

## **The Chronic Kidney Disease Improvement in Research and Treatment Act (H.R. 5027/S.4469)**

The American Nephrology Nurses Association (ANNA) is a nonprofit organization with a membership of approximately 7,000 registered nurses and other health care professionals at all levels of practice. ANNA members work in settings such as chronic kidney disease management, peritoneal dialysis, hemodialysis, continuous renal replacement therapy, transplantation, industry, and government/regulatory agencies.

### **Background on the Issue**

Over 37 million Americans are living with kidney disease and according to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), as many as 9 in 10 Americans living with kidney disease are not even aware they have the chronic condition. If the disease is left untreated, it can progress to kidney failure, also commonly referred to as End Stage Kidney Disease (ESKD), an irreversible medical condition that requires a transplant or dialysis. The National Institutes of Health estimates that by 2030, between 970,000 and 1.2 million Americans will be living with ESKD.

### **Overview of the Legislation**

The *Chronic Kidney Disease Improvement in Research and Treatment Act* (H.R. 5027/S.4469) aims to address the rising prevalence of chronic kidney disease. The legislation would do the following:

- Boost kidney disease prevention efforts by adding Chronic Kidney Disease (CKD) screening to the annual wellness benefit to allow Medicare beneficiaries at risk for kidney disease or kidney failure to screen for the disease and seek treatment to slow the progression if diagnosed.
- Expand access to education resources by expanding the Medicare Kidney Disease Education benefit to allow dialysis facilities to provide kidney disease education services and offer services to Medicare beneficiaries with Stage 5 CKD who are not yet on dialysis.
- Incentivize innovation by requiring the Centers for Medicare and Medicaid Services (CMS) to provide a long-term payment pathway for new drugs, biologics, devices, or other technologies.
- Develop a sustainable dialysis infrastructure and address the workforce crisis by ensuring that kidney care providers receive accurate annual payment updates and fostering the nephrology pipeline by including nephrologists and non-physician practitioners in the National Health Service Corp loan forgiveness program.
- Expand patient choice and coverage by guaranteeing access to Medigap policies for Medicare beneficiaries with kidney failure.

**Recommendation:** ANNA supports the *Chronic Kidney Disease Improvement in Research and Treatment Act* (H.R. 5027 and S. 4469) and encourages Members of Congress to cosponsor the important legislation.



## **H.R. 5027: The Chronic Kidney Disease Improvement in Research and Treatment Act**

### **Section-by-Section**

#### **Title I: Prevent Kidney Disease and Expanding Awareness and Education**

##### **Section 101: Expanding Medicare Annual Wellness Benefit to Include Kidney Disease Screening**

Often patients do not realize they have kidney diseases until their kidneys fail and they crash onto dialysis. This section would add Chronic Kidney Disease (CKD) screening to the annual wellness benefit to allow Medicare beneficiaries at risk for kidney disease and kidney failure to learn if they in fact have the disease and seek treatment to slow the progression toward kidney failure or better prepare for transplant or dialysis.

##### **Section 102: Increasing Access to Medicare Kidney Disease Education Benefit**

Currently, the ESRD Kidney Disease Education (KDE) benefit is woefully underutilized. This section would expand the benefit to: (1) allow dialysis facilities to provide kidney disease education services; (2) permit physician assistants, nurse practitioners, and clinical nurse specialists, in addition to physicians, to serve as referral sources for the benefit; and (3) to provide access to these services to Medicare beneficiaries with Stage 5 CKD not yet on dialysis.

#### **Title II – Incentivizing Kidney Care Innovation**

##### **Section 201: Support Kidney Care Innovative Therapies**

The ESRD program also has no sustainable pathway to incentivize improvements in kidney care for patients. This section would require the Secretary to adjust the ESRD PPS bundled rate when the current rate would not cover the cost of adding a new drug, biologic, device, or other technology into the bundle after the transitional payment period ends. It requires the Secretary of HHS to implement this no later than January 1, 2024.

