

117TH CONGRESS
1ST SESSION

H. R. 4065

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 22, 2021

Ms. SEWELL (for herself and Mr. BUCHANAN) introduced the following bill;
which was referred to the Committee on Energy and Commerce, and in
addition to the Committee on Ways and Means, for a period to be subse-
quently determined by the Speaker, in each case for consideration of such
provisions as fall within the jurisdiction of the committee concerned

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 2021”.

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—INCREASING AWARENESS, EXPANDING PREVENTIVE
SERVICES, AND IMPROVING CARE COORDINATION

- Sec. 101. Expanding Medicare annual wellness benefit to include kidney disease screening.
- Sec. 102. Increasing access to Medicare kidney disease education benefit.
- Sec. 103. Improving patient lives and quality of care through research and innovation.
- Sec. 104. Understanding the progression of kidney disease and treatment of kidney failure in minority populations.

TITLE II—CREATING AN ECONOMICALLY STABLE DIALYSIS
INFRASTRUCTURE AND INCENTIVIZING INNOVATION

- Sec. 201. Refining the end-stage renal disease payment system to improve accuracy in payment and support therapies.

TITLE III—INCREASING PATIENT ACCESS TO QUALITY PERFORMANCE BY IMPROVING THE ACCURACY AND TRANSPARENCY OF
END-STAGE RENAL DISEASE QUALITY PROGRAMS

- Sec. 301. Improving patient decision making and transparency by consolidating and modernizing quality programs.

TITLE IV—EMPOWERING PATIENTS

- Sec. 401. Medigap coverage for beneficiaries with end-stage renal disease.
- Sec. 402. Network adequacy requirements for dialysis services.
- Sec. 403. Allowing individuals with kidney failure to retain access to private insurance.

1 TITLE I—INCREASING AWARE-
2 NESS, EXPANDING PREVEN-
3 TIVE SERVICES, AND IMPROV-
4 ING CARE COORDINATION

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

- 8 (a) IN GENERAL.**—Section 1861(ww)(2) of the Social
9 Security Act (42 U.S.C. 1395x(ww)(2)) is amended—
10 (1) by redesignating subparagraph (O) as sub-
11 paragraph (P); and

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

3 “(O) Chronic kidney disease screening as
 4 defined by the Secretary.”.

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

8 **SEC. 102. INCREASING ACCESS TO MEDICARE KIDNEY DIS-**
 9 **EASE EDUCATION BENEFIT.**

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

12 (1) in paragraph (1)—

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

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

21 (2) in paragraph (2)—

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

23 (B) in subparagraph (A)—

24 (i) by striking “(A)” after “(2)”;

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

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

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

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

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

12 “(i) provide the services described in
 13 paragraph (1); and

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

18 (b) PAYMENT TO RENAL DIALYSIS FACILITIES.—
 19 Section 1881(b) of the Social Security Act (42 U.S.C.
 20 1395rr(b)) is amended by adding at the end the following
 21 new paragraph:

22 “(15) For purposes of paragraph (14), the sin-
 23 gle payment for renal dialysis services under such
 24 paragraph shall not take into account the amount of
 25 payment for kidney disease education services (as

1 defined in section 1861(ggg)). Instead, payment for
2 such services shall be made to the renal dialysis fa-
3 cility on an assignment-related basis under section
4 1848.”.

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

8 **SEC. 103. IMPROVING PATIENT LIVES AND QUALITY OF**
9 **CARE THROUGH RESEARCH AND INNOVA-**
10 **TION.**

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

16 (1) Any disincentives in the payment systems
17 under the Medicare program under title XVIII of
18 the Social Security Act that create barriers to kid-
19 ney transplants and post-transplant care for bene-
20 ficiaries with end-stage renal disease.

21 (2) The practices used by States with higher
22 than average donation rates and whether those prac-
23 tices and policies could be successfully utilized in
24 other States.

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

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

6 (5) Other areas determined appropriate by the
7 Secretary.

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

13 **SEC. 104. UNDERSTANDING THE PROGRESSION OF KIDNEY**
14 **DISEASE AND TREATMENT OF KIDNEY FAIL-**
15 **URE IN MINORITY POPULATIONS.**

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

19 (1) the social, behavioral, and biological factors
20 leading to kidney disease;

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

24 (3) treatment patterns associated with pro-
25 viding care, under the Medicare program under title

1 XVIII of the Social Security Act, the Medicaid pro-
 2 gram under title XIX of such Act, and through pri-
 3 vate health insurance, to minority populations that
 4 are disproportionately affected by kidney failure.

