

118TH CONGRESS  
2D SESSION

# S. 4469

To improve the understanding of, and promote access to treatment for,  
chronic kidney disease, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

JUNE 5, 2024

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

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## A BILL

To improve the understanding of, and promote access to  
treatment for, chronic kidney disease, 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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Chronic Kidney Disease Improvement in Research and  
6 Treatment Act of 2024”.

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

Sec. 1. Short title; table of contents.

TITLE I—PREVENTING KIDNEY DISEASE BY EXPANDING  
EDUCATION AND AWARENESS

- Sec. 101. Expanding Medicare annual wellness benefit to include kidney disease screening.
- Sec. 102. Increasing access to Medicare kidney disease education benefit.
- Sec. 103. Understanding the progression of kidney disease and treatment of kidney failure in minority populations.

#### TITLE II—INCENTIVIZING KIDNEY CARE INNOVATION

- Sec. 201. Refining the end-stage renal disease payment system to improve accuracy in payment and support therapies.
- Sec. 202. Ensuring Medicare Advantage supports kidney care innovative therapies.
- Sec. 203. Improving patient lives and quality of care through research and innovation.

#### TITLE III—ADDRESSING THE KIDNEY CARE WORKFORCE CRISIS.

- Sec. 301. Improving patient decision making and transparency by consolidating and modernizing quality programs.
- Sec. 302. Ensuring accuracy and stability in kidney care payment.

#### TITLE IV—EXPANDING PATIENT CHOICE OF COVERAGE

- Sec. 401. Medigap coverage for beneficiaries with end-stage renal disease.

## 1 **TITLE I—PREVENTING KIDNEY** 2 **DISEASE BY EXPANDING EDU-** 3 **CATION AND AWARENESS**

### 4 **SEC. 101. EXPANDING MEDICARE ANNUAL WELLNESS BEN-** 5 **EFIT TO INCLUDE KIDNEY DISEASE SCREEN-** 6 **ING.**

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

9 (1) by moving subparagraph (N) 2 ems to the  
10 left;

11 (2) by redesignating subparagraph (O) as sub-  
12 paragraph (P); and

13 (3) by inserting after subparagraph (N) the fol-  
14 lowing new subparagraph:

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

3           (b) EFFECTIVE DATE.—The amendments made by  
4 this section apply to items and services furnished on or  
5 after January 1, 2025.

6 **SEC. 102. 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)”;  
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 indenting appropriately; 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 apply to kidney disease education services fur-  
5 nished on or after January 1, 2025.

6 **SEC. 103. UNDERSTANDING THE PROGRESSION OF KIDNEY**  
7 **DISEASE AND TREATMENT OF KIDNEY FAIL-**  
8 **URE IN MINORITY POPULATIONS.**

9 (a) STUDY.—The Secretary of Health and Human  
10 Services (in this section referred to as the “Secretary”)  
11 shall conduct a study on—

12 (1) the social, behavioral, and biological factors  
13 associated with kidney disease onset and progres-  
14 sion;

15 (2) efforts to slow the progression of kidney dis-  
16 ease in minority populations that are disproportion-  
17 ately affected by such disease; and

18 (3) treatment patterns associated with pro-  
19 viding care, under the Medicare program under title  
20 XVIII of the Social Security Act, the Medicaid pro-  
21 gram under title XIX of such Act, and through pri-  
22 vate health insurance, to minority populations that  
23 are disproportionately affected by kidney disease.

24 (b) REPORT.—Not later than 1 year after the date  
25 of the enactment of this Act, the Secretary shall submit

1 to Congress a report on the study conducted under sub-  
 2 section (a), together with such recommendations as the  
 3 Secretary determines to be appropriate.

