

115TH CONGRESS
1ST SESSION

H. R. 4679

To amend title XVIII of the Social Security Act to provide for improvements to coverage and payment under the Medicare program for new drugs, devices, and technology.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 18, 2017

Mr. REED (for himself and Mr. REICHERT) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for improvements to coverage and payment under the Medicare program for new drugs, devices, and technology.

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 Equal Access
5 to Treatments Act of 2017”.

1 **SEC. 2. COVERAGE AND PAYMENT FOR NEW DRUGS, DE-**
2 **VICES, AND TECHNOLOGY UNDER THE MEDI-**
3 **CARE PROGRAM.**

4 (a) IMPROVEMENTS TO NTAP PAYMENT ADJUST-
5 MENT UNDER THE INPATIENT PROSPECTIVE PAYMENT
6 SYSTEM.—

7 (1) PAYMENT FOR COSTS OF NEW TECH-
8 NOLOGIES.—With respect to hospital discharges oc-
9 ccurring on or after October 1, 2018, for which pay-
10 ment is made under section 1886(d) of the Social
11 Security Act (42 U.S.C. 1395ww(d)), in calculating
12 the amount of the additional payment for a new
13 medical service or technology under paragraph
14 (5)(K) of such section with respect to such a dis-
15 charge, the Secretary of Health and Human Services
16 shall apply section 412.88 of title 42, Code of Fed-
17 eral Regulations—

18 (A) as if the reference to “50 percent”
19 each place it appears in such section were a ref-
20 erence to “75 percent”; and

21 (B) as if paragraph (b) of such section did
22 not include “Unless a discharge case qualifies
23 for outlier payment under § 412.84.”.

24 (2) REVISION TO THE COST THRESHOLD.—Sec-
25 tion 1886(d)(5)(K) of the Social Security Act (42
26 U.S.C. 1395ww(d)(5)(K)) is amended—

1 (A) in clause (ii)—

2 (i) in subclause (I), by striking “75
3 percent” each place it appears and insert-
4 ing “50 percent”; and

5 (ii) in subclause (II), by striking “not
6 less than two years and not more than
7 three years” and inserting “five years”;
8 and

9 (B) in clause (iii), by striking “Inter-
10 national Classification of Diseases, 9th Revi-
11 sion, Clinical Modification (“ICD–9–CM”)” and
12 inserting “International Classification of Dis-
13 eases, 10th Revision, Clinical Modification
14 (“ICD–10–CM”)”.

15 (3) REVISION TO THE COMMENCEMENT OF THE
16 PERIOD FOR COLLECTION OF COST DATA FOR NEW
17 TECHNOLOGIES.—Section 1886(d)(5)(K)(ii)(II) of
18 the Social Security Act (42 U.S.C.
19 1395ww(d)(5)(K)(ii)(II)) is amended by inserting
20 “the later of the date that is the date of the clear-
21 ance or approval by the Commissioner of Food and
22 Drugs of the service or technology or” after “begin-
23 ning on”.

24 (4) PERMITTING APPEALS OF NTAP DETER-
25 MINATIONS.—

1 (A) IN GENERAL.—Section 1886(d)(5)(K)
 2 of the Social Security Act (42 U.S.C.
 3 1395ww(d)(5)(K)) is amended by adding at the
 4 end the following new clause:

5 “(x)(I) An individual or entity that submits an appli-
 6 cation for additional payment under this subparagraph for
 7 a new technology shall be entitled to administrative review
 8 of an adverse determination by the Secretary with respect
 9 to such application.

10 “(II) The Secretary shall establish a process for ad-
 11 ministrative review for purposes of subclause (I). Under
 12 such process, administrative review shall be conducted by
 13 the Departmental Appeals Board of the Department of
 14 Health and Human Services. Under such process, the De-
 15 partmental Appeals Board shall complete administrative
 16 review within 90 days of the date of receipt of the request
 17 for such review.”.

18 (B) CONFORMING AMENDMENT.—Section
 19 1886(d)(7)(B) of such Act (42 U.S.C.
 20 1395ww(d)(7)(B)) is amended by inserting “but
 21 not including a denial by the Secretary of an
 22 application for additional payment under para-
 23 graph (5)(K)” after “paragraph (4)(D)”.

24 (5) REQUIRING NEW DRG CODES FOR NEW
 25 TECHNOLOGIES COMING OFF OF NEW TECHNOLOGY

1 ADD-ON.—Section 1886(d)(5)(K)(ii)(IV) of such Act
2 (42 U.S.C. 1395ww(d)(5)(K)(ii)(IV)) is amended by
3 striking “or existing”.

4 (6) LIMIT ON AGGREGATE ANNUAL ADJUST-
5 MENT.—Section 1886(d)(5) of such Act (42 U.S.C.
6 1395ww(d)(5)) is amended by adding at the end the
7 following new subparagraph:

8 “(M) LIMIT ON AGGREGATE ANNUAL AD-
9 JUSTMENT.—

10 “(i) IN GENERAL.—The total of the
11 additional payments made under subpara-
12 graphs (K) and (L) for covered services
13 furnished for discharges in a fiscal year (as
14 estimated by the Secretary before the be-
15 ginning of the fiscal year) may not exceed
16 the applicable percentage (specified in
17 clause (ii)) of the total program payments
18 estimated to be made under this subsection
19 for all covered services furnished for dis-
20 charges in that fiscal year. If this clause is
21 first applied to less than a full fiscal year,
22 the previous sentence shall apply only to
23 the portion of such fiscal year.

