I

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''New Era of Preventing End-Stage Kidney Disease Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. FINDINGS.

Congress finds the following:

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

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

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

(4) In the absence of approved treatment options, more than 100,000 people live with rare glomerular kidney disease and face dialysis, transplant, or death.

(5) Focal segmental glomerulosclerosis is associated with a 50 percent risk of end-stage kidney disease within 5 years of diagnosis if partial or complete remission is not achieved.

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

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

(8) Because approximately one-third of Black Americans with focal segmental glomerulosclerosis cases are associated with a particular gene, communities of color would benefit from additional resources to support earlier detection, including genetic and genomic testing and referrals to high-quality providers.

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

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

(10) Federal spending on end-stage kidney disease currently accounts for approximately 7 percent of Federal Medicare spending.

(11) The total Medicare spending on both chronic kidney disease and end-stage kidney disease patients exceeded $120,000,000,000 per year in recent years.

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

(13) Due in large part to the 21st Century Cures Act, new regulatory paradigms have unleashed a wave of clinical innovation in the rare kidney disease space.

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

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

therapies for patients living with rare kidney diseases, a new era of preventing end-stage kidney disease and related Federal costs, and the possibility of improving chronic kidney care writ large.

SEC. 4. DEFINITIONS.

In this Act:

(1) DIRECTOR OF NIH.—The term ''Director of NIH'' means the Director of the National Institutes of Health.

(2) NIH.—The term ''NIH'' means the National Institutes of Health.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE I—CENTERS OF EXCELLENCE AND RARE KIDNEY DISEASE RESEARCH

SEC. 101. NIDDK CENTERS ON RARE KIDNEY DISEASE RESEARCH.

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

''SEC. 426A. NIDDK CENTERS ON RARE KIDNEY DISEASE RESEARCH.

''(a) COOPERATIVE AGREEMENTS AND GRANTS.—

''(1) IN GENERAL.—The Director of the Institute may enter into cooperative agreements with, and make grants to, public and private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for, regional centers of excellence for rare kidney diseases, including primary glomerular disease. Such centers of excellence shall be known as NIDDK Centers on Rare Kidney Disease Research.

''(2) PURPOSES OF CENTERS.—The purposes of the centers of excellence funded pursuant to paragraph (1) shall be—

''(A) to increase public awareness of rare kidney diseases, particularly in communities of color; and

''(B) to develop resources for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for, rare kidney diseases.

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

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

under this section with similar activities that are related to rare kidney disease and conducted by other national research institutes, centers, and agencies of the National Institutes of Health and by the Food and Drug Administration.

''(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

''(1) basic operating costs, including such patient care costs as are required for research;

''(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare kidney diseases;

''(3) clinical research and demonstration programs;

''(4) education of members of the public, particularly through outreach to communities of color, on the diagnosis (including through routine urinalysis and through genetic testing), prevention, control, and treatment of rare kidney diseases; and

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

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

''(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—The period of support for a center of excellence under subsection (a) may not exceed 5 years, except that such period may be extended by the Director of the Institute for additional periods of not more than 5 years for each center if—

''(1) the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of the Institute; and

''(2) such group has recommended to the Director of the Institute that such period should be extended.

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $4,000,000 for each of fiscal years 2023 through 2027.''.

SEC. 102. RARE KIDNEY DISEASE PROGRESSION RESEARCH.

(a) NIH RESEARCH ON RARE KIDNEY DISEASES.—The Director of NIH may award grants or contracts to public and nonprofit private entities to conduct research

on the causes, etiology, symptoms, diagnosis, progression, and treatment of rare kidney diseases, including glomerular diseases.

(b) APPLICATION.—To seek a grant under this section, an eligible entity shall submit an application in such form, in such manner, and containing such agreements, assurances, and information as the Director of NIH determines to be necessary.

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

(1) may not include any consideration of quality-adjusted life years or disability-adjusted life years, or other similar mechanisms that discriminate against people with disabilities in value and cost-effectiveness assessments;

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

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

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $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.

