

119TH CONGRESS
1ST SESSION

S. 2730

To amend title XVIII of the Social Security Act to improve access to innovative treatment options for end-stage renal disease under the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 8, 2025

Mrs. BLACKBURN (for herself and Mr. BOOKER) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to improve access to innovative treatment options for end-stage renal disease under the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 (a) IN GENERAL.—This Act may be cited as the
5 “Kidney Care Access Protection Act”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title.

TITLE I—PROTECTING PATIENT ACCESS TO KIDNEY CARE
INNOVATION

Sec. 101. Refining the end-stage renal disease payment system to improve access to innovative treatment options.

Sec. 102. Ensuring Medicare Advantage supports kidney care innovative therapies.

TITLE II—ADDRESSING STAFFING BARRIERS WITH ESRD
MARKET BASKET LABOR ADJUSTMENTS

Sec. 201. Ensuring accuracy and stability in kidney care payment.

1 **TITLE I—PROTECTING PATIENT**
2 **ACCESS TO KIDNEY CARE IN-**
3 **NOVATION**

4 **SEC. 101. REFINING THE END-STAGE RENAL DISEASE PAY-**
5 **MENT SYSTEM TO IMPROVE ACCESS TO INNO-**
6 **VATIVE TREATMENT OPTIONS.**

7 (a) EXTENSION OF TRANSITIONAL DRUG ADD-ON
8 PAYMENT ADJUSTMENT (TDAPA) PERIOD.—The Sec-
9 retary of Health and Human Services (in this section re-
10 ferred to as the “Secretary”) shall pay the transitional
11 drug add-on payment adjustment under section
12 413.234(c) of title 42, Code of Federal Regulations (or
13 a successor regulation), for not less than 3 years for any
14 new renal dialysis drug or biological product—

15 (1) approved by the Food and Drug Adminis-
16 tration on or after January 1, 2020, under section
17 505 of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 355) or section 351 of the Public Health
19 Service Act (42 U.S.C. 262);

1 (2) that qualifies for such adjustment under
2 such section; and

3 (3) that is furnished on or after January 1,
4 2026.

5 (b) PERMANENT POST-TDAPA ADJUSTMENT.—Sec-
6 tion 1881(b)(14) of the Social Security Act (42 U.S.C.
7 1395rr(b)(14)) is amended by adding at the end the fol-
8 lowing new subparagraph:

9 “(J) PAYMENT FOR NEW AND INNOVATIVE
10 DRUGS, BIOLOGICALS, AND DEVICES THAT ARE
11 RENAL DIALYSIS SERVICES.—

12 “(i) IN GENERAL.—For any new renal di-
13 alysis drug or biological product that is used to
14 treat or manage a condition as defined in sec-
15 tion 413.234(a) of title 42, Code of Federal
16 Regulations that received a transitional drug
17 add-on payment adjustment (referred to in this
18 subparagraph as ‘TDAPA’) under section
19 413.234(c) of such title, and was furnished on
20 or after January 1, 2024, the Secretary shall
21 establish a permanent add-on adjustment to the
22 base rate for claims submitted on or after Jan-
23 uary 1, 2026, that includes the administration
24 of such drugs or biologicals.

1 “(ii) CALCULATION OF THE POST-TDAPA
2 ADD-ON ADJUSTMENT.—In calculating the add-
3 on adjustment described in clause (i), the Sec-
4 retary shall—

5 “(I) base the calculation on—

6 “(aa) except as provided in items
7 (bb) and (cc), the most recent 12-
8 month period of utilization for the
9 new renal dialysis drug or biological
10 product and the most recent available
11 full calendar quarter of average sales
12 price data for such drug or product;

13 “(bb) if the most recent available
14 full calendar quarter of average sales
15 price data reflects 0 or negative sales,
16 100 percent of the wholesale acquisi-
17 tion cost (as defined in section
18 1847A(c)(6)) of such drug or product;
19 or

20 “(cc) if the wholesale acquisition
21 cost is not available, the drug manu-
22 facturer’s invoice;

23 “(II) calculate the post-TDAPA add-
24 on payment adjustment as the expendi-
25 tures for the new renal dialysis drug or bi-

1 logical product divided by the total num-
2 ber of renal dialysis services during which
3 such drug or biological was administered
4 during the same period;

5 “(III) set the amount of the add-on
6 adjustment as an amount equal to 65 per-
7 cent of the amount calculated under sub-
8 clause (II);

9 “(IV) update the add-on adjustment
10 annually to account for inflationary
11 changes; and

12 “(V) apply the add-on adjustment
13 amount immediately upon the expiration of
14 the TDAPA period and availability of the
15 post-TDAPA add-on adjustment.

