

117TH CONGRESS
1ST SESSION

S. 1971

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

IN THE SENATE OF THE UNITED STATES

JUNE 8, 2021

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

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.

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

12 (2) by inserting after subparagraph (N) the fol-
13 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 apply to items and services furnished on or
5 after January 1, 2022.

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)”; 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 sin-
 21 gle payment for renal dialysis services under such
 22 paragraph shall not take into account the amount of
 23 payment for kidney disease education services (as
 24 defined in section 1861(ggg)). Instead, payment for
 25 such services shall be made to the renal dialysis fa-

1 cility on an assignment-related basis under section
2 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, 2022.

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

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 increasing kidney transplantation
12 rates. Such study shall include an analysis of each of the
13 following:

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

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

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

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

4 (5) Other areas determined appropriate by the
 5 Secretary.

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

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

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

17 (1) the social, behavioral, and biological factors
 18 leading to kidney disease;

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

22 (3) treatment patterns associated with pro-
 23 viding care, under the Medicare program under title
 24 XVIII of the Social Security Act, the Medicaid pro-
 25 gram under title XIX of such Act, and through pri-

1 vate health insurance, to minority populations that
 2 are disproportionately affected by kidney failure.

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

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

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

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

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

21 (2) by adding at the end the following new sub-
 22 paragraph:

23 “(J) For payment for renal dialysis serv-
 24 ices furnished on or after January 1, 2024,
 25 under the system under this paragraph—

1 “(i) the payment adjustment de-
 2 scribed in clause (i) of subparagraph (D)—

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

5 “(II) shall take into account age
 6 for purposes of distinguishing between
 7 individuals who are under 18 years of
 8 age and those who are 18 years of age
 9 and older but shall not include any
 10 other adjustment for age for patients
 11 18 years of age and older;

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

15 “(iii) the payment adjustment de-
 16 scribed in clause (ii) of such subparagraph
 17 shall not be included; and

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

21 (b) INCLUSION OF NETWORK FEE AS AN ALLOW-
 22 ABLE COST.—Section 1881(b)(14) of the Social Security
 23 Act (42 U.S.C. 1395rr(b)(14)), as amended by subsection
 24 (a), is amended by adding at the end the following new
 25 subparagraph:

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

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

9 (1) in subclause (I), by striking “For 2012”
 10 and inserting “Subject to subclause (IV), for 2012”;
 11 and

12 (2) by adding at the end, the following new sub-
 13 clause:

14 “(IV) For each of 2022 through
 15 2025, the productivity adjustment de-
 16 scribed in subclause (II) shall be zero
 17 for a payment system in any year in
 18 which the Medicare Payment Advisory
 19 Commission estimates that payments
 20 under this title pursuant to such pay-
 21 ment system, on an aggregate na-
 22 tional basis, exceed costs, on an ag-
 23 gregate national basis, by 3.0 percent
 24 or less.”.

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

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

10 “(i) IN GENERAL.—For drugs or
11 biologicals determined to be within a func-
12 tional category, the Secretary, in consulta-
13 tion with stakeholders, shall ensure that
14 the single payment amount is adequate to
15 cover the cost of new innovative drugs or
16 biologicals and increase the single payment
17 amount if the Secretary determines such
18 payment amount is not adequate to cover
19 such cost. In carrying out the preceding
20 sentence, the Secretary shall use the cost
21 and utilization data collected during the
22 three-year transitional payment period, as
23 otherwise described in the final regulation
24 published on November 14, 2018 (83 Fed.
25 Reg. 56922 et seq.).

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

12 (e) NEW DEVICES AND OTHER TECHNOLOGIES.—As
13 part of the promulgation of the annual rule for the Medi-
14 care end-stage renal disease prospective payment system
15 under section 1881(b)(14) of the Social Security Act (42
16 U.S.C. 1395rr(b)(14)) for calendar year 2022, and in con-
17 sultation with stakeholders, the Secretary shall ensure
18 that the single payment amount is adequate to cover the
19 cost of the new innovative device or other technology with
20 substantial clinical improvement and increase the single
21 payment amount if the Secretary determines such pay-
22 ment amount is not adequate to cover such cost. In car-
23 rying out the preceding sentence, the Secretary shall use
24 the cost and utilization data collected during a three-year
25 transitional payment period, as otherwise described in the

1 final regulation published on November 9, 2020 (85 Fed.
2 Reg. 71398 et seq.).

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

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

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

15 (1) by striking subparagraph (A) and inserting
16 the following:

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

1 may lead to beneficiary harm, patient safety,
2 and outcomes.”;

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

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

7 (4) by adding at the end the following new sub-
8 paragraphs:

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

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

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

22 (1) in clause (ii), by adding at the end the fol-
23 lowing new sentence: “The exception under the pre-
24 ceding sentence shall not apply to a measure that
25 the entity with a contract under section 1890(a) (or

1 a similar entity) considered but failed to endorse.”;
 2 and

3 (2) by adding at the end the following new
 4 clause:

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

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

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

20 “(i) shall assign stars using the same
 21 methodology and total performance score
 22 results from the quality incentive program
 23 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).”.

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