##### **Section 202: Ensuring Medicare Advantage Supports Kidney Care Innovative Therapies**

Currently, the Transitional Drug Add-On Payment Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPANIES) do not apply to drugs and devices taken by patients who have ESRD and are enrolled in Medicare Advantage (MA). This provision would require the Secretary of HHS to provide direct payment adjustments to providers or facilities if it is found that the cost of covering drugs and devices covered under TDAPA and TPANIES increases the cost to MA plans above the contracted benefit.

### **Section 203: Improving Patient Lives and Quality of Care Through Research and Innovation**

This section would require the Secretary of HHS, not later than 18 months after enactment, to submit a report to Congress on increasing kidney transplantation rates. The study would look at any disincentives in the Medicare payment systems; practices used by states with higher than average donation rates; increasing deceased donation rates among minority populations; and barriers to increasing living donor rates.

### **Title III: Addressing the Kidney Care Workforce Crisis**

#### **Section 301: Ensuring Accuracy and Stability in Kidney Care Payment**

Healthcare providers across the nation have long experienced an incredibly tight labor market due to the persistent workforce shortage, which was exacerbated by the COVID-19 pandemic. This has led to significantly higher costs to kidney care providers for wages, benefits, and training to attract skilled caregivers.

Currently, CMS must forecast annual payment updates and uses the latest available historical data to do so. However, the actual payment update for a given period can be higher or lower than the forecast and during times of economic uncertainty, the methodology can produce large forecast errors in either direction. This provision would require the Secretary of HHS to calculate the forecast error for a previous year and make an adjustment—up or down—to the annual payment update for kidney care providers.

#### **Section 302: Encouraging Kidney Care Workforce in Under Served Areas**

This section clarifies that nephrologists and non-physician practitioners providing renal dialysis services in underserved rural and/or urban areas may participate in the National Health Service Corp loan forgiveness program.

### **Title IV: Expanding Patient Choice of Coverage**

#### **Section 401: Providing Medigap Access to ESRD Beneficiaries**

The Social Security Act guarantees that Medicare beneficiaries over age 65 have access to Medigap plans – recognizing the role these plans have in helping patients plan and defray the cost of Medicare services. This section would guarantee access to Medigap policies to all ESRD Medicare beneficiaries, regardless of age.

118TH CONGRESS  
1ST SESSION

# H. R. 5027

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

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## IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2023

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

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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 This Act may be cited as the “Chronic Kidney Dis-  
5 ease Improvement in Research and Treatment Act of  
6 2023”.

1 **TITLE I—PREVENTING KIDNEY**  
2 **DISEASE AND EXPANDING**  
3 **AWARENESS AND EDUCATION**

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 redesignating subparagraph (O) as sub-  
10 subparagraph (P); and

11 (2) by inserting after subparagraph (N) the fol-  
12 lowing new subparagraph:

13 “(O) Chronic kidney disease screening as  
14 defined by the Secretary.”.

15 (b) EFFECTIVE DATE.—The amendments made by  
16 this section apply to items and services furnished on or  
17 after January 1, 2022.

18 **SEC. 102. INCREASING ACCESS TO MEDICARE KIDNEY DIS-**  
19 **EASE EDUCATION BENEFIT.**

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

22 (1) in paragraph (1)—

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

1 (B) in subparagraph (B), by inserting “or  
2 of a physician assistant, nurse practitioner, or  
3 clinical nurse specialist (as defined in section  
4 1861(aa)(5)) assisting in the treatment of the  
5 individual’s kidney condition” after “kidney  
6 condition”; and

7 (2) in paragraph (2)—

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

9 (B) in subparagraph (A)—

10 (i) by striking “(A)” after “(2)”;

11 (ii) by striking “and” at the end of  
12 clause (i);

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

15 (iv) by redesignating clauses (i) and  
16 (ii) as subparagraphs (A) and (B), respec-  
17 tively; and

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

19 “(C) a renal dialysis facility subject to the  
20 requirements of section 1881(b)(1) with per-  
21 sonnel who—

22 “(i) provide the services described in  
23 paragraph (1); and

24 “(ii) is a physician (as defined in sub-  
25 section (r)(1)) or a physician assistant,

1 nurse practitioner, or clinical nurse spe-  
2 cialist (as defined in subsection (aa)(5)).”.