5 (b) REPORT.—Not later than 1 year after the date
 6 of the enactment of this Act, the Secretary shall submit
 7 to Congress a report on the study conducted under sub-
 8 section (a), together with such recommendations as the
 9 Secretary determines to be appropriate.

10 **TITLE II—CREATING AN ECO-**
 11 **NOMICALLY STABLE DIALY-**
 12 **SIS INFRASTRUCTURE AND**
 13 **INCENTIVIZING INNOVATION**

14 **SEC. 201. REFINING THE END-STAGE RENAL DISEASE PAY-**
 15 **MENT SYSTEM TO IMPROVE ACCURACY IN**
 16 **PAYMENT AND SUPPORT THERAPIES.**

17 (a) IN GENERAL.—Section 1881(b)(14) of the Social
 18 Security Act (42 U.S.C. 1395rr(b)(14)) is amended—

19 (1) in subparagraph (D), in the matter pre-
 20 ceding clause (i), by striking “Such system” and in-
 21 serting “Subject to subparagraph (J), such system”;
 22 and

23 (2) by adding at the end the following new sub-
 24 paragraph:

“(J) For payment for renal dialysis services furnished on or after January 1, 2024, under the system under this paragraph—

“(i) the payment adjustment described in clause (i) of subparagraph (D)—

“(I) shall not take into account comorbidities; and

“(II) shall take into account age for purposes of distinguishing between individuals who are under 18 years of age and those who are 18 years of age and older but shall not include any other adjustment for age for patients 18 years of age and older;

“(ii) the Secretary shall reassess any adjustments related to patient weight under such clause;

“(iii) the payment adjustment described in clause (ii) of such subparagraph shall not be included; and

“(iv) take into account reasonable costs for determining the payment rate consistent with paragraph (2)(B).”.

(b) INCLUSION OF NETWORK FEE AS AN ALLOWABLE COST.—Section 1881(b)(14) of the Social Security

1 Act (42 U.S.C. 1395rr(b)(14)), as amended by subsection
2 (a), is amended by adding at the end the following new
3 subparagraph:

4 “(K) Not later than January 1, 2022, the
5 Secretary shall amend the ESRD facility cost
6 report to include the per treatment network fee
7 (as described in paragraph (7)) as an allowable
8 cost or offset to revenue.”.

9 (c) DETERMINATION OF PRODUCTIVITY ADJUST-
10 MENT.—Section 1886(b)(3)(B)(xi) of the Social Security
11 Act (42 U.S.C. 1395ww(b)(3)(B)(xi)) is amended—

12 (1) in subclause (I), by striking “For 2012”
13 and inserting “Subject to subclause (IV), for 2012”;
14 and

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

17 “(IV) For each of 2022 through
18 2025, the productivity adjustment de-
19 scribed in subclause (II) shall be zero
20 for a payment system in any year in
21 which the Medicare Payment Advisory
22 Commission estimates that payments
23 under this title pursuant to such pay-
24 ment system, on an aggregate na-
25 tional basis, exceed costs, on an ag-

1 aggregate national basis, by 3.0 percent
2 or less.”.

3 (d) PAYMENT FOR NEW AND INNOVATIVE DRUGS
4 AND BIOLOGICALS THAT ARE RENAL DIALYSIS SERV-
5 ICES.—Section 1881(b)(14) of the Social Security Act (42
6 U.S.C. 1395ww(b)(14)), as amended by subsections (a)
7 and (b), is amended by adding the following new subpara-
8 graph—

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

12 “(i) IN GENERAL.—For drugs or
13 biologicals determined to be within a func-
14 tional category, the Secretary, in consulta-
15 tion with stakeholders, shall ensure that
16 the single payment amount is adequate to
17 cover the cost of new innovative drugs or
18 biologicals and increase the single payment
19 amount if the Secretary determines such
20 payment amount is not adequate to cover
21 such cost. In carrying out the preceding
22 sentence, the Secretary shall use the cost
23 and utilization data collected during the
24 three-year transitional payment period, as
25 otherwise described in the final regulation

published on November 14, 2018 (83 Fed. Reg. 56922 et seq.).

“(ii) MONEY TO FOLLOW THE PATIENT.—The Secretary, through notice and comment rulemaking, shall implement a policy for any drug or biological that is not provided to the ‘average’ patient that results in the amount by which the single payment amount is increased pursuant to this subparagraph shall be paid only when a provider or renal dialysis facility has demonstrated that it has administered the drug or biological to a patient.”.

