

116TH CONGRESS
1ST SESSION

S. 1676

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

MAY 23 (legislative day, MAY 22), 2019

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 2019”.

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. Increasing access to Medicare kidney disease education benefit.
- Sec. 102. Improving patient lives and quality of care through research and innovation.
- Sec. 103. Understanding current utilization of palliative care services.
- Sec. 104. Understanding the progression of kidney disease and treatment of kidney failure in minority populations.
- Sec. 105. Improving access in underserved areas.
- Sec. 106. Improving care coordination for dialysis patients by requiring hospitals to provide information.

**TITLE II—INCENTIVIZING INNOVATION FOR TRULY INNOVATIVE
NEW DRUGS, BIOLOGICALS, DEVICES, AND OTHER TECHNOLOGIES**

- Sec. 201. Maintaining an economically stable dialysis infrastructure.

**TITLE III—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.

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

5 SEC. 101. INCREASING ACCESS TO MEDICARE KIDNEY DIS-
6 EASE EDUCATION BENEFIT.

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

9 (1) in paragraph (1)—

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

12 (B) in subparagraph (B), by inserting “or
 13 of a physician assistant, nurse practitioner, or
 14 clinical nurse specialist (as defined in section

1 1861(aa)(5)) assisting in the treatment of the
 2 individual's kidney condition" after "kidney
 3 condition"; and

4 (2) in paragraph (2)—

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

6 (B) in subparagraph (A)—

7 (i) by striking "(A)" after "(2)";

8 (ii) by striking "and" at the end of
 9 clause (i);

10 (iii) by striking the period at the end
 11 of clause (ii) and inserting "; and";

12 (iv) by redesignating clauses (i) and
 13 (ii) as subparagraphs (A) and (B), respec-
 14 tively; and

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

16 "(C) a renal dialysis facility subject to the
 17 requirements of section 1881(b)(1) with per-
 18 sonnel who—

19 "(i) provide the services described in
 20 paragraph (1); and

21 "(ii) is a physician (as defined in sub-
 22 section (r)(1)) or a physician assistant,
 23 nurse practitioner, or clinical nurse spe-
 24 cialist (as defined in subsection (aa)(5)).".

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

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

13 (c) EFFECTIVE DATE.—The amendments made by
 14 this section apply to kidney disease education services fur-
 15 nished on or after January 1, 2020.

16 **SEC. 102. 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 that create barriers to kid-
 2 ney transplants and post-transplant care for bene-
 3 ficiaries with end-stage renal disease.

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

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

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

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

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

20 **SEC. 103. UNDERSTANDING CURRENT UTILIZATION OF PAL-**
 21 **LIATIVE CARE SERVICES.**

22 (a) STUDY.—

23 (1) IN GENERAL.—The Comptroller General of
 24 the United States (in this section referred to as the
 25 “Comptroller General”) shall conduct a study on the

1 utilization of palliative care in treating individuals
2 with advanced kidney disease, from stage IV through
3 stage V, including individuals with kidney failure on
4 dialysis through any progression of the disease. Such
5 study shall include an analysis of—

6 (A) how palliative care can be utilized to
7 improve the quality of life of those with kidney
8 disease and facilitate care tailored to their indi-
9 vidual goals and values;

10 (B) the successful use of palliative care in
11 the care of patients with other chronic diseases
12 and serious illnesses;

13 (C) the utilization of palliative care at any
14 point in an illness, including when used at the
15 same time as curative treatment; and

16 (D) other areas determined appropriate by
17 the Comptroller General.

18 (2) DEFINITION OF PALLIATIVE CARE.—In this
19 section, the term “palliative care” means patient
20 and family centered care that optimizes quality of
21 life by anticipating, preventing, and treating suf-
22 fering. Such term includes care that is furnished
23 throughout the continuum of the illness that ad-
24 dresses physical, intellectual, emotional, social, and

1 spiritual needs and that facilitates patient autonomy,
2 access to information and choice.

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

8 **SEC. 104. UNDERSTANDING THE PROGRESSION OF KIDNEY**
9 **DISEASE AND TREATMENT OF KIDNEY FAIL-**
10 **URE IN MINORITY POPULATIONS.**

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—

14 (1) the social, behavioral, and biological factors
15 leading to kidney disease;

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

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

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

6 **SEC. 105. IMPROVING ACCESS IN UNDERSERVED AREAS.**

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

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

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

1 **SEC. 106. IMPROVING CARE COORDINATION FOR DIALYSIS**
 2 **PATIENTS BY REQUIRING HOSPITALS TO**
 3 **PROVIDE INFORMATION.**

4 Section 1881 of the Social Security Act (42 U.S.C.
 5 1395rr) is amended by adding at the end the following
 6 new subsection:

7 “(i) HOSPITALS REQUIRED TO PROVIDE INFORMA-
 8 TION.—

9 “(1) IN GENERAL.—The Secretary shall estab-
 10 lish a process under which a hospital or a critical ac-
 11 cess hospital shall provide a renal dialysis facility
 12 with health and treatment information with respect
 13 to an individual who is discharged from the hospital
 14 or critical access hospital and who subsequently re-
 15 ceives treatment at the facility.