3 (b) PAYMENT TO RENAL DIALYSIS FACILITIES.—  
4 Section 1881(b) of the Social Security Act (42 U.S.C.  
5 1395rr(b)) is amended by adding at the end the following  
6 new paragraph:

7 “(15) For purposes of paragraph (14), the sin-  
8 gle payment for renal dialysis services under such  
9 paragraph shall not take into account the amount of  
10 payment for kidney disease education services (as  
11 defined in section 1861(ggg)). Instead, payment for  
12 such services shall be made to the renal dialysis fa-  
13 cility on an assignment-related basis under section  
14 1848.”.

15 (c) EFFECTIVE DATE.—The amendments made by  
16 this section apply to kidney disease education services fur-  
17 nished on or after January 1, 2022.

## 18 **TITLE II—INCENTIVIZING** 19 **KIDNEY CARE INNOVATION**

### 20 **SEC. 201. REFINING THE END-STAGE RENAL DISEASE PAY-** 21 **MENT SYSTEM TO IMPROVE ACCURACY IN** 22 **PAYMENT AND SUPPORT THERAPIES.**

23 (a) IN GENERAL.—Section 1881(b)(14) of the Social  
24 Security Act (42 U.S.C. 1395ww(b)(14)) is amended by  
25 adding the following new subparagraph:

1                   “(J) PAYMENT FOR NEW AND INNOVATIVE  
2                   DRUGS, BIOLOGICALS, AND DEVICES THAT ARE  
3                   RENAL DIALYSIS SERVICES.—

4                   “(i) IN GENERAL.—For drugs or  
5                   biologicals defined as within a functional  
6                   category and furnished on or after Janu-  
7                   ary 1, 2024, the Secretary shall implement  
8                   an add-on adjustment for claims that in-  
9                   clude such drugs or biologicals that, among  
10                  other things, shall—

11                  “(I) calculate a per-treatment  
12                  cost using the most recent cost and  
13                  utilization data collected during a  
14                  transitional payment period of not less  
15                  than 3 years by dividing the total  
16                  spending for such drug or biological  
17                  during such transitional period by the  
18                  total number of treatments for which  
19                  such drug or biological was listed on  
20                  such claim during such period of time;

21                  “(II) offset the amount of the  
22                  add-on adjustment by an amount that  
23                  corresponds with the reduction in ex-  
24                  penditures for other formerly sepa-  
25                  rately billed renal dialysis drugs that



1 were directly the result of the inclu-  
2 sion of the new product;

3 “(III) update the add-on adjust-  
4 ment annually to account for infla-  
5 tionary changes; and

6 “(IV) be applied immediately  
7 upon the expiration of the TDAPA  
8 period for a product to avoid a gap  
9 between the TDAPA and availability  
10 of the post-TDAPA add-on adjust-  
11 ment.

12 “(ii) IMPLEMENTATION.—This policy  
13 shall not be implemented in a budget neu-  
14 tral manner.”.

15 (b) NEW DEVICES AND OTHER TECHNOLOGIES.—As  
16 part of the promulgation of the annual rule for the Medi-  
17 care end-stage renal disease prospective payment system  
18 under section 1881(b)(14) of the Social Security Act (42  
19 U.S.C. 1395rr(b)(14)) for calendar year 2022, and in con-  
20 sultation with stakeholders, the Secretary of Health and  
21 Human Services (in this section referred to as the “Sec-  
22 retary”) shall ensure that the single payment amount is  
23 adequate to cover the cost of the new innovative device  
24 or other technology with substantial clinical improvement  
25 and increase the single payment amount if the Secretary

1 determines such payment amount is not adequate to cover  
2 such cost. In carrying out the preceding sentence, the Sec-  
3 retary shall use the cost and utilization data collected dur-  
4 ing a 3-year transitional payment period, as otherwise de-  
5 scribed in the final regulation published on November 9,  
6 2020 (85 Fed. Reg. 71398 et seq.).

