
17 through device; or

18 “(B) in the case of a device that has not
19 received approval or clearance as a break-
20 through device by the Food and Drug Adminis-
21 tration before such payment system is updated
22 under subsection (c)(2)(A) to recognize the
23 unique temporary or permanent code or codes
24 assigned under subsection (c)(1) to such device,
25 on the date of such approval or clearance.

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

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

15 “(A) except as provided in subparagraph
16 (B), on the date that the Secretary, pursuant to
17 subsection (c)(2)(B), updates the payment sys-
18 tem under section 1833(t) to recognize the
19 unique temporary or permanent code or codes
20 assigned under subsection (c)(1) to such break-
21 through device; or

22 “(B) in the case of a device that has not
23 received approval or clearance as a break-
24 through device by the Food and Drug Adminis-
25 tration before such payment system is updated

1 under subsection (c)(2)(B) to recognize the
2 unique temporary or permanent code or codes
3 assigned under subsection (c)(1) to such device,
4 on the date of such approval or clearance.

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

12 “(3) OTHER PAYMENT SYSTEMS.—

13 “(A) IN GENERAL.—In the case of break-
14 through device that is furnished and for which
15 payment may be made under the payment sys-
16 tem established under section 1834, 1834A,
17 1848, 1886(j), 1886(m), 1886(s), or 1895 or
18 any other provision of this title (other than sec-
19 tions 1833(i), 1833(t), and 1886(d)), the Sec-
20 retary shall provide for an additional payment
21 for such breakthrough device under such appli-
22 cable payment system or an adjustment to such
23 applicable payment system, as the case may be.
24 The payment basis for such additional payment
25 or adjustment, as the case may be, shall equal

1 an amount that the Secretary determines covers
2 the costs of such breakthrough device.

3 “(B) COST INFORMATION.—In determining
4 the costs of a breakthrough device for purposes
5 of determining an additional payment or pay-
6 ment adjustment under subparagraph (A), the
7 Secretary shall use the most recently available
8 data and information on the costs of such
9 breakthrough device, which may include list
10 prices and invoice prices charged for such
11 breakthrough device.

12 “(C) RULE OF CONSTRUCTION.—Nothing
13 in this paragraph shall be construed to affect
14 the authority of the Secretary to use claims
15 data to establish new or modify existing ambu-
16 latory payment classification groups, diagnosis-
17 related groups, level II HCPCS codes or such
18 other groups or codes as the Secretary may es-
19 tablish under the annual rulemaking authority
20 under the provisions referred to in subpara-
21 graph (A).

22 “(D) CLINICAL DIAGNOSTIC LABORATORY
23 TESTS.—An additional payment or payment ad-
24 justment under subparagraph (A) for a break-
25 through device under the applicable payment

1 system established in section 1834A may be in
2 the form of an increase to the amount deter-
3 mined for the breakthrough device using cross-
4 walking under section 1834A(c)(1)(A), an ex-
5 tension of the initial period of payment applica-
6 ble to advance diagnostic laboratory tests under
7 section 1834A(d)(1)(A), and in such other form
8 or manner as the Secretary determines reflects
9 the costs for such breakthrough device under
10 the relevant provisions of section 1834A.

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

19 “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH
20 DEVICES.—

21 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH
22 DEVICES.—

23 “(A) IN GENERAL.—Subject to the suc-
24 ceeding provisions of this subsection and not-
25 withstanding any other provision of law, the

1 Secretary shall provide for coverage and pay-
2 ment pursuant to this section of a specified
3 breakthrough device (as defined in subpara-
4 graph (B)).

5 “(B) SPECIFIED BREAKTHROUGH DEVICE
6 DEFINED.—In this section, the term ‘specified
7 breakthrough device’ means a breakthrough de-
8 vice with respect to which no Medicare benefit
9 category exists.

10 “(2) PERIOD OF TRANSITIONAL COVERAGE.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (C), the provisions of subsection (b)(1)
13 (relating to the transitional coverage period and
14 payment for breakthrough devices, including the
15 use of the most recently available data and in-
16 formation on costs) shall apply to a specified
17 breakthrough device in the same manner as
18 such provisions apply to a breakthrough device.
19 The Secretary may use methodologies under ex-
20 isting payment systems established under this
21 title, may provide for appropriate adjustments
22 to such methodologies, or may establish a new
23 payment methodology under this title, to pro-
24 vide for payment for a specified breakthrough
25 device to ensure the payment basis for such

1 payment covers costs of the specified break-
2 through device are covered by such payment.

3 “(B) REPORT.—

4 “(i) IN GENERAL.—With respect to
5 each specified breakthrough device, the
6 Secretary shall submit to Congress a re-
7 port on the coverage of and payment for
8 such specified breakthrough device under
9 this section that includes the following in-
10 formation:

11 “(I) The manner in which cov-
12 erage is provided and payment is
13 made for the specified breakthrough
14 device, including how such device was
15 classified (such as an item of durable
16 medical equipment or otherwise) and
17 the payment methodology the Sec-
18 retary applied with respect to such de-
19 vice.