(2) CONSULTATION.—In carrying out paragraph (1), the Secretary shall consult with relevant stakeholders, including health care providers, medical professional societies, State-based societies, public health experts, State and local public health departments, State medical boards, patient groups, drug manufacturers, pharmacists, insurers, and other entities with experience in health care, public health, and rare disease, as appropriate.

(b) EARLY INTERVENTION ON GENETIC SCREENING.—

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

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

(B) whether genetic and genomic testing, and in particular testing of the APOL1 gene, may reduce disparities in the occurrence and treatment of rare kidney disease among different groups, including communities of color;

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

(i) encouraging the expansion of health insurance coverage of genetic and genomic testing, including diagnostic, predictive, and presymptomatic testing, and DNA sequencing clinical services;

(ii) supporting the collection of evidence for the clinical utility and appropriate use of genetic and genomic tests; and

(iii) improving access to genetic counselors, pathologists, and other relevant professions, including strengthening related workforce education and training efforts;

(D) the extent to which coverage provisions in the Medicare and Medicaid programs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq., 1396 et seq.) may restrain the use of genetic and genomic testing for rare kidney disease that may improve clinical outcomes for beneficiaries;

(E) whether the Centers for Medicare & Medicaid Services may make coverage determinations that better suit a precision medicine approach to treatment; and

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

(2) REPORT.—

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

(B) CONSULTATION.—In conducting the study under paragraph (1) and developing the report required by subparagraph (A), the Secretary shall consult with physicians, other health professionals, health educators, health professional organizations, relevant companies, patients, patient organizations, the Health Resources and Services Administration, the Director of NIH, the National Institute of Diabetes and Digestive and Kidney Diseases, and the Centers for Medicare & Medicaid Services. Such consultation shall include consultation activities conducted as part of the conference under subsection (a).

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

(A) means a determination of an exact sequence of deoxyribonucleic acid bases in the genome of such individual, and, if for the sole benefit of the individual, a biological parent of such individual for the purpose of determining whether one or more potentially disease-causing genetic variants are present in the genome of such individual or such biological parent; and

(B) includes—

(i) sequencing of the entire genome, of the exome, of a panel of genes, or other regions of the genome; and

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

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

TITLE III—COMMUNITIES OF COLOR

SEC. 301. UNDERSTANDING AND SLOWING THE PROGRESSION OF RARE KIDNEY DISEASE AND TREATMENT IN CERTAIN POPULATIONS.

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

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

(2) treatment patterns associated with providing care, under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.), and through private health insurance, to populations that are disproportionately affected by such disease;

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

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

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

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

(c) COORDINATION.—In carrying out the activities under subsections (a) and (b), the Secretary shall coordinate with the Director of NIH, the Administrator of the Center for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, and the Director of the Center for Medicare and Medicaid Innovation.

(d) CONSULTATION.—In carrying out the activities under subsections (a) and (b), the Secretary shall consult with relevant stakeholders, including health care providers, medical professional societies, State-based societies, public health experts, State and local public health departments, State medical boards, patient groups, drug manufacturers, pharmacists, insurers, and other entities with experience in health care, public health, health equity, and rare disease, as appropriate.

SEC. 302. COMMUNITIES OF COLOR SERVICE PROGRAM.

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

(1) by redesignating paragraph (7) as paragraph (8);

(2) in paragraph (6)(B), by striking ''; and'' and inserting a semicolon; and

(3) by inserting after paragraph (6) the following:

''(7) to award fellowships, which may include stipends, for postgraduate training in the field of nephrology, for the purposes of—

''(A) increasing providers' knowledge of issues related to prevention, diagnosis, and treatment of rare kidney disease among racial and ethnic minority populations, especially the prevalence of the gene APOL1;

''(B) improving the quality of rare kidney disease prevention, diagnosis, and treatment delivered to racial and ethnic minorities; and

''(C) increasing the number of culturally competent nephrologists; and''.

SEC. 303. NIH REPORT ON NIH RESEARCH PROGRAMS.

