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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ensuring Patient Access to Critical Breakthrough Products Act of 2016".

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

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

“SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES.

“(a) BREAKTHROUGH DEVICES.—

“(1) IN GENERAL.—For purposes of this section, the term ‘breakthrough device’ means a medical device that is a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) and that either—

“(A) is—

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

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

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

“(2) LIMITATION ON NUMBER OF 510(k) DEVICES.—With respect to a 5-year period, in no case may more than five medical devices described in paragraph (1)(B) be covered and paid for under this title by reason of this section during each such 5-year period.

“(b) COVERAGE.—

“(1) TRANSITIONAL COVERAGE.—

“(A) IN GENERAL.—During the transitional coverage period (as defined in subparagraph (B)) a breakthrough device shall be—

“(i) deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

“(ii) deemed to be approved for an additional payment under section 1886(d)(5)(K);

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

“(iv) insofar as such breakthrough device may be furnished in a setting for which payment is made under an applicable payment system described in subparagraphs (D) through (I) of subsection (c)(4), deemed eligible for an additional payment pursuant to subsection (d)(3) when furnished in a setting for which payment is made under such an applicable

payment system during such transitional coverage period.

"(B) TRANSITIONAL COVERAGE PERIOD DEFINED.—As used in this section, the term 'transitional coverage period' means, with respect to a breakthrough device, the period that—

"(i) begins on the date of the approval under section 515 of the Federal Food, Drug, and Cosmetic Act or of the clearance under section 510(k) of such Act, as applicable, of such device by the Secretary for the indication described in subparagraph (A)(ii) or (B) of subsection (a)(1), respectively; and

"(ii) ends on the last day of the 3-year period that begins on the date that the Secretary, pursuant to subsection (c)(2), updates the relevant applicable payment system (as defined in subsection (c)(4)) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device, except as provided in subsections (d)(1)(B) and (d)(2)(B).

"(2) PROCESS FOR REGULAR COVERAGE.—For purposes of the application of section 1862(a)(1)(A) to a breakthrough device furnished after the transitional coverage period (as defined in paragraph (1)(B)) for such device, the Secretary, acting through the Council for Technology and Innovation (established under section 1868(b)) in conjunction with the Coverage and Analysis Group of the Centers for Medicare & Medicaid Services, shall establish a process for the coverage of such breakthrough devices under this title after such period as follows:

"(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—

"(i) IN GENERAL.—With respect to a breakthrough device, not later than 1 year after the date of the approval of such device under section 515 of the Federal Food, Drug, and Cosmetic Act or of the clearance of such device under section 510(k) of such Act, as applicable, the Secretary shall identify whether any additional data or evidence is required with respect to any indications for such device for purposes of the application of such section 1862(a)(1)(A) to such device for such indications.

"(ii) NON-DUPLICATION OF DATA REQUESTS.—In carrying out clause (i) with respect to a breakthrough device, the Secretary shall ensure that data or evidence identified—

"(I) does not duplicate data required to be collected by the Food and Drug Administration with respect to such breakthrough device;

"(II) minimizes the administrative burdens of data collection and reporting on providers of services, suppliers, and manufacturers of breakthrough devices; and

"(III) is not otherwise unnecessary or redundant.

"(B) PROPOSAL FOR COVERAGE AFTER THE TRANSITIONAL COVERAGE PERIOD.—Not later than 2 years after the date of the approval or clearance of a breakthrough device by the Food and Drug Administration, the Secretary shall develop a proposal for coverage under this title of such breakthrough device for such indications as the Secretary determines to be appropriate, based on the data and evidence collected under subparagraph (A), for such devices furnished after the transitional coverage period under paragraph (1) for such device. If the Secretary does not, on a date that is before the end of such two-year period, take action to modify the indications for which coverage of a breakthrough device may be provided under this title after such period, for purposes of section 1862(a)(1)(A) coverage under this title of such breakthrough device shall be made for all indications for which such device is approved under section 515 of the Federal Food, Drug, and Cosmetic Act or cleared under section 510(k) of such Act.

