

114TH CONGRESS
2D SESSION

H. R. 5009

To amend titles XVIII and XIX of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare and Medicaid programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 20, 2016

Mr. BOUSTANY (for himself, Mr. NEAL, Mr. BILIRAKIS, and Mr. CÁRDENAS) 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 titles XVIII and XIX of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare and Medicaid programs, 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 2016”.

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 either—

13 “(A) is—

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

17 “(ii) approved under such section for
18 use in treating an indication; or

19 “(B) subject to paragraph (2), is cleared
20 under section 510(k) of such Act for use in
21 treating an indication.

22 “(2) LIMITATION ON NUMBER OF 510(k) DE-
23 VICES.—With respect to a 5-year period, in no case
24 may more than five medical devices described in
25 paragraph (1)(B) be covered and paid for under this

1 title by reason of this section during each such 5-
2 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 approved for an ad-
12 ditional payment under section
13 1886(d)(5)(K);

14 “(iii) deemed to be approved for pass-
15 through payment under section 1833(t)(6)
16 and section 1833(i); and

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

1 payment system during such transitional
2 coverage period.

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

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

16 “(ii) ends on the last day of the 3-
17 year period that begins on the date that
18 the Secretary, pursuant to subsection
19 (c)(2), updates the relevant applicable pay-
20 ment system (as defined in subsection
21 (c)(4)) to recognize the unique temporary
22 or permanent code or codes assigned under
23 subsection (c)(1) to such breakthrough de-
24 vice, except as provided in subsections
25 (d)(1)(B) and (d)(2)(B).

1 “(2) PROCESS FOR REGULAR COVERAGE.—For
2 purposes of the application of section 1862(a)(1)(A)
3 to a breakthrough device furnished after the transi-
4 tional coverage period (as defined in paragraph
5 (1)(B)) for such device, the Secretary, acting
6 through the Council for Technology and Innovation
7 (established under section 1868(b)) in conjunction
8 with the Coverage and Analysis Group of the Cen-
9 ters for Medicare & Medicaid Services, shall estab-
10 lish a process for the coverage of such breakthrough
11 devices under this title after such period as follows:

12 “(A) IDENTIFICATION OF ADDITIONAL EVI-
13 DENCE.—

14 “(i) IN GENERAL.—With respect to a
15 breakthrough device, not later than 1 year
16 after the date of the approval of such de-
17 vice under section 515 of the Federal
18 Food, Drug, and Cosmetic Act or of the
19 clearance of such device under section
20 510(k) of such Act, as applicable, the Sec-
21 retary shall identify whether any additional
22 data or evidence is required with respect to
23 any indications for such device for pur-
24 poses of the application of such section

1 1862(a)(1)(A) to such device for such indi-
2 cations.

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

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

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

17 “(III) is not otherwise unneces-
18 sary or redundant.

19 “(B) PROPOSAL FOR COVERAGE AFTER
20 THE TRANSITIONAL COVERAGE PERIOD.—Not
21 later than 2 years after the date of the approval
22 or clearance of a breakthrough device by the
23 Food and Drug Administration, the Secretary
24 shall develop a proposal for coverage under this
25 title of such breakthrough device for such indi-

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

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

19 “(A) affect the ability of the manufacturer
20 of a breakthrough device to seek approval for
21 pass-through payment status under section
22 1833(t)(6) or to seek approval for an additional
23 payment under section 1886(d)(5)(K) insofar
24 as such breakthrough device does not qualify

1 for transitional coverage under paragraph (1);
2 or

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

10 “(c) CODING.—

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

19 “(2) UPDATES.—

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

1 “(B) OPPTS.—The Secretary shall provide
2 for quarterly updates under the applicable pay-
3 ment system described in paragraph (4)(B) (re-
4 lating to the outpatient hospital prospective
5 payment system) to recognize the code or codes
6 assigned under paragraph (1).

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

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

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

18 “(B) with respect to outpatient hospital
19 services, the prospective payment system for
20 covered OPD services established under section
21 1833(t);

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

1 “(D) with respect to physicians’ services,
2 the physician fee schedules established under
3 section 1848;

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

7 “(F) with respect to diagnostic laboratory
8 tests, the fee schedule established under section
9 1834(h), the payment amounts under section
10 1834A, and the fee schedules establish under
11 section 1848, as the case may be;

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

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

20 “(I) with respect to inpatient hospital serv-
21 ices furnished by psychiatric hospitals and psy-
22 chiatric units, the prospective payment system
23 under section 1886(s).

