

117TH CONGRESS
2D SESSION

H. R. 7506

To amend the Public Health Service Act with respect to preventing end-stage kidney disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 14, 2022

Mr. BUTTERFIELD (for himself and Mr. BILIRAKIS) 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 subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act with respect to preventing end-stage 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.**

4 This Act may be cited as the “New Era of Preventing
5 End-Stage Kidney Disease Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Findings.
- Sec. 4. Definitions.

TITLE I—CENTERS OF EXCELLENCE AND RARE KIDNEY
DISEASE RESEARCH

- Sec. 101. NIDDK Centers on Rare Kidney Disease Research.
Sec. 102. Rare kidney disease progression research.

TITLE II—DIAGNOSTICS

- Sec. 201. Diagnostic issues relating to rare kidney disease.

TITLE III—COMMUNITIES OF COLOR

- Sec. 301. Understanding and slowing the progression of rare kidney disease
and treatment in certain populations.
Sec. 302. Communities of color service program.
Sec. 303. NIH report on NIH research programs.
Sec. 304. Partnerships with organizations and agencies.

TITLE IV—PROVIDER EDUCATION

- Sec. 401. Primary care provider training grant program.
Sec. 402. Grant program for development and implementation of curricula for
continuing education on kidney disease.

TITLE V—COVERAGE AND EXPERIMENTS TO REDUCE DIALYSIS
AND TRANSPLANT COSTS

- Sec. 501. Medical expertise in pharmacy and therapeutic committees.
Sec. 502. Reducing dialysis and transplant costs related to rare kidney disease.

1 SEC. 3. FINDINGS.

2 Congress finds the following:

3 (1) Approximately 37,000,000 adults in the
4 United States have a chronic kidney disease, and
5 kidney diseases are the ninth leading cause of death
6 in the United States.

7 (2) Each day in the United States, on average,
8 340 people begin dialysis and 13 people die waiting
9 for a kidney transplant.

10 (3) Rare kidney diseases like focal segmental
11 glomerulosclerosis and immunoglobulin A
12 nephropathy are particularly difficult to treat, and
13 there are no approved treatments for these diseases.

1 (4) In the absence of approved treatment op-
2 tions, more than 100,000 people live with rare glo-
3 merular kidney disease and face dialysis, transplant,
4 or death.

5 (5) Focal segmental glomerulosclerosis is asso-
6 ciated with a 50 percent risk of end-stage kidney
7 disease within 5 years of diagnosis if partial or com-
8 plete remission is not achieved.

9 (6) Between 20 and 40 percent of individuals
10 with immunoglobulin A nephropathy are expected to
11 develop end-stage kidney disease within 20 years.

12 (7) Rare kidney diseases disproportionately af-
13 fect Black Americans, who are 3.5 times more likely
14 to develop end-stage kidney disease, and 5 times
15 more likely than the general population to have focal
16 segmental glomerulosclerosis.

17 (8) Because approximately one-third of Black
18 Americans with focal segmental glomerulosclerosis
19 cases are associated with a particular gene, commu-
20 nities of color would benefit from additional re-
21 sources to support earlier detection, including ge-
22 netic and genomic testing and referrals to high-qual-
23 ity providers.

24 (9) The prevalence of end-stage kidney disease
25 is exacerbated by diagnostic challenges, barriers to

1 high-quality care, and lack of awareness of disease
2 risks.

3 (10) Federal spending on end-stage kidney dis-
4 ease currently accounts for approximately 7 percent
5 of Federal Medicare spending.

6 (11) The total Medicare spending on both
7 chronic kidney disease and end-stage kidney disease
8 patients exceeded \$120,000,000,000 per year in re-
9 cent years.

10 (12) A focus on renal health and the prevention
11 of end-stage kidney disease would improve patient
12 outcomes, extend lives, mitigate racial health care
13 disparities, and reduce government spending.

14 (13) Due in large part to the 21st Century
15 Cures Act, new regulatory paradigms have unleashed
16 a wave of clinical innovation in the rare kidney dis-
17 ease space.

18 (14) In 2020, the first-ever Rare Kidney Dis-
19 ease Roundtable outlined urgent needs in the areas
20 of diagnosis, education, communities of color, and
21 patient support for rare kidney disease patients and
22 their families in the United States.