16 “(iii) IMPLEMENTATION.—This subpara-
17 graph shall not be implemented in a budget
18 neutral manner and shall not be adjusted by
19 any applicable patient-level case-mix adjust-
20 ments described in section 413.235 of title 42,
21 Code of Federal Regulations (or any successor
22 regulation).”.

23 (c) CLARIFICATION TO DEFINITION OF RENAL DI-
24 ALYSIS SERVICES.—Section 1881(b)(14)(B) of the Social
25 Security Act (42 U.S.C. 1395rr(b)(14)(B)) is amended—

1 (1) by redesignating clauses (i) through (iv) as
2 subclauses (I) through (IV), respectively;

3 (2) by inserting “(i)” after “(B)”;

4 (3) in clause (i)(IV), as added by paragraph
5 (2), by striking “ clause (i)” and inserting “sub-
6 clause (I)”;

7 (4) in the flush text at the end, by striking
8 “Such term does not” and inserting the following:

9 “(ii) Such term—

10 “(I) does not”;

11 (5) in clause (ii), as added by paragraph (2)—

12 (A) in subclause (I), by striking the period
13 at the end and inserting “; and”; and

14 (B) by adding at the end the following:

15 “(II) does not include drugs or biological prod-
16 ucts used to treat a comorbid disease or condition
17 (including cardiovascular disease, an inflammatory
18 condition, cancer, diabetes, and obesity) that may
19 occur in an individual who has been determined to
20 have end-stage renal diseases and is receiving dialy-
21 sis and—

22 “(aa) that have been approved by the
23 Food and Drug Administration after De-
24 cember 31, 2025; and

1 “(bb) do not substitute for a drug or
2 biological included in the ESRD prospec-
3 tive payment system base rate.”; and

4 (6) by adding at the end the following new
5 clause:

6 “(iii) IMPLEMENTATION.—Beginning on the
7 date of enactment of this clause, for purposes of im-
8 plementing clause (ii)(II), the Secretary shall require
9 that a claim for a drug or biological product de-
10 scribed in such clause, that is payable under this
11 part and is furnished by a provider of services or
12 renal dialysis facility, contain the AY modifier (or a
13 successor modifier).”.

14 (d) REVISIONS TO TRANSITIONAL ADD-ON PAYMENT
15 ADJUSTMENT FOR NEW AND INNOVATIVE EQUIPMENT
16 AND SUPPLIES (TPNIES).—

17 (1) EXTENSION OF PERIOD.—The Secretary
18 shall pay the transitional add-on payment adjust-
19 ment for new and innovative equipment and supplies
20 under section 413.236 of title 42, Code of Federal
21 Regulations (or a successor regulation), for not less
22 than 3 years for any new renal dialysis device that—

23 (A) qualifies for such adjustment; and

24 (B) is furnished on or after January 1,
25 2026.

1 (2) ELIGIBILITY OF BREAKTHROUGH DE-
2 VICES.—Beginning January 1, 2026, a device des-
3 ignated for expedited development and priority re-
4 view under section 515B of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 360e–3) shall be eligi-
6 ble for a transitional add-on payment adjustment for
7 new and innovative equipment and supplies under
8 section 413.236 of title 42, Code of Federal Regula-
9 tions (or a successor regulation).

