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(Original Signature of Member)

118TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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

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IN THE HOUSE OF REPRESENTATIVES

Mr. WENSTRUP introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

\_\_\_\_\_  
**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 2023”.

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

11 “(1) provided with review priority by the Sec-  
12 retary under subsection (d)(5) of section 515 of such  
13 Act; and

14 “(2) approved or cleared pursuant to section  
15 510(k), 513(f), or 515 of such Act for use in treat-  
16 ing an indication on or after March 15, 2021.

17 Such term also includes a breakthrough device that is a  
18 specified breakthrough device (as defined in subsection  
19 (e)(1)(B)) approved or cleared pursuant to section 510(k),  
20 513(f), or 515 of such Act for use in treating an indication  
21 on or after March 15, 2021.

22 “(b) COVERAGE.—

23 “(1) TRANSITIONAL COVERAGE.—

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

1 “(i) deemed to be reasonable and nec-  
2 essary for purposes of section  
3 1862(a)(1)(A);

4 “(ii) deemed to be approved for an ad-  
5 ditional payment under section  
6 1886(d)(5)(K) (other than with respect to  
7 the cost criterion under clause (ii)(I) of  
8 such section);

9 “(iii) deemed to be approved for pass-  
10 through payment under section 1833(t)(6)  
11 and section 1833(i) (other than with re-  
12 spect to the cost criterion under section  
13 1833(t)(6)(A)(iv)); and

14 “(iv) insofar as such breakthrough de-  
15 vice may be furnished in a setting for  
16 which payment is made under an applica-  
17 ble payment system described in subpara-  
18 graphs (D) through (I) of subsection  
19 (c)(4), deemed eligible for an additional  
20 payment or payment adjustment, as the  
21 case may be, pursuant to subsection (d)(3)  
22 when furnished in a setting for which pay-  
23 ment is made under such an applicable  
24 payment system during such transitional  
25 coverage period.

1           “(B) TRANSITIONAL COVERAGE PERIOD  
2           DEFINED.—As used in this section, the term  
3           ‘transitional coverage period’ means, with re-  
4           spect to a breakthrough device, the period  
5           that—

6                       “(i) begins on the date of the approval  
7                       under section 515 of the Federal Food,  
8                       Drug, and Cosmetic Act or of the clear-  
9                       ance under section 510(k) of such Act, as  
10                      applicable, of such device by the Secretary  
11                      for the indication described in subsection  
12                      (a)(1); and

13                     “(ii) ends on the last day of the 4-  
14                     year period that begins on the date that  
15                     the Secretary, pursuant to subsection  
16                     (c)(2), updates the relevant applicable pay-  
17                     ment system (as defined in subsection  
18                     (c)(4)) to recognize the unique temporary  
19                     or permanent code or codes assigned under  
20                     subsection (c)(1) to such breakthrough de-  
21                     vice, except as provided in subsections  
22                     (d)(1)(B) and (d)(2)(B).

23           “(C) DATA USED TO MEET THE NTAP AND  
24           PASS-THROUGH COST CRITERIA.—In deter-  
25           mining whether a breakthrough device qualifies

1 for an additional payment under section  
2 1886(d)(5)(K) or for pass-through payment  
3 under section 1833(t)(6) or section 1833(i), the  
4 Secretary shall use the most recently available  
5 data and information on the costs of such  
6 breakthrough device, which may include list  
7 prices and invoice prices charged for such  
8 breakthrough device.

9 “(2) PROCESS FOR REGULAR COVERAGE.—For  
10 purposes of the application of section 1862(a)(1)(A)  
11 to a breakthrough device furnished after the transi-  
12 tional coverage period (as defined in paragraph  
13 (1)(B)) for such device, the Secretary shall establish  
14 a process for the coverage of such breakthrough de-  
15 vices under this title after such period as follows:

16 “(A) IDENTIFICATION OF ADDITIONAL EVI-  
17 DENCE.—

18 “(i) IN GENERAL.—With respect to a  
19 breakthrough device, not later than 1 year  
20 after the date of the approval of such de-  
21 vice under section 515 of the Federal  
22 Food, Drug, and Cosmetic Act or of the  
23 clearance of such device under section  
24 510(k) of such Act, as applicable, the Sec-  
25 retary shall identify whether any additional

1 data or evidence is required with respect to  
2 any indications for such device for pur-  
3 poses of the application of such section  
4 1862(a)(1)(A) to such device for such indi-  
5 cations.

6 “(ii) NON-DUPLICATION OF DATA RE-  
7 QUESTS.—In carrying out clause (i) with  
8 respect to a breakthrough device, the Sec-  
9 retary shall ensure that data or evidence  
10 identified—

11 “(I) does not duplicate data re-  
12 quired to be collected by the Food and  
13 Drug Administration with respect to  
14 such breakthrough device;

15 “(II) minimizes the administra-  
16 tive burdens of data collection and re-  
17 porting on providers of services, sup-  
18 pliers, and manufacturers of break-  
19 through devices; and

20 “(III) is not otherwise unneces-  
21 sary or redundant.

22 “(B) PROPOSAL FOR COVERAGE AFTER  
23 THE TRANSITIONAL COVERAGE PERIOD.—Not  
24 later than 2 years after the date of the approval  
25 or clearance of a breakthrough device by the

1 Food and Drug Administration, the Secretary  
2 shall develop a proposal for coverage under this  
3 title of such breakthrough device for such indi-  
4 cations as the Secretary determines to be ap-  
5 propriate, based on the data and evidence col-  
6 lected under subparagraph (A), for such devices  
7 furnished after the transitional coverage period  
8 under paragraph (1) for such device. If the Sec-  
9 retary does not, on a date that is before the end  
10 of such two-year period, take action to modify  
11 the indications for which coverage of a break-  
12 through device may be provided under this title  
13 after such period, for purposes of section  
14 1862(a)(1)(A) coverage under this title of such  
15 breakthrough device shall be made for all indi-  
16 cations for which such device is approved under  
17 section 515 of the Federal Food, Drug, and  
18 Cosmetic Act or cleared under section 510(k) of  
19 such Act.