23 (15) In 2021, there are over 30 ongoing clinical
24 trials underway for treatments for a range of rare
25 kidney diseases, offering the first hope for novel

1 therapies for patients living with rare kidney dis-
2 eases, a new era of preventing end-stage kidney dis-
3 ease and related Federal costs, and the possibility of
4 improving chronic kidney care writ large.

5 **SEC. 4. DEFINITIONS.**

6 In this Act:

7 (1) DIRECTOR OF NIH.—The term “Director of
8 NIH” means the Director of the National Institutes
9 of Health.

10 (2) NIH.—The term “NIH” means the Na-
11 tional Institutes of Health.

12 (3) SECRETARY.—The term “Secretary” means
13 the Secretary of Health and Human Services.

14 **TITLE I—CENTERS OF EXCEL-**
15 **LENCE AND RARE KIDNEY**
16 **DISEASE RESEARCH**

17 **SEC. 101. NIDDK CENTERS ON RARE KIDNEY DISEASE RE-**
18 **SEARCH.**

19 Subpart 3 of part C of title IV of the Public Health
20 Service Act (42 U.S.C. 281 et seq.) is amended by insert-
21 ing after section 426 (42 U.S.C. 285c) the following new
22 section:

23 **“SEC. 426A. NIDDK CENTERS ON RARE KIDNEY DISEASE RE-**
24 **SEARCH.**

25 “(a) COOPERATIVE AGREEMENTS AND GRANTS.—

1 “(1) IN GENERAL.—The Director of the Insti-
2 tute may enter into cooperative agreements with,
3 and make grants to, public and private nonprofit en-
4 tities to pay all or part of the cost of planning, es-
5 tablishing, or strengthening, and providing basic op-
6 erating support for, regional centers of excellence for
7 rare kidney diseases, including primary glomerular
8 disease. Such centers of excellence shall be known as
9 NIDDK Centers on Rare Kidney Disease Research.

10 “(2) PURPOSES OF CENTERS.—The purposes of
11 the centers of excellence funded pursuant to para-
12 graph (1) shall be—

13 “(A) to increase public awareness of rare
14 kidney diseases, particularly in communities of
15 color; and

16 “(B) to develop resources for clinical re-
17 search into, training in, and demonstration of
18 diagnostic, prevention, control, and treatment
19 methods for, rare kidney diseases.

20 “(3) POLICIES.—A cooperative agreement or
21 grant under paragraph (1) shall be entered into in
22 accordance with policies established by the Director
23 of the National Institutes of Health.

24 “(b) COORDINATION WITH OTHER INSTITUTES.—
25 The Director of the Institute shall coordinate the activities

1 under this section with similar activities that are related
2 to rare kidney disease and conducted by other national
3 research institutes, centers, and agencies of the National
4 Institutes of Health and by the Food and Drug Adminis-
5 tration.

6 “(c) USES FOR FEDERAL PAYMENTS UNDER COOP-
7 ERATIVE AGREEMENTS OR GRANTS.—Federal payments
8 made under a cooperative agreement or grant under sub-
9 section (a) may be used for—

10 “(1) basic operating costs, including such pa-
11 tient care costs as are required for research;

12 “(2) clinical training, including training for al-
13 lied health professionals, continuing education for
14 health professionals and allied health professions
15 personnel, and information programs for the public
16 with respect to rare kidney diseases;

17 “(3) clinical research and demonstration pro-
18 grams;

19 “(4) education of members of the public, par-
20 ticularly through outreach to communities of color,
21 on the diagnosis (including through routine urinal-
22 ysis and through genetic testing), prevention, con-
23 trol, and treatment of rare kidney diseases; and

24 “(5) education of individuals diagnosed with
25 rare kidney diseases on renal diet and lifestyle, ge-

1 netic testing, and programs to promote urinalysis,
2 and on mental and emotional health resources for
3 families of rare kidney disease patients.

4 “(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—

5 The period of support for a center of excellence under sub-
6 section (a) may not exceed 5 years, except that such period
7 may be extended by the Director of the Institute for addi-
8 tional periods of not more than 5 years for each center
9 if—

10 “(1) the operations of such center have been re-
11 viewed by an appropriate technical and scientific
12 peer review group established by the Director of the
13 Institute; and

14 “(2) such group has recommended to the Direc-
15 tor of the Institute that such period should be ex-
16 tended.

17 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
18 carry out this section, there is authorized to be appro-
19 priated \$4,000,000 for each of fiscal years 2023 through
20 2027.”.