7 **SEC. 202. ENSURING MEDICARE ADVANTAGE SUPPORTS**  
8 **KIDNEY CARE INNOVATIVE THERAPIES.**

9 Section 1853(c) of the Social Security Act (42 U.S.C.  
10 1395ww-23(c)) is amended by adding the following new  
11 paragraph:

12 “(8) ADJUSTMENT FOR INNOVATIVE PRODUCTS  
13 FOR ENROLLES WITH END STAGE RENAL DIS-  
14 EASE.—If the Secretary makes a determination with  
15 respect to the application of the End Stage Renal  
16 Disease Transitional Drug Add-On Payment Adjust-  
17 ment or the Transitional Add-on Payment Adjust-  
18 ment for New and Innovative Equipment and Sup-  
19 plies to a product under this title that will result in  
20 an increase in the costs to Medicare+Choice of pro-  
21 viding benefits under contracts under this part for  
22 the period of the Transitional Drug Add-On Pay-  
23 ment Adjustment or the Transitional Add-on Pay-  
24 ment Adjustment for New and Innovative Equip-  
25 ment and Supplies, the Secretary shall directly make

1 the payments adjustments to providers of services or  
2 independent dialysis facilities consistent with the ap-  
3 plication of such adjustments under the ESRD pro-  
4 spective payment system outlined in section  
5 1881(b)(14) of this title for the complete duration  
6 that the adjustment applies under such section.  
7 After the duration of such adjustment, the Secretary  
8 shall adjust appropriately the payments to such or-  
9 ganizations under this part.

10 “(9) POST-TDAPA PAYMENT ADD-ON ADJUST-  
11 MENT.—The Secretary shall require providers of  
12 services or independent dialysis facilities to apply the  
13 adjustment required under subparagraph (J) of sec-  
14 tion 1881(b)(14) to payments made under this  
15 part.”.

16 **SEC. 203. IMPROVING PATIENT LIVES AND QUALITY OF**  
17 **CARE THROUGH RESEARCH AND INNOVA-**  
18 **TION.**

19 (a) STUDY.—The Secretary of Health and Human  
20 Services (in this section referred to as the “Secretary”)  
21 shall conduct a study on increasing kidney transplantation  
22 rates. Such study shall include an analysis of each of the  
23 following:

24 (1) Any disincentives in the payment systems  
25 under the Medicare program under title XVIII of

1 the Social Security Act (42 U.S.C. 1395 et seq.)  
2 that create barriers to kidney transplants and post-  
3 transplant care for beneficiaries with end-stage renal  
4 disease.

5 (2) The practices used by States with higher  
6 than average donation rates and whether those prac-  
7 tices and policies could be successfully utilized in  
8 other States.

9 (3) Practices and policies that could increase  
10 deceased donation rates of minority populations.

11 (4) Whether cultural and policy barriers exist to  
12 increasing living donation rates, including an exam-  
13 ination of how to better facilitate chained donations.

14 (5) Other areas determined appropriate by the  
15 Secretary.

16 (b) REPORT.—Not later than 18 months after the  
17 date of the enactment of this Act, the Secretary shall sub-  
18 mit to Congress a report on the study conducted under  
19 subsection (a), together with such recommendations as the  
20 Secretary determines to be appropriate.

1 **TITLE III—ADDRESSING THE**  
2 **KIDNEY CARE WORKFORCE**  
3 **CRISIS**

4 **SEC. 301. ENSURING ACCURACY AND STABILITY IN KIDNEY**  
5 **CARE PAYMENT.**

6 Section 1881(b)(14) of the Social Security Act (42  
7 U.S.C. 1395ww(b)(14)) is amended by adding the fol-  
8 lowing new subparagraph:

9 “(K) Beginning with calendar year 2024,  
10 the Secretary shall compute an adjustment to  
11 the annual update of the previous calendar  
12 year’s rate to account for forecast error. The  
13 initial adjustment (in calendar year 2024) to  
14 the update of the previous calendar year’s rate  
15 will take into account the cumulative forecast  
16 error between calendar years 2021 and 2022.  
17 Subsequent adjustments in succeeding fiscal  
18 years will take into account the forecast error  
19 from the most recently available calendar year  
20 for which there is final data. The forecast error  
21 adjustment shall apply whenever the difference  
22 between the forecasted and actual percentage  
23 change in the ESRD market basket index ex-  
24 ceeds the threshold of 0.5 percentage points.”.