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

22 “(A) affect the ability of the manufacturer  
23 of a breakthrough device to seek approval for  
24 pass-through payment status under section  
25 1833(t)(6) or to seek approval for an additional

1 payment under section 1886(d)(5)(K) insofar  
2 as such breakthrough device does not qualify  
3 for transitional coverage under paragraph (1);

4 “(B) affect the application and approval  
5 process for pass-through payment status under  
6 section 1833(t)(6) or for an additional payment  
7 under section 1886(d)(5)(K) in the case of a  
8 medical device that is not approved by the Food  
9 and Drug Administration as a breakthrough de-  
10 vice; or

11 “(C) prohibit the Secretary from using ex-  
12 isting authority under this title to suspend or  
13 terminate coverage of a breakthrough device if  
14 the Secretary, based on clinical evidence, deter-  
15 mines that—

16 “(i) such breakthrough device offers  
17 no clinical benefit to Medicare bene-  
18 ficiaries; or

19 “(ii) furnishing such breakthrough de-  
20 vice to Medicare beneficiaries causes, or  
21 may cause, serious harm to Medicare bene-  
22 ficiaries.

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, the Secretary shall assign a unique  
3 temporary or permanent code or codes for purposes  
4 of coverage and payment for such breakthrough de-  
5 vice under the applicable payment systems (de-  
6 scribed 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 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 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 4-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 4-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 a  
14 breakthrough device that is furnished and for  
15 which payment may be made under the pay-  
16 ment system established under section 1834,  
17 1834A, 1848, 1886(j), 1886(m), 1886(s), or  
18 1895 or any other provision of this title (other  
19 than sections 1833(i), 1833(t), and 1886(d)),  
20 the Secretary shall provide for an additional  
21 payment for such breakthrough device under  
22 such applicable payment system or an adjust-  
23 ment to such applicable payment system, as the  
24 case may be. The payment basis for such addi-  
25 tional payment or adjustment, as the case may

1 be, shall equal an amount that the Secretary  
2 determines covers the costs of such break-  
3 through device.

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

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

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

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

12 “(4) PAYMENT FOR BREAKTHROUGH DEVICES  
13 AFTER THE TRANSITIONAL COVERAGE PERIOD.—

14 Payment for a breakthrough device that is furnished  
15 after the conclusion of the transitional coverage pe-  
16 riod under subsection (b)(1) for such device shall be  
17 made pursuant to the applicable payment system in-  
18 volved, taking into account the additional evidence  
19 and data collected under subsection (b)(2).

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

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

24 “(A) IN GENERAL.—Subject to the suc-  
25 ceeding provisions of this subsection and not-



1           withstanding any other provision of law, the  
2           Secretary shall provide for coverage and pay-  
3           ment pursuant to this section of a specified  
4           breakthrough device (as defined in subpara-  
5           graph (B)).

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

11          “(2) PERIOD OF TRANSITIONAL COVERAGE.—

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

1 device to ensure the payment basis for such  
2 payment covers costs of the specified break-  
3 through device are covered by such payment.

4 “(B) REPORT.—

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

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

21 “(II) The impact of the avail-  
22 ability of the specified breakthrough  
23 device to Medicare beneficiaries, in-  
24 cluding impacts on the quality of pa-

1 patient care, patient outcomes, and pa-  
2 tient experience.

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

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

10 “(ii) DEADLINE.—

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

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

1                   this clause may be extended for an  
2                   additional two years.

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

12                               “(i) two years; or

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

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

24                               “(A) improves the quality of care and pa-  
25                               tient outcomes;

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

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

4 (b) CONFORMING AMENDMENTS.—

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

9 “(x) Effective for discharges occurring on  
10 or after October 1, 2019, in the case of a new  
11 medical service or technology that is a break-  
12 through device (as defined in section  
13 1899C(a)), the additional payment established  
14 for such breakthrough device under this sub-  
15 paragraph shall be made for the 4-year period  
16 applicable to such breakthrough device under  
17 section 1899C(d)(1). In determining the  
18 amount of the additional payment for a break-  
19 through device under this subparagraph during  
20 such 4-year period, the Secretary shall apply  
21 section 412.88(b) of title 42, Code of Federal  
22 Regulations, as in effect on the date of the en-  
23 actment of this clause, except as if the ref-  
24 erence in such section to ‘65 percent’ were a

1 reference to ‘65 percent (or such greater per-  
2 cent specified by the Secretary)’.”.

3 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-  
4 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.  
5 1395l(t)(6)(C)) is amended by adding at the end the  
6 following new clause:

7 “(iii) SPECIAL RULE FOR BREAK-  
8 THROUGH DEVICES.—Notwithstanding  
9 clause (i) or (ii), or any other provision of  
10 this paragraph to the contrary, in the case  
11 of a breakthrough device (as defined in  
12 section 1899C(a)) that is furnished on or  
13 after January 1, 2020, payment under this  
14 paragraph for such breakthrough device  
15 shall be made for the 4-year period appli-  
16 cable to such breakthrough device under  
17 section 1899C(d)(2). The provisions of this  
18 clause shall also apply for purposes of  
19 transitional pass-through payment under  
20 section 1833(i)(2)(D).”.

21 (c) 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.