21 **SEC. 102. RARE KIDNEY DISEASE PROGRESSION RE-**
22 **SEARCH.**

23 (a) NIH RESEARCH ON RARE KIDNEY DISEASES.—

24 The Director of NIH may award grants or contracts to
25 public and nonprofit private entities to conduct research

1 on the causes, etiology, symptoms, diagnosis, progression,
2 and treatment of rare kidney diseases, including glomer-
3 ular diseases.

4 (b) APPLICATION.—To seek a grant under this sec-
5 tion, an eligible entity shall submit an application in such
6 form, in such manner, and containing such agreements,
7 assurances, and information as the Director of NIH deter-
8 mines to be necessary.

9 (c) RESEARCH FUNDED.—Research funded through
10 a grant under this section—

11 (1) may not include any consideration of qual-
12 ity-adjusted life years or disability-adjusted life
13 years, or other similar mechanisms that discriminate
14 against people with disabilities in value and cost-ef-
15 fectiveness assessments;

16 (2) shall include persons of color in populations
17 studied in the research; and

18 (3) shall include study of genotype-phenotype
19 relation to disease progression.

20 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
21 out this section, there is authorized to be appropriated
22 \$1,000,000 for each of fiscal years 2023 through 2027.

TITLE II—DIAGNOSTICS

SEC. 201. DIAGNOSTIC ISSUES RELATING TO RARE KIDNEY DISEASE.

(a) CONFERENCE.—

(1) **IN GENERAL.**—The Secretary shall, not later than 12 months after the date of the enactment of this Act, convene a conference to—

(A) analyze the impact of the decline of routine urinalysis on the timely diagnosis of rare kidney disease and on the quality of patient care following a diagnosis of such disease;

(B) analyze the quality and reliability of kidney biopsy in the diagnosis of rare kidney disease;

(C) analyze the impact of genetic and genomic testing on preventative care and precision medicine with respect to rare kidney disease;

(D) recommend strategies to reduce disparities in the occurrence and treatment of rare kidney disease among different groups, including communities of color; and

(E) recommend strategies to increase routine urinalysis and to improve technologies to diagnose such disease, including genetic testing.

1 (2) CONSULTATION.—In carrying out para-
2 graph (1), the Secretary shall consult with relevant
3 stakeholders, including health care providers, med-
4 ical professional societies, State-based societies, pub-
5 lic health experts, State and local public health de-
6 partments, State medical boards, patient groups,
7 drug manufacturers, pharmacists, insurers, and
8 other entities with experience in health care, public
9 health, and rare disease, as appropriate.

10 (b) EARLY INTERVENTION ON GENETIC SCREEN-
11 ING.—

12 (1) STUDY.—The Secretary shall conduct a
13 study on—

14 (A) whether genetic and genomic testing
15 may improve preventative care and precision
16 medicine with respect to rare kidney disease;

17 (B) whether genetic and genomic testing,
18 and in particular testing of the APOL1 gene,
19 may reduce disparities in the occurrence and
20 treatment of rare kidney disease among dif-
21 ferent groups, including communities of color;

22 (C) whether the Federal Government may
23 help to reduce barriers to genetic and genomic
24 testing for rare kidney disease, including by—

1 (i) encouraging the expansion of
2 health insurance coverage of genetic and
3 genomic testing, including diagnostic, pre-
4 dictive, and presymptomatic testing, and
5 DNA sequencing clinical services;

6 (ii) supporting the collection of evi-
7 dence for the clinical utility and appro-
8 priate use of genetic and genomic tests;
9 and

10 (iii) improving access to genetic coun-
11 selors, pathologists, and other relevant pro-
12 fessions, including strengthening related
13 workforce education and training efforts;

14 (D) the extent to which coverage provisions
15 in the Medicare and Medicaid programs under
16 titles XVIII and XIX of the Social Security Act
17 (42 U.S.C. 1395 et seq., 1396 et seq.) may re-
18 strain the use of genetic and genomic testing
19 for rare kidney disease that may improve clin-
20 ical outcomes for beneficiaries;

21 (E) whether the Centers for Medicare &
22 Medicaid Services may make coverage deter-
23 minations that better suit a precision medicine
24 approach to treatment; and

1 (F) whether genetic and genomic testing
2 may improve health outcomes for individuals
3 with rare kidney disease.