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

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

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

"(c) CODING.—

"(1) PROMPT ASSIGNMENT.—Not later than three months after the date of approval or clearance of a breakthrough device by the Food and Drug Administration, subject to subparagraph (B), the Secretary shall assign a unique temporary or permanent code or codes for purposes of coverage and payment for such breakthrough device under the applicable payment systems (described in paragraph (4)).

"(2) UPDATES.—

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

"(B) OPPS.—The Secretary shall provide for quarterly updates under the applicable payment system described in paragraph (4)(B) (relating to the outpatient hospital prospective payment system) to recognize the code or codes assigned under paragraph (1).

"(3) TRANSPARENCY.—The process for the assignment of a code or codes under this subsection shall provide for public notice and a meaningful opportunity for public comment from affected parties.

"(4) APPLICABLE PAYMENT SYSTEMS DESCRIBED.—For purposes of this subsection, the term 'applicable payment systems' means—

"(A) with respect to inpatient hospital services, the prospective payment system for inpatient hospital services established under section 1886(d);

"(B) with respect to outpatient hospital services, the prospective payment system for covered OPD services established under section 1833(t);

"(C) with respect to ambulatory surgical center services, the fee schedule for such services established under 1833(i);

"(D) with respect to physicians' services, the physician fee schedules established under section 1848;

"(E) with respect to covered items of durable medical equipment, the applicable fee schedules established under section 1834;

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

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

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

"(I) with respect to inpatient hospital services furnished by psychiatric hospitals and psychiatric units, the prospective payment system under section 1886(s).

"(d) PAYMENT.—

"(1) INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM: DEEMED ELIGIBILITY FOR BREAKTHROUGH PAYMENT.—The Secretary shall deem each breakthrough device as approved for an additional payment under section 1886(d)(5)(K) for the 3-year period that begins—

"(A) except as provided in subparagraph (B), on the date that the Secretary, pursuant to subsection (c)(2)(A), updates the payment system under section 1886(d) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device; or

"(B) in the case of a device that has not received approval or clearance as a breakthrough device by the Food and Drug Administration before such payment system is updated under subsection (c)(2)(A) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such device, on the date of such approval or clearance.

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

"(2) OUTPATIENT PROSPECTIVE PAYMENT SYSTEM: DEEMED ELIGIBILITY FOR PASS-THROUGH PAYMENT.—The Secretary shall deem each breakthrough device as approved for pass-through payment under section 1833(t)(6) (including for purposes of section 1833(i)(2)(D)) during the 3-year period that begins—

"(A) except as provided in subparagraph (B), on the date that the Secretary, pursuant to subsection (c)(2)(B), updates the payment system under section 1833(t) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device; or

"(B) in the case of a device that has not received approval or clearance as a breakthrough device by the Food and Drug Administration before such payment system is updated under subsection (c)(2)(B) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such device, on the date of such approval or clearance.

Nothing in this paragraph shall be construed to affect the authority of the Secretary

to use claims data to establish new ambulatory payment classification groups for breakthrough devices or to revise such groups to take into account breakthrough devices under annual rulemaking to carry out section 1833(t).

"(3) OTHER PAYMENT SYSTEMS.—

"(A) IN GENERAL.—In the case of breakthrough device that is furnished and for which payment may be made under the payment system established under sections 1834, 1834A, 1848, 1886(j), 1886(m), 1886(s), or any other relevant provision of this title (other than sections 1833(i), 1833(t), and 1886(d)), the Secretary shall provide for an additional payment for such breakthrough device under such payment systems in an amount equal to 80 percent of the costs of such breakthrough device.

"(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to affect the authority of the Secretary to use claims data to establish new or modify existing ambulatory payment classification groups, diagnosis-related groups, level II HCPCS codes or such other groups or codes as the Secretary may establish under the annual rulemaking authority under the provisions referred to in subparagraph (A).