4 **TITLE II—INCENTIVIZING**  
 5 **KIDNEY CARE INNOVATION**

6 **SEC. 201. REFINING THE END-STAGE RENAL DISEASE PAY-**  
 7 **MENT SYSTEM TO IMPROVE ACCURACY IN**  
 8 **PAYMENT AND SUPPORT THERAPIES.**

9 (a) IN GENERAL.—Section 1881(b)(14) of the Social  
 10 Security Act (42 U.S.C. 1395rr(b)(14)) is amended by  
 11 adding at the end the following new subparagraph:

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

15 “(i) IN GENERAL.—For any new renal dialysis  
 16 drug or biological product that is used to treat or  
 17 manage a condition for which there is a functional  
 18 category as defined in section 413.234(a) of title 42,  
 19 Code of Federal Regulations that received a transi-  
 20 tional drug add-on adjustment (referred to in this  
 21 subparagraph as ‘TDAPA’) under section  
 22 413.234(e)(2) of such title, and was furnished on or  
 23 after January 1, 2024, the Secretary shall establish  
 24 a permanent add-on adjustment to the base rate for  
 25 claims submitted on or after January 1, 2025, that

1 includes the administration of such drugs or  
2 biologicals.

3 “(ii) CALCULATION OF THE POST-TDAPA ADD-  
4 ON ADJUSTMENT.—In calculating the add-on adjust-  
5 ment described in clause (i), the Secretary shall—

6 “(I) base the calculation on—

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

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

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

23 “(II) calculate the post-TDAPA add-on  
24 payment adjustment as the expenditures for the  
25 new renal dialysis drug or biological product di-

1           vided by the total number of renal dialysis serv-  
 2           ices during which such drug or biological was  
 3           administered during the same period;

4           “(III) set the amount of the add-on adjust-  
 5           ment as an amount equal to 65 percent of the  
 6           amount calculated under subclause (II);

7           “(IV) update the add-on adjustment annu-  
 8           ally to account for inflationary changes; and

9           “(V) apply the add-on adjustment amount  
 10          immediately upon the expiration of the TDAPA  
 11          period and availability of the post-TDAPA add-  
 12          on adjustment.

13          “(iii) IMPLEMENTATION.—This subparagraph  
 14          shall not be implemented in a budget neutral man-  
 15          ner and shall not be adjusted by any applicable pa-  
 16          tient-level case-mix adjustments described in section  
 17          413.235 of title 42, Code of Federal Regulations (or  
 18          any successor regulation).”.

19          (b) EXTENSION OF TRANSITIONAL DRUG ADD-ON  
 20          ADJUSTMENT UNDER THE DRUG DESIGNATION POL-  
 21          ICY.—The Secretary shall pay the transitional drug add-  
 22          on adjustment under paragraph (c) of section 413.234 of  
 23          title 42, Code of Federal Regulations (or a successor regu-  
 24          lation) for a total of 3 years for any new renal dialysis  
 25          drug or biological product that—



1           (1) is used to treat or manage a condition for  
2           which there is a functional category as defined in  
3           paragraph (a) of such section;

4           (2) qualifies for such adjustment under para-  
5           graph (c)(2) of such section; and

6           (3) is furnished on or after January 1, 2024.

7           (c) NEW DEVICES AND OTHER TECHNOLOGIES.—

8           (1) IN GENERAL.—As part of the promulgation  
9           of the annual rule for the Medicare end-stage renal  
10          disease prospective payment system under section  
11          1881(b)(14) of the Social Security Act (42 U.S.C.  
12          1395rr(b)(14)) for calendar year 2026, and in con-  
13          sultation with stakeholders, the Secretary of Health  
14          and Human Services (referred to in this subsection  
15          as the “Secretary”) shall—

16                (A) ensure that the single payment amount  
17                is adequate to cover the cost of any new innova-  
18                tive device or other technology with substantial  
19                clinical improvement; and

20                (B) increase the single payment amount if  
21                the Secretary determines such payment amount  
22                is not adequate to cover such cost.

23          (2) COST AND UTILIZATION DATA.—In carrying  
24          out paragraph (1), the Secretary shall use the cost  
25          and utilization data collected during a 3-year transi-

1 tional payment period, as described in the final regu-  
2 lation published on November 9, 2020 (85 Fed. Reg.  
3 71398).