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 3-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 3-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 sections 1834, 1834A,
13 1848, 1886(j), 1886(m), 1886(s), or any other
14 relevant 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 pay-
18 ment systems in an amount equal to 80 percent
19 of the costs of such breakthrough device.

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

1 other groups or codes as the Secretary may es-
2 tablish under the annual rulemaking authority
3 under the provisions referred to in subpara-
4 graph (A).

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

13 “(e) TREATMENT OF BREAKTHROUGH DEVICES
14 UNDER PAY-FOR-PERFORMANCE PROGRAMS.—

15 “(1) PAY-FOR-PERFORMANCE PROGRAMS DE-
16 FINED.—In this subsection, the term ‘pay-for-per-
17 formance programs’ means, with respect to items
18 and services for which payment is made under the
19 applicable payment systems under this title, pay-
20 ment initiatives designed to improve the quality, effi-
21 ciency, and overall value of health care furnished to
22 individuals entitled to benefits under part A or en-
23 rolled under part B through financial incentives to
24 providers of services and suppliers for meeting or ex-
25 ceeding certain quality or performance measures or

1 through financial penalties on providers that fail to
2 achieve specified goals or cost savings, or both. Such
3 term includes—

4 “(A) the Medicare shared savings program
5 under established section 1899;

6 “(B) shared savings programs tested by
7 the Center for Medicare and Medicaid Innova-
8 tion under section 1115A, including the Pioneer
9 ACO program;

10 “(C) the National Pilot Program on Pay-
11 ment Bundling under section 1866D;

12 “(D) bundled payment programs tested by
13 the Center for Medicare and Medicaid Innova-
14 tion under section 1115A; and

15 “(E) any other similar program conducted
16 under this title or under applicable authorities
17 under title XI.

18 “(2) EXCLUSION OF ADDITIONAL COSTS OF
19 BREAKTHROUGH DEVICES.—Insofar as the amount
20 of payment for a breakthrough device exceeds the
21 amount of payment that the item or service would
22 otherwise receive under a pay-for-performance pro-
23 gram for which shared savings or shared losses are
24 calculated, the Secretary shall exclude from the cal-
25 culation of such shared savings or losses under such

1 program for such period the amount by which the
2 payment for the breakthrough device involved ex-
3 ceeds the payment amount for such other item or
4 service that would have been made but for the use
5 of the breakthrough device.

6 “(3) ADJUSTMENT TO QUALITY PROCESS MEAS-
7 URES FOR BREAKTHROUGH DEVICES.—

8 “(A) IN GENERAL.—In the case that the
9 furnishing by a provider of services or supplier
10 participating in a pay-for-performance program
11 of a breakthrough device to an individual enti-
12 tled to benefits under part A or enrolled under
13 part B and participating in such program would
14 result in such provider or supplier, with respect
15 to the condition and episode of care for which
16 such device is furnished, receiving a poor or
17 failing score for a quality measure under such
18 program that measures whether such provider
19 or supplier gave the treatment known to give
20 the best results for most patients with a par-
21 ticular condition (commonly known as a ‘clinical
22 process of care’ measure), the Secretary shall
23 exclude such quality measure from any deter-
24 mination of whether such provider or supplier
25 met applicable quality performance thresholds

1 under such program with respect to such condi-
2 tion and episode of care of such individual.

3 “(B) INAPPLICABILITY TO CLINICAL OUT-
4 COMES MEASURES.—Nothing in subparagraph
5 (A) may be construed to allow for the exclusion,
6 with respect to a breakthrough device furnished
7 to an individual by a provider or supplier under
8 a pay-for-performance program, of any quality
9 measure designed to reflect the results of care
10 furnished to such individual by such provider or
11 supplier (commonly known as a ‘clinical out-
12 come’ measure) from a determination described
13 in such subparagraph.”.

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

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

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

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

8 (B) determine the number of such devices
9 that were not breakthrough devices for pur-
10 poses of such section 1899C by reason of the
11 limitation under subsection (a)(2) of such sec-
12 tion; and

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

18 (3) REPORT.—Not later than 6 years after the
19 date of the enactment of this Act, the Secretary
20 shall submit to Congress a report on the study con-
21 ducted under this subsection and shall include such
22 recommendations for legislative or administrative
23 changes as the Secretary determines to be appro-
24 priate.