4 (2) REPORT.—

5 (A) IN GENERAL.—Not later than 18
6 months after the date of the enactment of this
7 Act, the Secretary shall submit a report to the
8 Congress on the proceedings of the conference
9 under subsection (a) and the results of the
10 study under paragraph (1).

11 (B) CONSULTATION.—In conducting the
12 study under paragraph (1) and developing the
13 report required by subparagraph (A), the Sec-
14 retary shall consult with physicians, other
15 health professionals, health educators, health
16 professional organizations, relevant companies,
17 patients, patient organizations, the Health Re-
18 sources and Services Administration, the Direc-
19 tor of NIH, the National Institute of Diabetes
20 and Digestive and Kidney Diseases, and the
21 Centers for Medicare & Medicaid Services. Such
22 consultation shall include consultation activities
23 conducted as part of the conference under sub-
24 section (a).

1 (3) DEFINITION.—In this subsection, the term
2 “DNA sequencing clinical services”, with respect to
3 an individual—

4 (A) means a determination of an exact se-
5 quence of deoxyribonucleic acid bases in the ge-
6 nome of such individual, and, if for the sole
7 benefit of the individual, a biological parent of
8 such individual for the purpose of determining
9 whether one or more potentially disease-causing
10 genetic variants are present in the genome of
11 such individual or such biological parent; and

12 (B) includes—

13 (i) sequencing of the entire genome, of
14 the exome, of a panel of genes, or other re-
15 gions of the genome; and

16 (ii) any analysis, interpretation, and
17 data report derived from such sequencing.

18 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
19 out this section, there is authorized to be appropriated
20 \$5,000,000 for the period of fiscal years 2023 through
21 2027.

1 **TITLE III—COMMUNITIES OF**
2 **COLOR**

3 **SEC. 301. UNDERSTANDING AND SLOWING THE PROGRES-**
4 **SION OF RARE KIDNEY DISEASE AND TREAT-**
5 **MENT IN CERTAIN POPULATIONS.**

6 (a) STUDY.—The Secretary shall conduct a study
7 on—

8 (1) the social, behavioral, and biological factors
9 leading to rare kidney disease;

10 (2) treatment patterns associated with pro-
11 viding care, under the Medicare program under title
12 XVIII of the Social Security Act (42 U.S.C. 1395 et
13 seq.), the Medicaid program under title XIX of such
14 Act (42 U.S.C. 1396 et seq.), and through private
15 health insurance, to populations that are dispropor-
16 tionately affected by such disease;

17 (3) access to nephrologists among populations
18 that are disproportionately affected by such disease;

19 (4) ongoing efforts and recommendations to
20 slow the progression of end-stage kidney disease in
21 populations that are disproportionately affected by
22 rare kidney disease; and

23 (5) patient trust of treating providers among
24 populations that are disproportionately affected by
25 such disease.

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

6 (c) COORDINATION.—In carrying out the activities
7 under subsections (a) and (b), the Secretary shall coordi-
8 nate with the Director of NIH, the Administrator of the
9 Center for Medicare & Medicaid Services, the Adminis-
10 trator of the Health Resources and Services Administra-
11 tion, and the Director of the Center for Medicare and
12 Medicaid Innovation.

13 (d) CONSULTATION.—In carrying out the activities
14 under subsections (a) and (b), the Secretary shall consult
15 with relevant stakeholders, including health care pro-
16 viders, medical professional societies, State-based soci-
17 eties, public health experts, State and local public health
18 departments, State medical boards, patient groups, drug
19 manufacturers, pharmacists, insurers, and other entities
20 with experience in health care, public health, health equity,
21 and rare disease, as appropriate.

22 **SEC. 302. COMMUNITIES OF COLOR SERVICE PROGRAM.**

23 Section 736(b) of the Public Health Service Act (42
24 U.S.C. 293) is amended—

1 (1) by redesignating paragraph (7) as para-
2 graph (8);

3 (2) in paragraph (6)(B), by striking “; and”
4 and inserting a semicolon; and

5 (3) by inserting after paragraph (6) the fol-
6 lowing:

7 “(7) to award fellowships, which may include
8 stipends, for postgraduate training in the field of ne-
9 phrology, for the purposes of—

10 “(A) increasing providers’ knowledge of
11 issues related to prevention, diagnosis, and
12 treatment of rare kidney disease among racial
13 and ethnic minority populations, especially the
14 prevalence of the gene APOL1;

15 “(B) improving the quality of rare kidney
16 disease prevention, diagnosis, and treatment de-
17 livered to racial and ethnic minorities; and

18 “(C) increasing the number of culturally
19 competent nephrologists; and”.