4 **SEC. 202. ENSURING MEDICARE ADVANTAGE SUPPORTS**  
5 **KIDNEY CARE INNOVATIVE THERAPIES.**

6 Section 1853(c) of the Social Security Act (42 U.S.C.  
7 1395w–23(c)) is amended by adding at the end the fol-  
8 lowing new paragraph:

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

12 “(A) IN GENERAL.—The Secretary shall  
13 make direct payment adjustments to providers  
14 of services or renal dialysis facilities for—

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

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

24 “(B) AMOUNT OF DIRECT PAYMENT.—The  
25 amount of the adjustment shall equal the

1 amount determined under the end stage renal  
2 disease prospective payment system described in  
3 section 1881(b)(14).

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

10 **SEC. 203. IMPROVING PATIENT LIVES AND QUALITY OF**  
11 **CARE THROUGH RESEARCH AND INNOVA-**  
12 **TION.**

13 (a) STUDY.—The Secretary of Health and Human  
14 Services (referred to in this section as the “Secretary”)  
15 shall conduct a study on increasing kidney transplantation  
16 rates. Such study shall include an analysis of each of the  
17 following:

18 (1) Any disincentives in the payment systems  
19 under the Medicare program under title XVIII of  
20 the Social Security Act (42 U.S.C. 1395 et seq.)  
21 that create barriers to kidney transplants and post-  
22 transplant care for beneficiaries with end-stage renal  
23 disease.

24 (2) The practices used by donation service  
25 areas with higher than average donation rates and

1       whether those practices and policies could be suc-  
2       cessfully utilized in other donation service areas.

3               (3) Practices and policies that could increase  
4       donation rates among minority populations.

5               (4) Whether cultural and policy barriers exist to  
6       increasing living donation rates, including an exam-  
7       ination of how to better facilitate kidney paired do-  
8       nations.

9               (5) Criteria for transplant recipients for refer-  
10      ral and for getting on the waitlist to receive a kid-  
11      ney.

12              (6) Other areas determined appropriate by the  
13      Secretary.

14      (b) REPORT.—Not later than 18 months after the  
15      date of enactment of this Act, the Secretary shall submit  
16      to Congress a report on the study conducted pursuant to  
17      subsection (a), together with such recommendations as the  
18      Secretary determines to be appropriate.

1 **TITLE III—INCREASING PATIENT**  
2 **ACCESS TO QUALITY PER-**  
3 **FORMANCE BY IMPROVING**  
4 **THE ACCURACY AND TRANS-**  
5 **PARENCY OF END-STAGE**  
6 **RENAL DISEASE QUALITY**  
7 **PROGRAMS**

8 **SEC. 301. IMPROVING PATIENT DECISION MAKING AND**  
9 **TRANSPARENCY BY CONSOLIDATING AND**  
10 **MODERNIZING QUALITY PROGRAMS.**

11 (a) MEASURES.—Section 1881(h)(2) of the Social  
12 Security Act (42 U.S.C. 1395rr(h)(2)) is amended—

13 (1) by striking subparagraph (A) and inserting  
14 the following:

15 “(A) The measures specified under this  
16 paragraph with respect to the year involved  
17 shall be selected by the Secretary in consulta-  
18 tion with stakeholders to promote improvement  
19 in beneficiary outcomes and shared decision-  
20 making with beneficiaries and their caregivers.  
21 When selecting measures specified under this  
22 paragraph, the Secretary shall take into ac-  
23 count clinical gaps in care, underutilization that  
24 may lead to beneficiary harm, patient safety,  
25 and outcomes.”;

1           (2) in subparagraph (B)(i), by striking “sub-  
2       paragraph (A)(iv)” and inserting “subparagraph  
3       (A)”;

4           (3) by striking subparagraph (E); and

5           (4) by adding at the end the following new sub-  
6       paragraphs:

7           “(E) WEIGHTING LIMITATION.—No single  
8       measure specified by the Secretary or individual  
9       measure within a composite measure so speci-  
10      fied may be weighted less than 10 percent of  
11      the total performance score.