1 **SEC. 302. ENCOURAGING KIDNEY CARE WORKFORCE IN**  
2 **UNDER SERVED AREAS.**

3 (a) **DEFINITION OF PRIMARY CARE SERVICES.**—Sec-  
4 tion 331(a)(3)(D) of the Public Health Service Act (42  
5 U.S.C. 254d(a)(3)(D)) is amended by inserting “renal di-  
6 alysis,” after “dentistry,”.

7 (b) **NATIONAL HEALTH SERVICE CORPS SCHOLAR-**  
8 **SHIP PROGRAM.**—Section 338A(a)(2) of the Public Health  
9 Service Act (42 U.S.C. 254l(a)(2)) is amended by insert-  
10 ing “, which may include nephrology health professionals”  
11 before the period at the end.

12 (c) **NATIONAL HEALTH SERVICE CORPS LOAN RE-**  
13 **PAYMENT PROGRAM.**—Section 338B(a)(2) of the Public  
14 Health Service Act (42 U.S.C. 254l-1(a)(2)) is amended  
15 by inserting “, which may include nephrology health pro-  
16 fessionals” before the period at the end.

17 **TITLE IV—EXPANDING PATIENT**  
18 **CHOICE OF COVERAGE**

19 **SEC. 401. MEDIGAP COVERAGE FOR BENEFICIARIES WITH**  
20 **END-STAGE RENAL DISEASE.**

21 (a) **GUARANTEED AVAILABILITY OF MEDIGAP POLI-**  
22 **CIES TO ALL ESRD MEDICARE BENEFICIARIES.**—

23 (1) **IN GENERAL.**—Section 1882(s) of the So-  
24 cial Security Act (42 U.S.C. 1395ss(s)) is amend-  
25 ed—

26 (A) in paragraph (2)—

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

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

6 “(ii) entitled to benefits under  
 7 226A(b) and is enrolled for benefits under  
 8 part B.”; and

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

13 (B) in paragraph (3)(B)—

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

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

19 (2) EFFECTIVE DATE.—The amendments made  
 20 by paragraph (1) shall apply to Medicare supple-  
 21 mental policies effective on or after January 1,  
 22 2022.

23 (b) ADDITIONAL ENROLLMENT PERIOD FOR CER-  
 24 TAIN INDIVIDUALS.—

25 (1) ONE-TIME ENROLLMENT PERIOD.—

1           (A) IN GENERAL.—In the case of an indi-  
2           vidual described in subparagraph (B), the Sec-  
3           retary of Health and Human Services shall es-  
4           tablish a one-time enrollment period during  
5           which such an individual may enroll in any  
6           Medicare supplemental policy under section  
7           1882 of the Social Security Act (42 U.S.C.  
8           1395ss) of the individual’s choosing.

9           (B) ENROLLMENT PERIOD.—The enroll-  
10          ment period established under subparagraph  
11          (A) shall begin on January 1, 2023, and shall  
12          end June 30, 2023.

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

15               (A) is entitled to hospital insurance bene-  
16               fits under part A of title XVIII of the Social  
17               Security Act under section 226A(b) of such Act  
18               (42 U.S.C. 426–1);

19               (B) is enrolled for benefits under part B of  
20               such title XVIII; and

21               (C) would not, but for the provisions of,  
22               and amendments made by, subsection (a) be eli-  
23               gible for the guaranteed issue of a Medicare  
24               supplemental policy under paragraph (2) or (3)



1 of section 1882(s) of such Act (42 U.S.C.  
2 1395ss(s)).

○

117TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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

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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)).