20 **SEC. 303. NIH REPORT ON NIH RESEARCH PROGRAMS.**

21 The Director of NIH shall prepare and publish on
22 the public website of the agency a report on diversity with-
23 in the programs of the NIH to research kidney disease,
24 including—

1 (1) the diversity of recipients of research
2 grants; and

3 (2) the extent to which grants are awarded to
4 research kidney disease among communities of color,
5 including disparities in the prevention, diagnosis,
6 and treatment of kidney disease among racial and
7 ethnic minority populations.

8 **SEC. 304. PARTNERSHIPS WITH ORGANIZATIONS AND**
9 **AGENCIES.**

10 (a) HHS PROGRAM.—Under this section or other ap-
11 plicable provisions of law, the Secretary shall establish a
12 program to provide grants to eligible entities to provide
13 education and appropriate medical and other referrals for
14 patients in communities of color regarding kidney disease,
15 including rare kidney disease.

16 (b) ELIGIBILITY.—To be eligible to receive a grant
17 under this section, an entity shall—

18 (1) be—

19 (A) a nonprofit or community-based orga-
20 nization, including any community health cen-
21 ter; or

22 (B) a State or local governmental agency;

23 and

24 (2) submit to the Secretary an application—

1 (A) at such time and in such manner as
2 the Secretary may require; and

3 (B) containing—

4 (i) a description of how the applicant
5 proposes to use the grant funds; and

6 (ii) such other information as the Sec-
7 retary may require.

8 (c) REPORTING.—

9 (1) BY GRANTEE.—A recipient of a grant under
10 this section shall submit annually to the Secretary,
11 and make publicly available, a report on the activi-
12 ties conducted using funds received through the
13 grant.

14 (2) BY SECRETARY.—Not later than the end of
15 fiscal year 2026, the Secretary shall submit to the
16 Congress a report that includes—

17 (A) a summary of the reports received
18 under paragraph (1);

19 (B) an evaluation of the effectiveness of
20 grants awarded under this section; and

21 (C) any recommendations the Secretary
22 may have.

23 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
24 out this section, there is authorized to be appropriated
25 \$2,000,000 for each of fiscal years 2023 through 2027.

1 **TITLE IV—PROVIDER**
2 **EDUCATION**

3 **SEC. 401. PRIMARY CARE PROVIDER TRAINING GRANT PRO-**
4 **GRAM.**

5 Subpart I of part C of title VII of the Public Health
6 Service Act (42 U.S.C. 293k et seq.) is amended by insert-
7 ing after section 747A (42 U.S.C. 293k–1) the following:

8 **“SEC. 747B. RARE KIDNEY DISEASE TRAINING FOR PRI-**
9 **MARY CARE PROVIDERS.**

10 “(a) IN GENERAL.—The Secretary may make grants
11 to an accredited public or nonprofit private hospital,
12 school of medicine, or academically affiliated physician as-
13 sistant training program, to a public or private nonprofit
14 entity that the Secretary has determined is capable of car-
15 rying out such grant, or to any consortium of such hos-
16 pitals, schools, programs, or entities, to plan, develop, and
17 operate a professional training program in the field of ne-
18 phrology for primary care residents, physicians, physician
19 assistants, or nurse practitioners, on—

20 “(1) methods to detect and diagnose rare kid-
21 ney disease, including urinalysis and genetic testing;

22 “(2) implementing such diagnostic methods in
23 their practices;

24 “(3) establishing treatment protocols for indi-
25 viduals diagnosed with rare kidney disease; and

1 “(4) implementing a collaborative care model to
2 coordinate care of patients diagnosed with rare kid-
3 ney disease among health care providers.

4 “(b) PRIORITIES IN MAKING AWARDS.—In awarding
5 grants under this section, the Secretary may give priority
6 to qualified applicants that—

7 “(1) have a record of training primary care pro-
8 viders;

9 “(2) establish formal relationships and submit
10 joint applications with Federally qualified health
11 centers, rural health clinics, or clinics located in un-
12 derserved areas or that serve underserved popu-
13 lations; or

14 “(3) teach trainees the skills to provide inter-
15 professional, integrated care through collaboration
16 among health professionals, including specialists.

