

119TH CONGRESS
1ST SESSION

H. R. 6214

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 HOUSE OF REPRESENTATIVES

NOVEMBER 20, 2025

Mrs. MILLER of West Virginia (for herself and Ms. SEWELL) 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 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”.

(b) TABLE OF CONTENTS.—The table of contents of 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.

TITLE III—PREVENTING KIDNEY DISEASE AND EXPANDING
AWARENESS AND EDUCATION

Sec. 301. Expanding medicare annual wellness benefit to include kidney disease screening.

Sec. 302. Increasing access to medicare kidney disease education benefit.

3 TITLE I—PROTECTING PATIENT
4 ACCESS TO KIDNEY CARE IN-
5 NOVATION

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

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

1 (1) approved by the Food and Drug Adminis-
2 tration on or after January 1, 2020, under section
3 505 of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 355) or section 351 of the Public Health
5 Service Act (42 U.S.C. 262);

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

8 (3) that is furnished on or after January 1,
9 2026.

10 (b) PERMANENT POST-TDAPA ADJUSTMENT.—Sec-
11 tion 1881(b)(14) of the Social Security Act (42 U.S.C.
12 1395rr(b)(14)) is amended by adding at the end the fol-
13 lowing new subparagraph:

14 “(J) PAYMENT FOR NEW AND INNOVATIVE
15 DRUGS, BIOLOGICALS, AND DEVICES THAT ARE
16 RENAL DIALYSIS SERVICES.—

17 “(i) IN GENERAL.—For any new renal di-
18 alysis drug or biological product that is used to
19 treat or manage a condition as defined in sec-
20 tion 413.234(a) of title 42, Code of Federal
21 Regulations that received a transitional drug
22 add-on payment adjustment (referred to in this
23 subparagraph as ‘TDAPA’) under section
24 413.234(c) of such title, and was furnished on
25 or after January 1, 2024, the Secretary shall

1 establish a permanent add-on adjustment to the
2 base rate for claims submitted on or after Jan-
3 uary 1, 2026, that includes the administration
4 of such drugs or biologicals.

5 “(ii) CALCULATION OF THE POST-TDAPA
6 ADD-ON ADJUSTMENT.—In calculating the add-
7 on adjustment described in clause (i), the Sec-
8 retary shall—

9 “(I) base the calculation on—

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

17 “(bb) if the most recent available
18 full calendar quarter of average sales
19 price data reflects 0 or negative sales,
20 100 percent of the wholesale acquisi-
21 tion cost (as defined in section
22 1847A(c)(6)) of such drug or product;
23 or

1 “(cc) if the wholesale acquisition
2 cost is not available, the drug manu-
3 facturer’s invoice;

4 “(II) calculate the post-TDAPA add-
5 on payment adjustment as the expendi-
6 tures for the new renal dialysis drug or bi-
7 ological product divided by the total num-
8 ber of renal dialysis services during which
9 such drug or biological was administered
10 during the same period;

11 “(III) set the amount of the add-on
12 adjustment as an amount equal to 65 per-
13 cent of the amount calculated under sub-
14 clause (II);

15 “(IV) update the add-on adjustment
16 annually to account for inflationary
17 changes; and

18 “(V) apply the add-on adjustment
19 amount immediately upon the expiration of
20 the TDAPA period and availability of the
21 post-TDAPA add-on adjustment.

22 “(iii) IMPLEMENTATION.—This subpara-
23 graph shall not be implemented in a budget
24 neutral manner and shall not be adjusted by
25 any applicable patient-level case-mix adjust-

1 ments described in section 413.235 of title 42,
 2 Code of Federal Regulations (or any successor
 3 regulation).”.

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

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

9 (2) by inserting “(i)” after “(B)”;

10 (3) in clause (i)(IV), as added by paragraph
 11 (2), by striking “clause (i)” and inserting “subclause
 12 (I)”;

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

15 “(ii) Such term—

16 “(I) does not”;

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

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

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

21 “(II) does not include drugs or biological prod-
 22 ucts used to treat a comorbid disease or condition
 23 (including cardiovascular disease, an inflammatory
 24 condition, cancer, diabetes, and obesity) that may
 25 occur in an individual who has been determined to

1 have end-stage renal diseases and is receiving dialy-
 2 sis and—

3 “(aa) that have been approved by the
 4 Food and Drug Administration after De-
 5 cember 31, 2025; and

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

9 (6) by adding at the end the following new
 10 clause:

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

19 (d) REVISIONS TO TRANSITIONAL ADD-ON PAYMENT
 20 ADJUSTMENT FOR NEW AND INNOVATIVE EQUIPMENT
 21 AND SUPPLIES (TPNIES).—

22 (1) EXTENSION OF PERIOD.—The Secretary
 23 shall pay the transitional add-on payment adjust-
 24 ment for new and innovative equipment and supplies
 25 under section 413.236 of title 42, Code of Federal

1 Regulations (or a successor regulation), for not less
2 than 3 years for any new renal dialysis device that—

3 (A) qualifies for such adjustment; and

4 (B) is furnished on or after January 1,
5 2026.