24 “(ii) APPLICABLE PERCENTAGE.—For
25 purposes of clause (i), the term “applicable

percentage” for fiscal year 2019 and each subsequent fiscal year, is a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

“(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a fiscal year that the amount of the additional payments under subparagraphs (K) and (L) for the fiscal year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause (i), the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that fiscal year (or portion thereof) in order to ensure that the aggregate additional payments under subparagraphs (K) and (L) (as so estimated) do not exceed such limit.”.

(7) EFFECTIVE DATE.—The amendments made by paragraphs (2), (3), (4), (5), and (6) shall take effect on the date of the enactment of this Act and shall apply with respect to hospital discharges occur-

1 ring on or after October 1, 2018, for inpatient hos-
 2 pital services for which payment is made under sec-
 3 tion 1886(d) of the Social Security Act (42 U.S.C.
 4 1395ww).

5 (b) IMPROVEMENTS TO PAYMENT ADJUSTMENT
 6 UNDER THE MEDICARE OUTPATIENT PROSPECTIVE PAY-
 7 MENT SYSTEM FOR CERTAIN DRUGS AND DEVICES ELIGI-
 8 BLE OR PREVIOUSLY ELIGIBLE FOR PASS-THROUGH.—

9 (1) REQUIRING SEPARATE AMBULATORY PAY-
 10 MENT CLASSIFICATION FOR CERTAIN DRUGS AND
 11 DEVICES PREVIOUSLY ELIGIBLE FOR PASS-THROUGH
 12 PAYMENTS.—Section 1833(t) of the Social Security
 13 Act (42 U.S.C. 1395l(t)) is amended—

14 (A) in paragraph (2)—

15 (i) in subparagraph (G), by striking
 16 “and” at the end;

17 (ii) in subparagraph (H), by striking
 18 the period at the end and inserting “;
 19 and”; and

20 (iii) by adding at the end the fol-
 21 lowing new subparagraph:

22 “(I) the Secretary shall create additional
 23 groups of covered OPD services that classify
 24 separately procedures and services that employ
 25 medical devices and drugs described in a sub-

1 paragraph of paragraph (22), in accordance
2 with such paragraph.”; and

3 (B) by adding at the end the following new
4 paragraph:

5 “(22) SEPARATE ADDITIONAL PAYMENT
6 GROUPS FOR CERTAIN DRUGS AND DEVICES PRE-
7 VIOUSLY ELIGIBLE FOR PASS-THROUGH PAY-
8 MENTS.—For purposes of paragraph (2)(I), the fol-
9 lowing shall apply:

10 “(A) IN GENERAL.—For payments under
11 this subsection for services furnished on or
12 after January 1, 2020, the Secretary shall, in
13 accordance with subparagraph (B), create addi-
14 tional groups of covered OPD services to clas-
15 sify separately from other covered OPD services
16 the following:

17 “(i) EXISTING PASS-THROUGH DRUGS
18 AND DEVICES.—Medical devices and drugs
19 that met the requirements of paragraph
20 (6)(A)(iv) and were receiving payment
21 under paragraph (6) by reason of satis-
22 fying such requirements beginning on or
23 after the date of enactment of this para-
24 graph.

1 “(ii) RETIRED PASS-THROUGH DRUGS
2 AND DEVICES.—Medical devices and drugs
3 that had met the requirements of para-
4 graph (6)(A)(iv) and were receiving pay-
5 ment under paragraph (6) by reason of
6 satisfying such requirements before the
7 date of enactment of this paragraph but
8 after January 1, 2010.

9 “(B) CONSIDERATIONS.—In carrying out
10 subparagraph (A), the Secretary shall—

11 “(i) bundle procedures and services
12 that employ a device to which such sub-
13 paragraph applies with all relevant diag-
14 nostic tests and surgical procedures, as ap-
15 plicable;

16 “(ii) bundle procedures and services
17 that employ a drug, with respect to which
18 payment is not made on or after the date
19 specified in subparagraph (A) in accord-
20 ance with the methodology under section
21 1847A and to which such subparagraph
22 applies, with all relevant diagnostic tests
23 and surgical procedures, as applicable; and

24 “(iii) include such relevant diagnostic
25 tests and surgical procedures in more than

1 one group created under such subpara-
2 graph, as necessary.”.

3 (2) REVISION TO PASS-THROUGH PERIOD
4 UNDER OPPS.—Section 1833(t)(6) of the Social Se-
5 curity Act (42 U.S.C. 1395l(t)(6)) is amended—

6 (A) in subparagraph (B)(iii), by striking
7 “at least 2 years, but not more than 3 years”
8 and inserting “5 years”; and

9 (B) in subparagraph (C)(i), by striking “at
10 least 2 years, but not more than 3 years” and
11 inserting “5 years”.

12 (3) APPEALS PROCESS.—Section 1833(t)(6) of
13 the Social Security Act (42 U.S.C. 1395l(t)(6)) is
14 amended by adding at the end the following new
15 subparagraph:

16 “(F) APPEALS PROCESS.—

17 “(i) IN GENERAL.—An individual or
18 entity that submits an application for addi-
19 tional payment under this paragraph for a
20 new technology shall be entitled to admin-
21 istrative review of an adverse determina-
22 tion by the Secretary with respect to such
23 application.

24 “(ii) PROCESS.—The Secretary shall
25 establish a process for administrative re-

1 view for purposes of clause (i). Under such
2 process, administrative review shall be con-
3 ducted by the Departmental Appeals
4 Board of the Department of Health and
5 Human Services. Under such process, the
6 Department official involved shall complete
7 administrative review within 90 days of re-
8 ceipt of a request for such review.”.

9 (4) EFFECTIVE DATE.—The amendments made
10 by paragraphs (2) and (3) shall take effect on the
11 date of enactment of this Act and shall apply with
12 respect to items and services furnished on or after
13 January 1, 2020.

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