

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO SUBTITLE I  
OFFERED BY M . \_\_\_\_\_**

Add at the end the following new section:

1 **SEC. 30904. COVERAGE AND PAYMENT FOR BREAK-**  
2 **THROUGH DEVICES UNDER THE MEDICARE**  
3 **PROGRAM.**

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

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

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

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

15 “(2) approved or cleared pursuant to section  
16 510(k), 513(f), or 515 of such Act for use in treat-  
17 ing an indication on or after March 15, 2019.

18 Such term also includes a breakthrough device that is a  
19 specified breakthrough device (as defined in subsection

1 (e)(1)(B)) approved or cleared pursuant to section 510(k),  
2 513(f), or 515 of such Act for use in treating an indication  
3 on or after March 15, 2019.

4 “(b) COVERAGE.—

5 “(1) TRANSITIONAL COVERAGE.—

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

9 “(i) deemed to be reasonable and nec-  
10 essary for purposes of section  
11 1862(a)(1)(A);

12 “(ii) deemed to be approved for an ad-  
13 ditional payment under section  
14 1886(d)(5)(K) (other than with respect to  
15 the cost criterion under clause (ii)(I) of  
16 such section);

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

22 “(iv) insofar as such breakthrough de-  
23 vice may be furnished in a setting for  
24 which payment is made under an applica-  
25 ble payment system described in subpara-

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

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

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

21 “(ii) ends on the last day of the 4-  
22 year period that begins on the date that  
23 the Secretary, pursuant to subsection  
24 (c)(2), updates the relevant applicable pay-  
25 ment system (as defined in subsection

1 (c)(4)) to recognize the unique temporary  
2 or permanent code or codes assigned under  
3 subsection (c)(1) to such breakthrough de-  
4 vice, except as provided in subsections  
5 (d)(1)(B) and (d)(2)(B).

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

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

24 “(A) IDENTIFICATION OF ADDITIONAL EVI-  
25 DENCE.—

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

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

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

23                         “(II) minimizes the administra-  
24                         tive burdens of data collection and re-  
25                         porting on providers of services, sup-

1                   pliers, and manufacturers of break-  
2                   through devices; and

3                               “(III) is not otherwise unneces-  
4                               sary or redundant.

5                   “(B) PROPOSAL FOR COVERAGE AFTER  
6                   THE TRANSITIONAL COVERAGE PERIOD.—Not  
7                   later than 2 years after the date of the approval  
8                   or clearance of a breakthrough device by the  
9                   Food and Drug Administration, the Secretary  
10                  shall develop a proposal for coverage under this  
11                  title of such breakthrough device for such indi-  
12                  cations as the Secretary determines to be ap-  
13                  propriate, based on the data and evidence col-  
14                  lected under subparagraph (A), for such devices  
15                  furnished after the transitional coverage period  
16                  under paragraph (1) for such device. If the Sec-  
17                  retary does not, on a date that is before the end  
18                  of such two-year period, take action to modify  
19                  the indications for which coverage of a break-  
20                  through device may be provided under this title  
21                  after such period, for purposes of section  
22                  1862(a)(1)(A) coverage under this title of such  
23                  breakthrough device shall be made for all indi-  
24                  cations for which such device is approved under  
25                  section 515 of the Federal Food, Drug, and

1           Cosmetic Act or cleared under section 510(k) of  
2           such Act.

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

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

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

20          “(c) CODING.—

21                   “(1) PROMPT ASSIGNMENT.—Not later than  
22                   three months after the date of approval or clearance  
23                   of a breakthrough device by the Food and Drug Ad-  
24                   ministration, the Secretary shall assign a unique  
25                   temporary or permanent code or codes for purposes

1 of coverage and payment for such breakthrough de-  
2 vice under the applicable payment systems (de-  
3 scribed in paragraph (4)).

4 “(2) UPDATES.—

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

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

17 “(C) OTHER PAYMENT SYSTEMS.—The  
18 Secretary shall provide for semiannual or quar-  
19 terly updates, as the case may be, under the ap-  
20 plicable payment systems described in subpara-  
21 graphs (C) through (K) of paragraph (4) to  
22 recognize the code or codes assigned under  
23 paragraph (1).

24 “(3) TRANSPARENCY.—The process for the as-  
25 signment of a code or codes under this subsection



1 shall provide for public notice and a meaningful op-  
2 portunity for public comment from affected parties.

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

6 “(A) with respect to inpatient hospital  
7 services, the prospective payment system for in-  
8 patient hospital services established under sec-  
9 tion 1886(d);

10 “(B) with respect to outpatient hospital  
11 services, the prospective payment system for  
12 covered OPD services established under section  
13 1833(t);

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

17 “(D) with respect to physicians’ services,  
18 the physician fee schedules established under  
19 section 1848;

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

23 “(F) with respect to diagnostic laboratory  
24 tests, the payment amounts under section

1 1834A and the fee schedules establish under  
2 section 1848, as the case may be;

3 “(G) with respect to inpatient hospital  
4 services furnished by rehabilitation facilities,  
5 the prospective payment system established  
6 under section 1886(j);

7 “(H) with respect to inpatient hospital  
8 services furnished by long-term care hospitals,  
9 the prospective payment system under section  
10 1886(m);

11 “(I) with respect to inpatient hospital serv-  
12 ices furnished by psychiatric hospitals and psy-  
13 chiatric units, the prospective payment system  
14 under section 1886(s);

15 “(J) with respect to home health services,  
16 the prospective payment system under section  
17 1895; and

18 “(K) with respect to items and services, or  
19 a provider of services or supplier, not described  
20 in subparagraphs (A) through (K), the payment  
21 system established under this title for such  
22 items and services when furnished by such pro-  
23 vider of services or supplier.