"(4) PAYMENT FOR BREAKTHROUGH DEVICES AFTER THE TRANSITIONAL COVERAGE PERIOD.—Payment for a breakthrough device that is furnished after the conclusion of the transitional coverage period under subsection (b)(1) for such device shall be made pursuant to the applicable payment system involved, taking into account the additional evidence and data collected under subsection (b)(2).

"(e) TREATMENT OF BREAKTHROUGH DEVICES UNDER PAY-FOR-PERFORMANCE PROGRAMS.—

"(1) PAY-FOR-PERFORMANCE PROGRAMS DEFINED.—In this subsection, the term 'pay-for-performance programs' means, with respect to items and services for which payment is made under the applicable payment systems under this title, payment initiatives designed to improve the quality, efficiency, and overall value of health care furnished to individuals entitled to benefits under part A or enrolled under part B through financial incentives to providers of services and suppliers for meeting or exceeding certain quality or performance measures or through financial penalties on providers that fail to achieve specified goals or cost savings, or both. Such term includes—

"(A) the Medicare shared savings program under established section 1899;

"(B) shared savings programs tested by the Center for Medicare and

Medicaid Innovation under section 1115A, including the Pioneer ACO program;

"(C) the National Pilot Program on Payment Bundling under section 1866D;

"(D) bundled payment programs tested by the Center for Medicare and Medicaid Innovation under section 1115A; and

"(E) any other similar program conducted under this title or under applicable authorities under title XI.

"(2) EXCLUSION OF ADDITIONAL COSTS OF BREAKTHROUGH DEVICES.—Insofar as the amount of payment for a breakthrough device exceeds the amount of payment that the item or service would otherwise receive under a pay-for-performance program for which shared savings or shared losses are calculated, the Secretary shall exclude from the calculation of such shared savings or losses under such program for such period the amount by which the payment for the breakthrough device involved exceeds the payment amount for such other item or service that would have been made but for the use of the breakthrough device.

"(3) ADJUSTMENT TO QUALITY PROCESS MEASURES FOR BREAKTHROUGH DEVICES.—

"(A) IN GENERAL.—In the case that the furnishing by a provider of services or supplier participating in a pay-for-performance program of a breakthrough device to an individual entitled to benefits under part A or enrolled under part B and participating in such program would result in such provider or supplier, with respect to the condition and episode of care for which such device is furnished, receiving a poor or failing score for a quality measure under such program that measures whether such provider or supplier gave the treatment known to give the best results for most patients with a particular condition (commonly known as a 'clinical process of care' measure), the Secretary shall exclude such quality measure from any determination of whether such provider or supplier met applicable quality performance thresholds under such program with respect to such condition and episode of care of such individual.

"(B) INAPPLICABILITY TO CLINICAL OUTCOMES MEASURES.—Nothing in subparagraph (A) may be construed to allow for the exclusion, with respect to a breakthrough device furnished to an individual by a provider or supplier under a pay-for-performance program, of any quality measure designed to reflect the results of care furnished to such individual by such provider or supplier

(commonly known as a ‘clinical outcome’ measure) from a determination described in such subparagraph.”.

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

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

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

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

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

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

(3) REPORT.—Not later than 6 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under this subsection and shall include such recommendations for legislative or administrative changes as the Secretary determines to be appropriate.

(c) MODIFICATIONS TO THE COUNCIL FOR TECHNOLOGY AND INNOVATION.—

(1) EXPANSION OF DUTIES.—Paragraph (3) of section 1868(b) of the Social Security Act (42 U.S.C. 1395ee(b)) is amended by adding at the end the following: “The Council shall also coordinate activities of the Secretary for the implementation of section 1899C (relating to breakthrough devices), especially with respect to timely coverage, coding, evidence-gathering, and payment for such devices.”.

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

(A) in paragraph (1), by striking “within the Centers” and all that follows through the end and inserting “within the Center for Medicare and Medicaid Innovation established under section 1115A (in this subsection referred to as

'CMMI').''; and

(B) in paragraph (4), by striking "the Administrator of CMS" and inserting "the Director of the CMMI".