20 “(II) The impact of the avail-
21 ability of the specified breakthrough
22 device to Medicare beneficiaries, in-
23 cluding impacts on the quality of pa-
24 tient care, patient outcomes, and pa-
25 tient experience.

1 “(III) The impact of the avail-
2 ability of the specified breakthrough
3 device to Medicare beneficiaries on
4 program expenditures under this title.

5 “(IV) Such other information as
6 the Secretary determines to be appro-
7 priate.

8 “(ii) DEADLINE.—

9 “(I) IN GENERAL.—Except as
10 provided in subclause (II), the Sec-
11 retary shall submit a report required
12 under this subparagraph no later than
13 the end of the transitional period of
14 coverage and payment applicable to
15 such specified breakthrough device.

16 “(II) EXTENSION TO GENERATE
17 ADDITIONAL DATA.—If the Secretary
18 determines that additional data or evi-
19 dence is required to complete a report
20 required under this subparagraph
21 with respect to a specified break-
22 through device, the deadline under
23 this clause may be extended for an
24 additional two years.

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

10 “(i) two years; or

11 “(ii) the amount of additional time re-
12 quired for the submission of the report
13 with respect to such device.

14 “(3) COVERAGE AND PAYMENT AFTER THE
15 TRANSITIONAL PERIOD.—The Secretary may con-
16 tinue to provide for coverage of and payment for a
17 specified breakthrough device after the end of the
18 transitional period of coverage and payment for
19 breakthrough devices through the national coverage
20 determination process if the Secretary determines
21 that the specified breakthrough device—

22 “(A) improves the quality of care and pa-
23 tient outcomes;

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

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

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

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

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

16 (A) determine the number of medical de-
17 vices cleared under such section 510(k) during
18 the 5-year period beginning on the date of the
19 enactment of this Act;

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

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

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

13 (c) CONFORMING AMENDMENTS.—

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

18 “(x) Effective for discharges occurring on
19 or after October 1, 2019, in the case of a new
20 medical service or technology that is a break-
21 through device (as defined in section
22 1899C(a)), the additional payment established
23 for such breakthrough device under this sub-
24 paragraph shall be made for the 3-year period
25 applicable to such breakthrough device under

1 section 1899C(d)(1). In determining the
2 amount of the additional payment for a break-
3 through device under this subparagraph during
4 such 3-year period, the Secretary shall apply
5 section 412.88(b) of title 42, Code of Federal
6 Regulations (or any successor regulation), as if
7 the reference to ‘50 percent’ in such section
8 were a reference to ‘80 percent’.”

9 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
10 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
11 1395l(t)(6)(C)) is amended by adding at the end the
12 following new clause:

13 “(iii) SPECIAL RULE FOR BREAK-
14 THROUGH DEVICES.—Notwithstanding
15 clause (i) or (ii), or any other provision of
16 this paragraph to the contrary, in the case
17 of a breakthrough device (as defined in
18 section 1899C(a)) that is furnished on or
19 after January 1, 2020, payment under this
20 paragraph for such breakthrough device
21 shall be made for the 3-year period appli-
22 cable to such breakthrough device under
23 section 1899C(d)(2). The provisions of this
24 clause shall also apply for purposes of

1 transitional pass-through payment under
2 section 1833(i)(2)(D).”.

3 (3) COMPETITIVE BIDDING PROGRAM.—Section
4 1847(a) of such Act (42 U.S.C. 1395w-3(a)) is
5 amended—

6 (A) in paragraph (2)(A)—

7 (i) by striking “and excluding drugs”
8 and inserting “excluding drugs”; and

9 (ii) by inserting before the period at
10 the end the following: “and excluding
11 breakthrough devices (as defined in section
12 1899C(a))”; and

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

15 “(C) BREAKTHROUGH DEVICES.—A break-
16 through device described in paragraph (2)(A)
17 that is furnished during the transitional cov-
18 erage period (as defined in section
19 1899C(b)(1)(B)) applicable to such device
20 under section 1899C.”.

21 (d) EFFECTIVE DATE.—This section, and the amend-
22 ments made by this section, shall take effect on the date
23 of the enactment of this Act and, unless otherwise speci-
24 fied in this section (or in an amendment made by this sec-
25 tion), shall apply to breakthrough devices (as defined in

1 section 1899C(a) of the Social Security Act, as added by
2 subsection (a)), approved or cleared on or after July 1,
3 2019, or, in the case of a specified breakthrough device
4 (as defined in such section as so added), approved or
5 cleared on or after December 1, 2018.

○