(e) NEW DEVICES AND OTHER TECHNOLOGIES.—As part of the promulgation of the annual rule for the Medicare end-stage renal disease prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2022, and in consultation with stakeholders, the Secretary shall ensure that the single payment amount is adequate to cover the cost of the new innovative device or other technology with substantial clinical improvement and increase the single payment amount if the Secretary determines such payment amount is not adequate to cover such cost. In carrying out the preceding sentence, the Secretary shall use

1 the cost and utilization data collected during a three-year
2 transitional payment period, as otherwise described in the
3 final regulation published on November 9, 2020 (85 Fed.
4 Reg. 71398 et seq.).

5 **TITLE III—INCREASING PATIENT**
6 **ACCESS TO QUALITY PER-**
7 **FORMANCE BY IMPROVING**
8 **THE ACCURACY AND TRANS-**
9 **PARENCY OF END-STAGE**
10 **RENAL DISEASE QUALITY**
11 **PROGRAMS**

12 **SEC. 301. IMPROVING PATIENT DECISION MAKING AND**
13 **TRANSPARENCY BY CONSOLIDATING AND**
14 **MODERNIZING QUALITY PROGRAMS.**

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

17 (1) by striking subparagraph (A) and inserting
18 the following:

19 “(A) The measures specified under this
20 paragraph with respect to the year involved
21 shall be selected by the Secretary in consulta-
22 tion with stakeholders to promote improvement
23 in beneficiary outcomes and shared decision-
24 making with beneficiaries and their caregivers.
25 When selecting measures specified under this

1 paragraph, the Secretary shall take into ac-
2 count clinical gaps in care, underutilization that
3 may lead to beneficiary harm, patient safety,
4 and outcomes.”;

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

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

9 (4) by adding at the end the following new sub-
10 paragraphs:

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

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

21 (b) ENDORSEMENT.—Section 1881(h)(2)(B) of the
22 Social Security Act (42 U.S.C. 1395rr(h)(2)(B)) is
23 amended—

24 (1) in clause (ii), by adding at the end the fol-
25 lowing new sentence: “The exception under the pre-

1 ceding sentence shall not apply to a measure that
 2 the entity with a contract under section 1890(a) (or
 3 a similar entity) considered but failed to endorse.”;
 4 and

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

7 “(iii) COMPOSITE MEASURES.—
 8 Clauses (i) and (ii) shall apply to com-
 9 posite measures in the same manner as
 10 such clauses apply to individual meas-
 11 ures.”.

12 (c) REQUIREMENTS FOR DIALYSIS FACILITY COM-
 13 PARE STAR RATING PROGRAM.—Section 1881(h)(6) of
 14 the Social Security Act (42 U.S.C. 1395rr(h)(6)) is
 15 amended by adding at the end the following new subpara-
 16 graph:

17 “(E) REQUIREMENTS FOR ANY DIALYSIS
 18 FACILITY COMPARE STAR RATING PROGRAM.—
 19 To the extent that the Secretary maintains a
 20 dialysis facility compare star rating program,
 21 under such a program the Secretary—

22 “(i) shall assign stars using the same
 23 methodology and total performance score
 24 results from the quality incentive program
 25 under this subsection;

1 “(ii) shall determine the stars using
 2 the same methodology used under such
 3 quality incentive program; and

4 “(iii) shall not use a forced bell curve
 5 when determining the stars or rebaselining
 6 the stars.”.

7 (d) INCENTIVE PAYMENTS.—Section 1881(h)(1) of
 8 the Social Security Act (42 U.S.C. 1395rr(h)(1)) is
 9 amended by adding at the end the following new subpara-
 10 graph:

11 “(D) INCENTIVE PAYMENTS.—

12 “(i) IN GENERAL.—In the case of a
 13 provider of services or a renal dialysis fa-
 14 cility that the Secretary determines exceeds
 15 the attainment performance standards
 16 under paragraph (4) with respect to a
 17 year, the Secretary may make a bonus
 18 payment to the provider or facility (pursu-
 19 ant to a process established by the Sec-
 20 retary).

21 “(ii) FUNDING.—The total amount of
 22 bonus payments under clause (i) in a year
 23 shall be equal to the total amount of re-
 24 duced payments in a year under subpara-
 25 graph (A).

1 “(iii) NO EFFECT IN SUBSEQUENT
 2 YEARS.—The provisions of subparagraph
 3 (C) shall apply to a bonus payment under
 4 this subparagraph in the same manner
 5 subparagraph (C) applies to a reduction
 6 under such subparagraph.”.