1 (c) MODIFICATIONS TO THE COUNCIL FOR TECH-
2 NOLOGY AND INNOVATION.—

3 (1) EXPANSION OF DUTIES.—Paragraph (3) of
4 section 1868(b) of the Social Security Act (42
5 U.S.C. 1395ee(b)) is amended by adding at the end
6 the following: “The Council shall also coordinate ac-
7 tivities of the Secretary for the implementation of
8 section 1899C (relating to breakthrough devices), es-
9 pecially with respect to timely coverage, coding, evi-
10 dence-gathering, and payment for such devices.”.

11 (2) REORGANIZATION WITHIN THE CMMI.—
12 Such section is further amended—

13 (A) in paragraph (1), by striking “within
14 the Centers” and all that follows through the
15 end and inserting “within the Center for Medi-
16 care and Medicaid Innovation established under
17 section 1115A (in this subsection referred to as
18 ‘CMMI’).”; and

19 (B) in paragraph (4), by striking “the Ad-
20 ministrator of CMS” and inserting “the Direc-
21 tor of the CMMI”.

22 (d) IMPROVEMENTS TO NTAP PAYMENT ADJUST-
23 MENT UNDER THE INPATIENT PROSPECTIVE PAYMENT
24 SYSTEM.—

1 (1) PAYMENT FOR COSTS OF NEW TECH-
2 NOLOGIES.—With respect to hospital discharges for
3 which payment is made under section 1886(d) of the
4 Social Security Act (42 U.S.C. 1395ww(d)) occur-
5 ring on or after October 1, 2016, in calculating the
6 amount of the additional payment for a new medical
7 service or technology under paragraph (5)(K) of
8 such section with respect to such a discharge, the
9 Secretary of Health and Human Services shall apply
10 section 412.88 of title 42, Code of Federal Regula-
11 tions, as if the reference to “50 percent” each place
12 it appears in such section were a reference to “80
13 percent”.

14 (2) CLARIFICATION REGARDING PAYMENTS FOR
15 NEW TECHNOLOGIES.—

16 (A) IPPS NEW TECHNOLOGY PAYMENT.—

17 Section 1886(d)(5)(K) of the Social Security
18 Act (42 U.S.C. 1395ww(d)(5)(K)) is amended
19 by adding at the end the following new clause:

20 “(x) During the period with respect to
21 which a new medical service or technology
22 is eligible for an additional payment under
23 this subsection by reason of this subpara-
24 graph, any local coverage determination
25 (as defined in section 1869(f)(2)(B)) that

1 would affect the coverage of, or the addi-
2 tional payment under this subsection for,
3 such new medical service or technology
4 shall have no force or effect in law or regu-
5 lation.”.

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

11 “(G) PROHIBITION ON USE OF LOCAL COV-
12 ERAGE DETERMINATIONS TO AFFECT COV-
13 ERAGE OF AND PAYMENT FOR PASS-THROUGH
14 DEVICES.—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 (C) EFFECTIVE DATE.—This paragraph,
24 and the amendments made by this paragraph,
25 shall apply with respect to items and services

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

12 (3) REVISION TO THE COST THRESHOLD.—

13 (A) IN GENERAL.—Section
14 1886(d)(5)(K)(ii)(I) of the Social Security Act
15 (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended
16 by striking “75 percent” each place it appears
17 and inserting “50 percent”.

18 (B) EFFECTIVE DATE.—The amendment
19 made by subparagraph (A) shall take effect on
20 the date of the enactment of this Act.

21 (4) USE OF BEST AVAILABLE COST DATA FOR
22 MS-DRG CLASSIFICATION.—

23 (A) IN GENERAL.—Section 1886(d)(5)(K)
24 of the Social Security Act (42 U.S.C.
25 1395ww(d)(5)(K)), as amended by paragraph

1 (2)(A)), is further amended by adding at the
2 end the following new clause:

3 “(xi) In carrying out the requirement
4 under clause (ii)(IV) for classification of a
5 new medical service or technology to a new
6 or existing diagnosis-related group after
7 the close of the period under clause (ii)(II),
8 the Secretary shall use the most recently
9 available data and information on the costs
10 of such service or technology in making
11 such a classification for the service or tech-
12 nology, including data and information
13 from surveys of providers of services and
14 suppliers conducted by the Secretary, pri-
15 vate payers, health plans, physician spe-
16 cialty societies, or manufacturers as well as
17 commercial price data and data from man-
18 ufacturer invoices.”.