24 “(d) PAYMENT.—

1           “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-  
2           MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-  
3           THROUGH PAYMENT.—The Secretary shall deem  
4           each breakthrough device as approved for an addi-  
5           tional payment under section 1886(d)(5)(K) for the  
6           4-year period that begins—

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

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

22           Nothing in this paragraph shall be construed to af-  
23           fect the authority of the Secretary to use claims  
24           data to establish new diagnosis or procedure codes  
25           for breakthrough devices or to identify appropriate

1 diagnosis-related groups for the assignment of  
2 breakthrough devices under annual rulemaking to  
3 carry out section 1886(d)(5)(K).

4 “(2) OUTPATIENT PROSPECTIVE PAYMENT SYS-  
5 TEM: DEEMED ELIGIBILITY FOR PASS-THROUGH  
6 PAYMENT.—The Secretary shall deem each break-  
7 through device as approved for pass-through pay-  
8 ment under section 1833(t)(6) (including for pur-  
9 poses of section 1833(i)(2)(D)) during the 4-year pe-  
10 riod that begins—

11 “(A) except as provided in subparagraph  
12 (B), on the date that the Secretary, pursuant to  
13 subsection (c)(2)(B), updates the payment sys-  
14 tem under section 1833(t) 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)(B) 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 ambulatory payment classifica-  
4 tion groups for breakthrough devices or to revise  
5 such groups to take into account breakthrough de-  
6 vices under annual rulemaking to carry out section  
7 1833(t).

8 “(3) OTHER PAYMENT SYSTEMS.—

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

24 “(B) COST INFORMATION.—In determining  
25 the costs of a breakthrough device for purposes

1 of determining an additional payment or pay-  
2 ment adjustment under subparagraph (A), the  
3 Secretary shall use the most recently available  
4 data and information on the costs of such  
5 breakthrough device, which may include list  
6 prices and invoice prices charged for such  
7 breakthrough device.

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

18 “(D) CLINICAL DIAGNOSTIC LABORATORY  
19 TESTS.—An additional payment or payment ad-  
20 justment under subparagraph (A) for a break-  
21 through device under the applicable payment  
22 system established in section 1834A may be in  
23 the form of an increase to the amount deter-  
24 mined for the breakthrough device using cross-  
25 walking under section 1834A(c)(1)(A), an ex-

1           tension of the initial period of payment applica-  
2           ble to advance diagnostic laboratory tests under  
3           section 1834A(d)(1)(A), and in such other form  
4           or manner as the Secretary determines reflects  
5           the costs for such breakthrough device under  
6           the relevant provisions of section 1834A.

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

15          “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH  
16          DEVICES.—

17                 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH  
18          DEVICES.—

19                         “(A) IN GENERAL.—Subject to the suc-  
20                         ceeding provisions of this subsection and not-  
21                         withstanding any other provision of law, the  
22                         Secretary shall provide for coverage and pay-  
23                         ment pursuant to this section of a specified  
24                         breakthrough device (as defined in subpara-  
25                         graph (B)).

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

6           “(2) PERIOD OF TRANSITIONAL COVERAGE.—

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

24          “(B) REPORT.—



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

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

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

23                  “(III) The impact of the avail-  
24                  ability of the specified breakthrough

1 device to Medicare beneficiaries on  
2 program expenditures under this title.

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

6 “(ii) DEADLINE.—

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

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

23 “(C) ADDITIONAL PERIOD OF TRANSI-  
24 TIONAL COVERAGE TO DEVELOP ADDITIONAL  
25 DATA.—Insofar as the Secretary determines

1           that additional data or evidence is required to  
2           complete a report required under subparagraph  
3           (B) with respect to a specified breakthrough de-  
4           vice, the transitional coverage period of cov-  
5           erage and payment for such device shall be ex-  
6           tended by the lesser of—

7                       “(i) two years; or

8                       “(ii) the amount of additional time re-  
9                       quired for the submission of the report  
10                      with respect to such device.

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

19                      “(A) improves the quality of care and pa-  
20                      tient outcomes;

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

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

24           (b) CONFORMING AMENDMENTS.—

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

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

23           (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-  
24           TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.

1 13951(t)(6)(C)) is amended by adding at the end the  
2 following new clause:

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

17 (c) EFFECTIVE DATE.—This section, and the amend-  
18 ments made by this section, shall take effect on the date  
19 of the enactment of this Act and, unless otherwise speci-  
20 fied in this section (or in an amendment made by this sec-  
21 tion), shall apply to breakthrough devices (as defined in  
22 section 1899C(a) of the Social Security Act, as added by  
23 subsection (a)), approved or cleared on or after July 1,  
24 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.