(d) IMPROVEMENTS TO NTAP PAYMENT ADJUSTMENT UNDER THE INPATIENT PROSPECTIVE PAYMENT SYSTEM.—

(1) PAYMENT FOR COSTS OF NEW TECHNOLOGIES.—With respect to hospital discharges for which payment is made under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) occurring on or after October 1, 2016, in calculating the amount of the additional payment for a new medical service or technology under paragraph (5)(K) of such section with respect to such a discharge, the Secretary of Health and Human Services shall apply section 412.88 of title 42, Code of Federal Regulations, as if the reference to "50 percent" each place it appears in such section were a reference to "80 percent".

(2) CLARIFICATION REGARDING PAYMENTS FOR NEW TECHNOLOGIES.—

(A) IPPS NEW TECHNOLOGY PAYMENT.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

"(x) During the period with respect to which a new medical service or technology is eligible for an additional payment under this subsection by reason of this subparagraph, any local coverage determination (as defined in section 1869(f)(2)(B)) that would affect the coverage of, or the additional payment under this subsection for, such new medical service or technology shall have no force or effect in law or regulation.".

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

"(G) PROHIBITION ON USE OF LOCAL COVERAGE DETERMINATIONS TO AFFECT COVERAGE OF AND PAYMENT FOR PASS-THROUGH DEVICES.—During the period with respect to which a drug, biological, or medical device is eligible for an additional payment under this paragraph, any local coverage determination (as defined in section 1869(f)(2)(B)) that would affect the coverage of, or the additional payment under this paragraph for, such drug, biological, or medical device shall have no force or effect in law or regulation.".

(C) FFECTIVE DATE.—This paragraph, and the amendments made by this

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paragraph, shall apply with respect to items and services furnished on or after the date of the enactment of this Act, including any such item or service that is eligible on such date for an additional payment under section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) or under section 1886(d) of such Act (42 U.S.C. 1395ww(d)) by reason of paragraph (5)(K) of such section, or that would have been so eligible on such date but for a local coverage determination that limits or denies coverage of and such additional payment for the item or service.

(3) REVISION TO THE COST THRESHOLD.—

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

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

(4) USE OF BEST AVAILABLE COST DATA FOR MS–DRG CLASSIFICATION.—

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

"(xi) In carrying out the requirement under clause (ii)(IV) for classification of a new medical service or technology to a new or existing diagnosis-related group after the close of the period under clause (ii)(II), the Secretary shall use the most recently available data and information on the costs of such service or technology in making such a classification for the service or technology, including data and information from surveys of providers of services and suppliers conducted by the Secretary, private payers, health plans, physician specialty societies, or manufacturers as well as commercial price data and data from manufacturer invoices.".

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

(5) CRITERIA APPLIED IN MAKING SUBSTANTIAL IMPROVEMENT DETERMINATIONS.—

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

"(xii) (I) In making a determination under this subparagraph whether a new medical service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries relative to a medical service or technology that was previously available, the Secretary shall also consider whether such new medical service or technology meets one or more of the following criteria:

"(aa) The use of the new medical service or technology can result in a reduction of the length of a hospital stay.

"(bb) The use of the new medical service or technology can improve patient quality of life.

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

"(dd) The use of the new medical service or technology can address patient-centered objectives (as defined by the Secretary).

"(ee) The use of the new medical service or technology can meet such other criteria as the Secretary may specify.

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

"(aa) Evidence described in well-documented case histories, including registry data.

"(bb) Studies published in peer-reviewed journals.

"(cc) Data collected in countries other than the United States so long as such data otherwise meet the criteria specified in this clause.".

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

(6) REVISION TO THE NEWNESS CRITERION.—

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

(i) by inserting "(I)" after "(vi)"; and

(ii) by adding at the end the following new subclauses:

"(II) Under the criteria established under this clause with respect to the determination of whether a medical service or technology is considered new for purposes of this subparagraph and subparagraph (L), the Secretary shall include devices that involve a significant technological change that do not raise different questions of safety and effectiveness (in a comparison to the predicate device) and result in enhanced clinical advantages or reduced cost, even though they use the same or similar mechanism of action or are assigned to the same diagnosis-related group.