10 (3) INCLUSION OF CAPITAL-RELATED ASSETS
11 IN THE TRANSITIONAL ADD-ON PAYMENT ADJUST-
12 MENT FOR NEW AND INNOVATIVE EQUIPMENT AND
13 SUPPLIES AND POST-TRANSITIONAL ADD-ON PAY-
14 MENT ADJUSTMENT FOR NEW AND INNOVATIVE
15 EQUIPMENT AND SUPPLIES.—Beginning January 1,
16 2026, the Secretary shall not apply the criterion de-
17 scribed in section 413.236(b)(6) of title 42, Code of
18 Federal Regulations (or a successor regulation), that
19 excludes capital-related assets from the transitional
20 add-on payment adjustment for new and innovative
21 equipment and supplies and shall calculate such ad-
22 justment for capital-related assets that are devices
23 that otherwise meet the requirements for the transi-
24 tional add-on payment adjustment for new and inno-
25 vative equipment.

1 (e) EFFECTIVE DATE.—The amendments made by
2 this section shall take effect on January 1, 2026, and
3 apply to items and services furnished on or after such
4 date.

5 **SEC. 102. ENSURING MEDICARE ADVANTAGE SUPPORTS**
6 **KIDNEY CARE INNOVATIVE THERAPIES.**

7 (a) IN GENERAL.—Section 1853(c) of the Social Se-
8 curity Act (42 U.S.C. 1395w–23(c)) is amended by adding
9 at the end the following new paragraph:

10 “(8) TREATMENT OF INNOVATIVE PRODUCTS
11 FOR ENROLLEES WITH END-STAGE RENAL DIS-
12 EASE.—

13 “(A) IN GENERAL.—Beginning January 1,
14 2026, the Secretary shall make direct payment
15 adjustments to providers of services or renal di-
16 alysis facilities for—

17 “(i) any new renal dialysis drug or bi-
18 ological product that receives a transitional
19 drug add-on payment adjustment under
20 section 413.234(c) of title 42, Code of
21 Federal Regulations; or

22 “(ii) an item or service that receives a
23 transitional add-on payment adjustment
24 for new and innovative equipment and sup-
25 plies under section 413.236 of such title.

1 “(B) AMOUNT OF DIRECT PAYMENT.—The
2 amount of the adjustment shall equal the
3 amount determined under the end-stage renal
4 disease prospective payment system described in
5 section 1881(b)(14).

6 “(C) DURATION OF DIRECT PAYMENT.—
7 The Secretary shall make payments under sub-
8 paragraph (A) for the duration of the transi-
9 tional payment under the end-stage renal dis-
10 ease prospective payment system described in
11 such section.”.

12 (b) CONFORMING AMENDMENTS.—Section 1851(i) of
13 the Social Security Act (42 U.S.C. 1395w–21) is amend-
14 ed—

15 (1) in paragraph (1), by inserting
16 “1853(c)(8),” after “1886(h)(3)(D),”; and

17 (2) in paragraph (2), by inserting
18 “1853(c)(8),” after “1853(h),”.

1 **TITLE II—ADDRESSING STAFF-**
2 **ING BARRIERS WITH ESRD**
3 **MARKET BASKET LABOR AD-**
4 **JUSTMENTS**

5 **SEC. 201. ENSURING ACCURACY AND STABILITY IN KIDNEY**
6 **CARE PAYMENT.**

7 Section 1881(b)(14)(F)(i) of the Social Security Act
8 (42 U.S.C. 1395rr(b)(14)(F)(i)) is amended—

9 (1) in subclause (I), by striking “subclauses
10 (II) and (III)” and inserting “subclauses (II), (III),
11 and (IV)”;

12 (2) in subclause (II), by inserting “and after
13 application of subclause (IV)” after “subclause (I)”;
14 and

15 (3) by adding at the end the following new sub-
16 clause:

17 “(IV) Beginning with 2026, the Sec-
18 retary shall compute an adjustment to the
19 increase factor described in subclause (I)
20 for the annual update of the payment
21 amounts established under this paragraph
22 for the previous year to account for fore-
23 cast error (referred to in this subclause as
24 the ‘forecast error adjustment’). The initial
25 adjustment (in 2026) to the increase factor

1 shall take into account the cumulative fore-
2 cast error for 2021 and 2022. Subsequent
3 adjustments in succeeding years shall take
4 into account the forecast error from the
5 most recently available year for which
6 there is final data. The forecast error ad-
7 justment under this subclause shall apply
8 whenever the difference between the fore-
9 casted and actual percentage change in the
10 prices of an appropriate mix of goods and
11 services included in renal dialysis services
12 exceeds 0.5 percentage points.”.

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