7 (e) EFFECTIVE DATE.—The amendments made by
 8 this section shall apply to items and services furnished on
 9 or after January 1, 2022.

10 **TITLE IV—EMPOWERING** 11 **PATIENTS**

12 **SEC. 401. MEDIGAP COVERAGE FOR BENEFICIARIES WITH** 13 **END-STAGE RENAL DISEASE.**

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

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

19 (A) in paragraph (2)—

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

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

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

3 (ii) in subparagraph (D), in the mat-
4 ter preceding clause (i), by inserting “(or
5 is entitled to benefits under 226A(b))”
6 after “is 65 years of age or older”; and
7 (B) in paragraph (3)(B)—

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

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

13 (2) EFFECTIVE DATE.—The amendments made
14 by paragraph (1) shall apply to Medicare supple-
15 mental policies effective on or after January 1,
16 2022.

17 (b) ADDITIONAL ENROLLMENT PERIOD FOR CER-
18 TAIN INDIVIDUALS.—

19 (1) ONE-TIME ENROLLMENT PERIOD.—

20 (A) IN GENERAL.—In the case of an indi-
21 vidual described in subparagraph (B), the Sec-
22 retary of Health and Human Services shall es-
23 tablish a one-time enrollment period during
24 which such an individual may enroll in any
25 Medicare supplemental policy under section

1 1882 of the Social Security Act (42 U.S.C.
2 1395ss) of the individual's choosing.

3 (B) ENROLLMENT PERIOD.—The enroll-
4 ment period established under subparagraph
5 (A) shall begin on January 1, 2023, and shall
6 end June 30, 2023.

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

9 (A) is entitled to hospital insurance bene-
10 fits under part A of title XVIII of the Social
11 Security Act under section 226A(b) of such Act
12 (42 U.S.C. 426–1);

13 (B) is enrolled for benefits under part B of
14 such title XVIII; and

15 (C) would not, but for the provisions of,
16 and amendments made by, subsection (a) be eli-
17 gible for the guaranteed issue of a Medicare
18 supplemental policy under paragraph (2) or (3)
19 of section 1882(s) of such Act (42 U.S.C.
20 1395ss(s)).

21 **SEC. 402. NETWORK ADEQUACY STANDARDS FOR DIALYSIS**
22 **SERVICES.**

23 Section 1852(d) of the Social Security Act (42 U.S.C.
24 1395w–22(d)) is amended by adding at the end the fol-
25 lowing new paragraph:

1 “(7) NETWORK ADEQUACY REQUIREMENTS FOR
 2 DIALYSIS SERVICES.—For plan year 2022 and sub-
 3 sequent plan years, the Secretary shall apply the
 4 network adequacy standards under this subsection
 5 with respect to access to dialysis services—

6 “(A) using the time and distance stand-
 7 ards in effect for plan year 2020; and

8 “(B) without regard to the final rule titled
 9 ‘Medicare Program; Contract Year 2021 Policy
 10 and Technical Changes to the Medicare Advan-
 11 tage Program, Medicare Prescription Drug
 12 Benefit Program, and Medicare Cost Plan Pro-
 13 gram’ (85 Fed. Reg. 33796).”.

14 **SEC. 403. ALLOWING INDIVIDUALS WITH KIDNEY FAILURE**
 15 **TO RETAIN ACCESS TO PRIVATE INSURANCE.**

16 (a) IN GENERAL.—Section 1862(b)(1)(C) of the So-
 17 cial Security Act (42 U.S.C. 1395y(b)(1)(C)) is amend-
 18 ed—

19 (1) in the last sentence, by inserting “and be-
 20 fore January 1, 2022” after “prior to such date”;
 21 and

22 (2) by adding at the end the following new sen-
 23 tence: “Effective for items and services furnished on
 24 or after January 1, 2022 (with respect to periods
 25 beginning on or after the date that is 42 months

1 prior to such date), clauses (i) and (ii) shall be ap-
2 plied by substituting ‘42-month’ for ‘12-month’ each
3 place it appears.”.

4 (b) EFFECTIVE DATE.—The amendments made by
5 this subsection shall take effect on the date of enactment
6 of this Act. For purposes of determining an individual’s
7 status under section 1862(b)(1)(C) of the Social Security
8 Act (42 U.S.C. 1395y(b)(1)(C)), as amended by sub-
9 section (a), an individual who is within the coordinating
10 period as of the date of enactment of this Act shall have
11 that period extended to the full 42 months described in
12 the last sentence of such section, as added by the amend-
13 ment made by subsection (a)(2).

○