16 “(2) ELEMENTS.—Under the process estab-
 17 lished under paragraph (1)—

18 “(A) the request for health and treatment
 19 information may be initiated by the individual
 20 prior to discharge or upon request by the renal
 21 dialysis facility after the individual is dis-
 22 charged; and

23 “(B) the information requested must be
 24 provided to the facility within 7 days of the re-
 25 quest being made.”.

1 **TITLE II—INCENTIVIZING INNO-**
2 **VATION FOR TRULY INNOVA-**
3 **TIVE NEW DRUGS, BIOLOGI-**
4 **CALS, DEVICES, AND OTHER**
5 **TECHNOLOGIES**

6 **SEC. 201. MAINTAINING AN ECONOMICALLY STABLE DIALY-**
7 **SIS INFRASTRUCTURE.**

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

10 (1) in subparagraph (D), in the matter pre-
11 ceding clause (i), by striking “Such system” and in-
12 serting “Subject to subparagraph (J), such system”;
13 and

14 (2) by adding at the end the following new sub-
15 paragraph:

16 “(J) For payment for renal dialysis serv-
17 ices furnished on or after January 1, 2020,
18 under the system under this paragraph—

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

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

23 “(II) shall only take into account
24 age for purposes of distinguishing be-
25 tween individuals who are under 18

1 years of age and those who are 18
2 years of age and older but shall not
3 include any other adjustment for age;

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

7 “(iii) the payment adjustment de-
8 scribed in clause (ii) of such subparagraph
9 shall not be included;

10 “(iv) the standardization factor de-
11 scribed in the final rule published in the
12 Federal Register on November 8, 2012 (77
13 Fed. Reg. 67470), shall be established
14 using the most currently available data
15 (and not historical data) and adjusted on
16 an annual basis, based on such available
17 data, to account for any change in utiliza-
18 tion of drugs and any modification in ad-
19 justors applied under this paragraph; and

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

23 (b) INCLUSION OF NETWORK FEE AS AN ALLOW-
24 ABLE COST.—Section 1881(b)(14) of the Social Security
25 Act (42 U.S.C. 1395rr(b)(14)), as amended by subsection

1 (a), is amended by adding at the end the following new
 2 subparagraph:

3 “(K) Not later than January 1, 2020, the
 4 Secretary shall amend the ESRD facility cost
 5 report to include the per treatment network fee
 6 (as described in paragraph (7)) as an allowable
 7 cost or offset to revenue.”.

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

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

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

16 “(IV) For each of 2020 through
 17 2024, the productivity adjustment de-
 18 scribed in subclause (II) shall be zero
 19 for a payment system in any year in
 20 which the Medicare Payment Advisory
 21 Commission estimates that payments
 22 under this title pursuant to such pay-
 23 ment system, on an aggregate na-
 24 tional basis, exceed costs, on an ag-

1 gregate 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 two-year transitional payment period, as
25 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 2021, and in consultation with stakeholders, the Secretary shall establish a process for identifying and determining appropriate payment amounts for incorporating new devices and technologies into the bundled payment under such system.

1 **TITLE III—IMPROVING THE AC-**
 2 **CURACY AND TRANSPARENCY**
 3 **OF END STAGE RENAL DIS-**
 4 **EASE QUALITY PROGRAMS**

5 **SEC. 301. IMPROVING PATIENT DECISION MAKING AND**
 6 **TRANSPARENCY BY CONSOLIDATING AND**
 7 **MODERNIZING QUALITY PROGRAMS.**

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

10 (1) by striking subparagraph (A) and inserting
 11 the following:

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

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

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

2 (4) by adding at the end the following new sub-
3 paragraphs:

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

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

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

17 (1) in clause (ii), by adding at the end the fol-
18 lowing new sentence: “The exception under the pre-
19 ceding sentence shall not apply to a measure that
20 the entity with a contract under section 1890(a) (or
21 a similar entity) considered but failed to endorse.”;
22 and

23 (2) by adding at the end the following new
24 clause:

1 “(iii) COMPOSITE MEASURES.—
 2 Clauses (i) and (ii) shall apply to com-
 3 posite measures in the same manner as
 4 such clauses apply to individual meas-
 5 ures.”.

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

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

16 “(i) shall assign stars using the same
 17 methodology and total performance score
 18 results from the quality incentive program
 19 under this subsection;

20 “(ii) shall determine the stars using
 21 the same methodology used under such
 22 quality incentive program; and

23 “(iii) shall not use a forced bell curve
 24 when determining the stars or rebaselining
 25 the stars.”.

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

5 “(D) INCENTIVE PAYMENTS.—

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

15 “(ii) FUNDING.—The total amount of
 16 bonus payments under clause (i) in a year
 17 shall be equal to the total amount of re-
 18 duced payments in a year under subpara-
 19 graph (A).

20 “(iii) NO EFFECT IN SUBSEQUENT
 21 YEARS.—The provisions of subparagraph
 22 (C) shall apply to a bonus payment under
 23 this subparagraph in the same manner
 24 subparagraph (C) applies to a reduction
 25 under such subparagraph.”.

1 (e) EFFECTIVE DATE.—The amendments made by
 2 this section shall apply to items and services furnished on
 3 or after January 1, 2020.

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 2021.

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, 2021, and shall
24 end June 30, 2021.

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)).

○