"(III) Under the criteria established under this clause with respect to the determination of whether a medical service or technology is considered new for purposes of this subparagraph and subparagraph (L), the Secretary shall not disqualify a new medical service or technology as not meeting the newness criterion solely on the basis of a finding of a de minimis number of claims for such medical service or technology in Medicare claims data. For purposes of this subclause, the term 'de minimis' means, with respect to claims, an amount that is fewer than 50.".

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

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

(A) IN GENERAL.—Section 1886(d)(5)(K)(ii)(II) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(ii)(II)) is amended by inserting "the later of the date that is the date of the clearance or approval by the Commissioner of Food and Drugs of the service or technology or" after "beginning on".

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall take effect on the date of the enactment of this Act, and shall apply with respect to hospital discharges for inpatient hospital services for which payment is made under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww) occurring on or after October 1, 2016.

(8) PERMITTING APPEALS OF NTAP DETERMINATIONS.—

(A) IN GENERAL.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)), as amended by paragraphs (2)(A), (4)(A), and (5)

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

"(xiii) (I) An individual or entity that submits an application for additional payment under this subparagraph for a new technology shall be entitled to administrative review of an adverse determination by the Secretary with respect to such application.

"(II) The Secretary shall establish a process for administrative review for purposes of subclause (I). Under such process, administrative review shall be conducted by an official of the Department of Health and Human Services (other than an official of the Centers for Medicare & Medicaid Services). Under such process, the Department official involved shall complete administrative review within 90 days of receipt of a request for such review.

"(III) In the case of an application for additional payment under this subparagraph for a new technology that is approved under administrative review, the Secretary shall provide for such additional payment for such new technology during the period that—

"(aa) begins on the date that is the first day of the first calendar quarter that begins after the date of the completion of such administrative review; and

"(bb) ends on the date that is not less than 2 years and not more than 3 years after the date referred to in item (aa).".

(B) CONFORMING AMENDMENT.—Section 1886(d)(7)(B) of such Act (42 U.S.C. 1395ww(d)(7)(B)) is amended by inserting "but not including a denial by the Secretary of an application for additional payment under paragraph (5)(K) with respect to a discharge occurring on or after the date of the date of the enactment of the Ensuring Patient Access to Critical Breakthrough Products Act of 2016" after "paragraph (4)(D)".

(C) EFFECTIVE DATE.—The amendments made by this paragraph shall take effect on the date of the enactment of this Act, and shall apply with respect to hospital discharges for inpatient hospital services for which payment is made under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww) occurring on or after October 1, 2016.

(e) CONFORMING AMENDMENTS.—

(1) INPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1886(d)(5)(K)(i) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(i)) is amended by adding at the

end the following new sentence: “Effective for discharges occurring on or after October 1, 2016, in the case of a new medical service or technology that is a breakthrough device (as defined in section 1899C(a)) payment for such breakthrough device shall be made for the 3-year period applicable to such breakthrough device under section 1899C(d)(1).”.

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

“(iii) SPECIAL RULE FOR BREAKTHROUGH DEVICES.—Notwithstanding clause (i) or (ii), or any other provision of this paragraph to the contrary, in the case of a breakthrough device (as defined in section 1899C(a)) that is furnished on or after January 1, 2017, payment under this paragraph for such breakthrough device shall be made for the 3-year period applicable to such breakthrough device under section 1899C(d)(2). The provisions of this clause shall also apply for purposes of transitional pass-through payment under section 1833(i)(2)(D).”.

(f) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect on the date of the enactment of this Act and, unless otherwise specified in this section (or in an amendment made by this section), shall apply to breakthrough devices (as defined in section 1899C(a), as added by subsection (a)) approved on or after January 1, 2017.