19 (B) EFFECTIVE DATE.—The amendment
20 made by subparagraph (A) shall take effect on
21 the date of the enactment of this Act.

22 (5) CRITERIA APPLIED IN MAKING SUBSTAN-
23 TIAL IMPROVEMENT DETERMINATIONS.—

24 (A) IN GENERAL.—Section 1886(d)(5)(K)
25 of the Social Security Act (42 U.S.C.

1 1395ww(d)(5)(K)), as amended by paragraphs
2 (2)(A) and (4)(A), is further amended by add-
3 ing at the end the following new clause:

4 “(xii)(I) In making a determination
5 under this subparagraph whether a new
6 medical service or technology represents an
7 advance in medical technology that sub-
8 stantially improves the diagnosis or treat-
9 ment of Medicare beneficiaries relative to a
10 medical service or technology that was pre-
11 viously available, the Secretary shall also
12 consider whether such new medical service
13 or technology meets one or more of the fol-
14 lowing criteria:

15 “(aa) The use of the new medical
16 service or technology can result in a
17 reduction of the length of a hospital
18 stay.

19 “(bb) The use of the new medical
20 service or technology can improve pa-
21 tient quality of life.

22 “(cc) The use of the new medical
23 service or technology can create long-
24 term clinical efficiencies in treatment.

1 “(dd) The use of the new medical
2 service or technology can address pa-
3 tient-centered objectives (as defined
4 by the Secretary).

5 “(ee) The use of the new medical
6 service or technology can meet such
7 other criteria as the Secretary may
8 specify.

9 “(II) In considering whether a new
10 medical service or technology potentially
11 meets the criteria under subclause (I), the
12 Secretary shall consider the following
13 forms of evidence:

14 “(aa) Evidence described in well-
15 documented case histories, including
16 registry data.

17 “(bb) Studies published in peer-
18 reviewed journals.

19 “(cc) Data collected in countries
20 other than the United States so long
21 as such data otherwise meet the cri-
22 teria specified in this clause.”.

23 (B) EFFECTIVE DATE.—The amendment
24 made by subparagraph (A) shall take effect on
25 the date of the enactment of this Act.

1 (6) REVISION TO THE NEWNESS CRITERION.—

2 (A) IN GENERAL.—Section
3 1886(d)(5)(K)(vi) of the Social Security Act
4 (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

5 (i) by inserting “(I)” after “(vi)”; and

6 (ii) by adding at the end the following

7 new subclauses:

8 “(II) Under the criteria estab-
9 lished under this clause with respect
10 to the determination of whether a
11 medical service or technology is con-
12 sidered new for purposes of this sub-
13 paragraph and subparagraph (L), the
14 Secretary shall include devices that in-
15 volve a significant technological
16 change that do not raise different
17 questions of safety and effectiveness
18 (in a comparison to the predicate de-
19 vice) and result in enhanced clinical
20 advantages or reduced cost, even
21 though they use the same or similar
22 mechanism of action or are assigned
23 to the same diagnosis-related group.

24 “(III) Under the criteria estab-
25 lished under this clause with respect

1 to the determination of whether a
2 medical service or technology is con-
3 sidered new for purposes of this sub-
4 paragraph and subparagraph (L), the
5 Secretary shall not disqualify a new
6 medical service or technology as not
7 meeting the newness criterion solely
8 on the basis of a finding of a de mini-
9 mis number of claims for such med-
10 ical service or technology in Medicare
11 claims data. For purposes of this sub-
12 clause, the term ‘de minimis’ means,
13 with respect to claims, an amount
14 that is fewer than 50.”.

15 (B) EFFECTIVE DATE.—The amendment
16 made by subparagraph (A) shall take effect on
17 the date of the enactment of this Act.

18 (7) REVISION TO THE COMMENCEMENT OF THE
19 PERIOD FOR COLLECTION OF COST DATA FOR NEW
20 TECHNOLOGIES.—

21 (A) IN GENERAL.—Section
22 1886(d)(5)(K)(ii)(II) of the Social Security Act
23 (42 U.S.C. 1395ww(d)(5)(K)(ii)(II)) is amend-
24 ed by inserting “the later of the date that is the
25 date of the clearance or approval by the Com-

1 missioner of Food and Drugs of the service or
2 technology or” after “beginning on”.