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

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

1 equipment and supplies and shall calculate such ad-
 2 justment for capital-related assets that are devices
 3 that otherwise meet the requirements for the transi-
 4 tional add-on payment adjustment for new and inno-
 5 vative equipment.

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

10 **SEC. 102. ENSURING MEDICARE ADVANTAGE SUPPORTS**
 11 **KIDNEY CARE INNOVATIVE THERAPIES.**

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

15 “(8) TREATMENT OF INNOVATIVE PRODUCTS
 16 FOR ENROLLEES WITH END STAGE RENAL DIS-
 17 EASE.—

18 “(A) IN GENERAL.—Beginning January 1,
 19 2026, the Secretary shall make direct payment
 20 adjustments to providers of services or renal di-
 21 alysis facilities for—

22 “(i) any new renal dialysis drug or bi-
 23 ological product that receives a transitional
 24 drug add-on payment adjustment under

1 section 413.234(c) of title 42, Code of
 2 Federal Regulations; or

3 “(ii) an item or service that receives a
 4 transitional add-on payment adjustment
 5 for new and innovative equipment and sup-
 6 plies under section 413.236 of such title.

7 “(B) AMOUNT OF DIRECT PAYMENT.—The
 8 amount of the adjustment shall equal the
 9 amount determined under the end-stage renal
 10 disease prospective payment system described in
 11 section 1881(b)(14).

12 “(C) DURATION OF DIRECT PAYMENT.—
 13 The Secretary shall make payments under sub-
 14 paragraph (A) for the duration of the transi-
 15 tional payment under the end-stage renal dis-
 16 ease prospective payment system described in
 17 such section.”.

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

21 (1) in paragraph (1), by inserting
 22 “1853(c)(8),” after “1886(h)(3)(D),”; and

23 (2) in paragraph (2), by inserting
 24 “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.”.

13 **TITLE III—PREVENTING KIDNEY**
 14 **DISEASE AND EXPANDING**
 15 **AWARENESS AND EDUCATION**

16 **SEC. 301. EXPANDING MEDICARE ANNUAL WELLNESS BEN-**
 17 **EFIT TO INCLUDE KIDNEY DISEASE SCREEN-**
 18 **ING.**

19 (a) IN GENERAL.—Section 1861(ww)(2) of the Social
 20 Security Act (42 U.S.C. 1395x(ww)(2)) is amended—

21 (1) by redesignating subparagraph (O) as sub-
 22 paragraph (P); and

23 (2) by inserting after subparagraph (N) the fol-
 24 lowing new subparagraph:

1 “(O) Chronic kidney disease screening as
2 defined by the Secretary.”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to items and services furnished on
5 or after January 1, 2026.

6 **SEC. 302. INCREASING ACCESS TO MEDICARE KIDNEY DIS-**
7 **EASE EDUCATION BENEFIT.**

8 (a) IN GENERAL.—Section 1861(ggg) of the Social
9 Security Act (42 U.S.C. 1395x(ggg)) is amended—

10 (1) in paragraph (1)—

11 (A) in subparagraph (A), by inserting “or
12 stage V” after “stage IV”; and

13 (B) in subparagraph (B), by inserting “or
14 of a physician assistant, nurse practitioner, or
15 clinical nurse specialist (as defined in section
16 1861(aa)(5)) assisting in the treatment of the
17 individual’s kidney condition” after “kidney
18 condition”; and

19 (2) in paragraph (2)—

20 (A) by striking subparagraph (B); and

21 (B) in subparagraph (A)—

22 (i) by striking “(A)” after “(2)”; and

23 (ii) by striking “and” at the end of
24 clause (i);

1 (iii) by striking the period at the end
2 of clause (ii) and inserting “; and”;

3 (iv) by redesignating clauses (i) and
4 (ii) as subparagraphs (A) and (B), respec-
5 tively; and

6 (v) by adding at the end the following:

7 “(C) a renal dialysis facility subject to the
8 requirements of section 1881(b)(1) with per-
9 sonnel who—

10 “(i) provide the services described in
11 paragraph (1); and

12 “(ii) is a physician (as defined in sub-
13 section (r)(1)) or a physician assistant,
14 nurse practitioner, or clinical nurse spe-
15 cialist (as defined in subsection (aa)(5)).”.

16 (b) PAYMENT TO RENAL DIALYSIS FACILITIES.—
17 Section 1881(b) of the Social Security Act (42 U.S.C.
18 1395rr(b)) is amended by adding at the end the following
19 new paragraph:

20 “(15) For purposes of paragraph (14), the single pay-
21 ment for renal dialysis services under such paragraph shall
22 not take into account the amount of payment for kidney
23 disease education services (as defined in section
24 1861(ggg)). Instead, payment for such services shall be

1 made to the renal dialysis facility on an assignment-re-
2 lated basis under section 1848.”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to kidney disease education serv-
5 ices furnished on or after January 1, 2026.