12          “(F) STATISTICALLY VALID AND RELI-  
13      ABLE.—In specifying measures under subpara-  
14      graph (A), the Secretary shall only specify  
15      measures that have been shown to be statis-  
16      tically valid and reliable through testing.”.

17          (b) ENDORSEMENT.—Section 1881(h)(2)(B)(ii) of  
18      the Social Security Act (42 U.S.C. 1395rr(h)(2)(B)(ii)) is  
19      amended by adding at the end the following new sentence:  
20      “The exception under the preceding sentence shall not  
21      apply to a measure that the entity with a contract under  
22      section 1890(a) (or a similar entity) considered but failed  
23      to endorse.”.

1 (e) EFFECTIVE DATE.—The amendments made by  
 2 this section shall apply to items and services furnished on  
 3 or after January 1, 2025.

## 4 **TITLE IV—EMPOWERING** 5 **PATIENTS**

6 **SEC. 401. MEDIGAP COVERAGE FOR BENEFICIARIES WITH**  
 7 **END-STAGE RENAL DISEASE.**

8 (a) GUARANTEED AVAILABILITY OF MEDIGAP POLI-  
 9 CIES TO ALL ESRD MEDICARE BENEFICIARIES.—

10 (1) IN GENERAL.—Section 1882(s) of the So-  
 11 cial Security Act (42 U.S.C. 1395ss(s)) is amend-  
 12 ed—

13 (A) in paragraph (2)—

14 (i) in subparagraph (A), by striking  
 15 “is 65” and all that follows through the  
 16 period and inserting the following: “is—

17 “(i) 65 years of age or older and is enrolled for  
 18 benefits under part B; or

19 “(ii) entitled to benefits under 226A(b) and is  
 20 enrolled for benefits under part B.”; and

21 (ii) in subparagraph (D), in the mat-  
 22 ter preceding clause (i), by inserting “(or  
 23 is entitled to benefits under 226A(b))”  
 24 after “is 65 years of age or older”; and

25 (B) in paragraph (3)(B)—

1 (i) in clause (ii), by inserting “(or is  
2 entitled to benefits under 226A(b))” after  
3 “is 65 years of age or older”; and

4 (ii) in clause (vi), by inserting “(or  
5 under 226A(b))” after “at age 65”.

6 (2) EFFECTIVE DATE.—The amendments made  
7 by paragraph (1) shall apply to Medicare supple-  
8 mental policies effective on or after January 1,  
9 2026.

10 (b) ADDITIONAL ENROLLMENT PERIOD FOR CER-  
11 TAIN INDIVIDUALS.—

12 (1) ONE-TIME ENROLLMENT PERIOD.—

13 (A) IN GENERAL.—In the case of an indi-  
14 vidual described in subparagraph (B), the Sec-  
15 retary of Health and Human Services shall es-  
16 tablish a one-time enrollment period during  
17 which such an individual may enroll in any  
18 Medicare supplemental policy under section  
19 1882 of the Social Security Act (42 U.S.C.  
20 1395ss) of the individual’s choosing.

21 (B) ENROLLMENT PERIOD.—The enroll-  
22 ment period established under subparagraph  
23 (A) shall begin on January 1, 2026, and shall  
24 end June 30, 2026.



1           (2) INDIVIDUAL DESCRIBED.—An individual de-  
2       scribed in this paragraph is an individual who—

3           (A) is entitled to hospital insurance bene-  
4       fits under part A of title XVIII of the Social  
5       Security Act under section 226A(b) of such Act  
6       (42 U.S.C. 426–1);

7           (B) is enrolled for benefits under part B of  
8       such title XVIII; and

9           (C) would not, but for the provisions of,  
10      and amendments made by, subsection (a) be eli-  
11      gible for the guaranteed issue of a Medicare  
12      supplemental policy under paragraph (2) or (3)  
13      of section 1882(s) of such Act (42 U.S.C.  
14      1395ss(s)).

○