3 (B) EFFECTIVE DATE.—The amendment
4 made by subparagraph (A) shall take effect on
5 the date of the enactment of this Act, and shall
6 apply with respect to hospital discharges for in-
7 patient hospital services for which payment is
8 made under section 1886(d) of the Social Secu-
9 rity Act (42 U.S.C. 1395ww) occurring on or
10 after October 1, 2016.

11 (8) PERMITTING APPEALS OF NTAP DETER-
12 MINATIONS.—

13 (A) IN GENERAL.—Section 1886(d)(5)(K)
14 of the Social Security Act (42 U.S.C.
15 1395ww(d)(5)(K)), as amended by paragraphs
16 (2)(A), (4)(A), and (5)(A), is further amended
17 by adding at the end the following new clause:

18 “(xiii)(I) An individual or entity that
19 submits an application for additional pay-
20 ment under this subparagraph for a new
21 technology shall be entitled to administra-
22 tive review of an adverse determination by
23 the Secretary with respect to such applica-
24 tion.

1 “(II) The Secretary shall establish a
2 process for administrative review for pur-
3 poses of subclause (I). Under such process,
4 administrative review shall be conducted by
5 an official of the Department of Health
6 and Human Services (other than an offi-
7 cial of the Centers for Medicare & Med-
8 icaid Services). Under such process, the
9 Department official involved shall complete
10 administrative review within 90 days of re-
11 ceipt of a request for such review.

12 “(III) In the case of an application
13 for additional payment under this subpara-
14 graph for a new technology that is ap-
15 proved under administrative review, the
16 Secretary shall provide for such additional
17 payment for such new technology during
18 the period that—

19 “(aa) begins on the date that is
20 the first day of the first calendar
21 quarter that begins after the date of
22 the completion of such administrative
23 review; and

24 “(bb) ends on the date that is
25 not less than 2 years and not more

1 than 3 years after the date referred to
2 in item (aa).”.

3 (B) CONFORMING AMENDMENT.—Section
4 1886(d)(7)(B) of such Act (42 U.S.C.
5 1395ww(d)(7)(B)) is amended by inserting “but
6 not including a denial by the Secretary of an
7 application for additional payment under para-
8 graph (5)(K) with respect to a discharge occur-
9 ring on or after the date of the date of the en-
10 actment of the Ensuring Patient Access to Crit-
11 ical Breakthrough Products Act of 2016” after
12 “paragraph (4)(D)”.

13 (C) EFFECTIVE DATE.—The amendments
14 made by this paragraph shall take effect on the
15 date of the enactment of this Act, and shall
16 apply with respect to hospital discharges for in-
17 patient hospital services for which payment is
18 made under section 1886(d) of the Social Secu-
19 rity Act (42 U.S.C. 1395ww) occurring on or
20 after October 1, 2016.

21 (e) CONFORMING AMENDMENTS.—

22 (1) INPATIENT PROSPECTIVE PAYMENT SYS-
23 TEM.—Section 1886(d)(5)(K)(i) of the Social Secu-
24 rity Act (42 U.S.C. 1395ww(d)(5)(K)(i)) is amended
25 by adding at the end the following new sentence:

1 “Effective for discharges occurring on or after Octo-
2 ber 1, 2016, in the case of a new medical service or
3 technology that is a breakthrough device (as defined
4 in section 1899C(a)) payment for such breakthrough
5 device shall be made for the 3-year period applicable
6 to such breakthrough device under section
7 1899C(d)(1).”.

8 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
9 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
10 13951(t)(6)(C)) is amended by adding at the end the
11 following new clause:

12 “(iii) SPECIAL RULE FOR BREAK-
13 THROUGH DEVICES.—Notwithstanding
14 clause (i) or (ii), or any other provision of
15 this paragraph to the contrary, in the case
16 of a breakthrough device (as defined in
17 section 1899C(a)) that is furnished on or
18 after January 1, 2017, payment under this
19 paragraph for such breakthrough device
20 shall be made for the 3-year period appli-
21 cable to such breakthrough device under
22 section 1899C(d)(2). The provisions of this
23 clause shall also apply for purposes of
24 transitional pass-through payment under
25 section 1833(i)(2)(D).”.

1 (f) EFFECTIVE DATE.—This section and the amend-
2 ments made by this section shall take effect on the date
3 of the enactment of this Act and, unless otherwise speci-
4 fied in this section (or in an amendment made by this sec-
5 tion), shall apply to breakthrough devices (as defined in
6 section 1899C(a), as added by subsection (a)) approved
7 on or after January 1, 2017.

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