The Director of NIH shall prepare and publish on the public website of the agency a report on diversity within the programs of the NIH to research kidney disease, including—

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

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

SEC. 304. PARTNERSHIPS WITH ORGANIZATIONS AND AGENCIES.

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

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

(1) be—

(A) a nonprofit or community-based organization, including any community health center; or

(B) a State or local governmental agency; and

(2) submit to the Secretary an application—

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

(B) containing—

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

(ii) such other information as the Secretary may require.

(c) REPORTING.—

(1) BY GRANTEE.—A recipient of a grant under this section shall submit annually to the Secretary, and make publicly available, a report on the activities conducted using funds received through the grant.

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

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

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

(C) any recommendations the Secretary may have.

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

TITLE IV—PROVIDER EDUCATION

SEC. 401. PRIMARY CARE PROVIDER TRAINING GRANT PROGRAM.

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

"SEC. 747B. RARE KIDNEY DISEASE TRAINING FOR PRIMARY CARE PROVIDERS.

''(a) IN GENERAL.—The Secretary may make grants to an accredited public or nonprofit private hospital, school of medicine, or academically affiliated physician assistant training program, to a public or private nonprofit entity that the Secretary has determined is capable of carrying out such grant, or to any consortium of such hospitals, schools, programs, or entities, to plan, develop, and operate a professional training program in the field of nephrology for primary care residents, physicians, physician assistants, or nurse practitioners, on—

''(1) methods to detect and diagnose rare kidney disease, including urinalysis and genetic testing;

''(2) implementing such diagnostic methods in their practices;

''(3) establishing treatment protocols for individuals diagnosed with rare kidney disease; and

''(4) implementing a collaborative care model to coordinate care of patients diagnosed with rare kidney disease among health care providers.

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

''(1) have a record of training primary care providers;

''(2) establish formal relationships and submit joint applications with Federally qualified health centers, rural health clinics, or clinics located in underserved areas or that serve underserved populations; or

''(3) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals, including specialists.

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

SEC. 402. GRANT PROGRAM FOR DEVELOPMENT AND IMPLEMENTATION OF CURRICULA FOR CONTINUING EDUCATION ON KIDNEY DISEASE.

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

(1) in the part heading, by striking ''**AND PEDIATRIC DENTISTRY**'' and inserting ''**PEDIATRIC DENTISTRY, AND KIDNEY DISEASE**''; and

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

''Subpart III—Continuing Education in Kidney Disease

''SEC. 749C. CURRICULA FOR CONTINUING EDUCATION ON KIDNEY DISEASE.

''(a) GRANTS.—The Secretary may award grants to eligible entities for the development and implementation of curricula for providing continuing education and training to health care professionals on identifying, referring, and treating individuals with kidney disease.

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

''(1) provides continuing education or training to health care professionals; or

''(2) applies for the grant in partnership with another entity that provides such education and training.

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

ties proposing to develop and implement curricula for providing continuing education and training to—

''(1) primary care providers; or

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

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $1,600,000 for each of fiscal years 2023 through 2027.''.

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

SEC. 501. MEDICAL EXPERTISE IN PHARMACY AND THERAPEUTIC COMMITTEES.

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

''(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include—

''(I) at least one practicing physician and at least one practicing pharmacist, each of whom—

''(aa) is independent and free of conflict with respect to the sponsor and plan; and

''(bb) has expertise in the care of elderly or disabled persons; and

''(II) in the case of a drug approved to treat a rare disease or condition as defined in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), at least two members that meet the requirements described in items (aa) and (bb) of subclause (I) and have expertise in the field of medicine related to that drug.''.

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

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

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

''(B) The Secretary shall conduct a comprehensive study of methods to increase public awareness of rare kidney disease, including in communities of color.

''(C) The Secretary shall submit to Congress, not later than 24 months after the date of the enactment of the New Era of Preventing End-Stage Kidney Disease Act, a report on the experiments and study conducted under subparagraphs (A) and (B). Such report shall include recommendations for legislative changes that the Secretary finds necessary or desirable as a result of such experiments and study.''.

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