17 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
18 is authorized to be appropriated to carry out this section
19 \$800,000 for each of fiscal years 2023 through 2027.”.

20 **SEC. 402. GRANT PROGRAM FOR DEVELOPMENT AND IM-**
21 **PLEMENTATION OF CURRICULA FOR CON-**
22 **TINUING EDUCATION ON KIDNEY DISEASE.**

23 Part C of title VII of the Public Health Service Act
24 (42 U.S.C. 293k et seq.) is amended—

1 (1) in the part heading, by striking “**AND PE-**
2 **DIATRIC DENTISTRY**” and inserting “**PEDIATRIC**
3 **DENTISTRY, AND KIDNEY DISEASE**”; and

4 (2) by inserting after subpart II (42 U.S.C.
5 293m) the following:

6 **“Subpart III—Continuing Education in Kidney**
7 **Disease**

8 **“SEC. 749C. CURRICULA FOR CONTINUING EDUCATION ON**
9 **KIDNEY DISEASE.**

10 “(a) GRANTS.—The Secretary may award grants to
11 eligible entities for the development and implementation
12 of curricula for providing continuing education and train-
13 ing to health care professionals on identifying, referring,
14 and treating individuals with kidney disease.

15 “(b) ELIGIBLE ENTITIES.—To be eligible to seek a
16 grant under this section, an entity shall be a public or
17 nonprofit entity that—

18 “(1) provides continuing education or training
19 to health care professionals; or

20 “(2) applies for the grant in partnership with
21 another entity that provides such education and
22 training.

23 “(c) PREFERENCE.—In awarding grants under this
24 section, the Secretary shall give preference to eligible enti-

1 ties proposing to develop and implement curricula for pro-
 2 viding continuing education and training to—

3 “(1) primary care providers; or

4 “(2) health care professionals who are required,
 5 as a condition of State licensure, to participate in
 6 continuing education or training.

7 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
 8 carry out this section, there is authorized to be appro-
 9 priated \$1,600,000 for each of fiscal years 2023 through
 10 2027.”.

11 **TITLE V—COVERAGE AND EX-**
 12 **PERIMENTS TO REDUCE DI-**
 13 **ALYSIS AND TRANSPLANT**
 14 **COSTS**

15 **SEC. 501. MEDICAL EXPERTISE IN PHARMACY AND THERA-**
 16 **PEUTIC COMMITTEES.**

17 Section 1860D–4(b)(3)(A) of the Social Security Act
 18 (42 U.S.C. 1395w–104(b)(3)(A)) is amended by striking
 19 clause (ii) and inserting the following:

20 “(ii) INCLUSION OF INDEPENDENT
 21 EXPERTS.—Such committee shall in-
 22 clude—

23 “(I) at least one practicing physi-
 24 cian and at least one practicing phar-
 25 macist, each of whom—

1 “(aa) is independent and
2 free of conflict with respect to
3 the sponsor and plan; and

4 “(bb) has expertise in the
5 care of elderly or disabled per-
6 sons; and

7 “(II) in the case of a drug ap-
8 proved to treat a rare disease or con-
9 dition as defined in section 526 of the
10 Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360bb), at least two
12 members that meet the requirements
13 described in items (aa) and (bb) of
14 subclause (I) and have expertise in
15 the field of medicine related to that
16 drug.”.

17 **SEC. 502. REDUCING DIALYSIS AND TRANSPLANT COSTS**
18 **RELATED TO RARE KIDNEY DISEASE.**

19 Section 1881(f) of the Social Security Act (42 U.S.C.
20 1395rr(f)) is amended by adding at the end the following
21 new paragraph:

22 “(9)(A) The Secretary shall conduct experiments to
23 evaluate methods for treating rare kidney disease, giving
24 particular attention to treatments that would delay or
25 eliminate the need for dialysis and transplant.

1 “(B) The Secretary shall conduct a comprehensive
2 study of methods to increase public awareness of rare kid-
3 ney disease, including in communities of color.

4 “(C) The Secretary shall submit to Congress, not
5 later than 24 months after the date of the enactment of
6 the New Era of Preventing End-Stage Kidney Disease
7 Act, a report on the experiments and study conducted
8 under subparagraphs (A) and (B). Such report shall in-
9 clude recommendations for legislative changes that the
10 Secretary finds necessary or desirable as a result of such
11 experiments and study.”.

○