

118TH CONGRESS
1ST SESSION

H. R. 6790

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 14, 2023

Mr. BILIRAKIS (for himself and Ms. SEWELL) 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”.

1 **SEC. 2. CENTERS OF EXCELLENCE ON RARE KIDNEY DIS-**
2 **EASE RESEARCH IN NATIONAL INSTITUTE OF**
3 **DIABETES AND DIGESTIVE AND KIDNEY DIS-**
4 **EASES.**

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

9 **“SEC. 426A. CENTERS OF EXCELLENCE ON RARE KIDNEY**
10 **DISEASE RESEARCH IN NATIONAL INSTITUTE**
11 **OF DIABETES AND DIGESTIVE AND KIDNEY**
12 **DISEASES.**

13 **“(a) COOPERATIVE AGREEMENTS AND GRANTS.—**

14 **“(1) IN GENERAL.—**The Director of the Insti-
15 tute may enter into cooperative agreements with,
16 and make grants to, public and private nonprofit en-
17 tities to pay all or part of the cost of planning, es-
18 tablishing, or strengthening, and providing basic op-
19 erating support for, regional centers of excellence for
20 rare kidney diseases, including primary glomerular
21 disease. Such centers of excellence shall be known as
22 NIDDK Centers of Excellence on Rare Kidney Dis-
23 ease Research (referred to in this section as ‘Centers
24 of Excellence’).

1 “(2) PURPOSES OF CENTERS.—The purposes of
2 the Centers of Excellence funded pursuant to para-
3 graph (1) shall be—

4 “(A) to conduct research on the causes,
5 etiology, symptoms, diagnosis, progression, and
6 treatment of rare kidney diseases, including glo-
7 merular diseases;

8 “(B) to increase public awareness of rare
9 kidney diseases, particularly in rural and under-
10 served communities; and

11 “(C) to develop resources for clinical re-
12 search into, training in, and demonstration of
13 diagnostic, prevention, control, and treatment
14 methods for, rare kidney diseases.

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

19 “(b) COORDINATION WITH OTHER INSTITUTES.—
20 The Director of the Institute shall coordinate the activities
21 under this section with similar activities that are related
22 to rare kidney disease and conducted by other national
23 research institutes, centers, and agencies of the National
24 Institutes of Health and by the Food and Drug Adminis-
25 tration.

1 “(c) USE OF FUNDS.—An entity that enters into a
2 cooperative agreement or receives a grant under sub-
3 section (a) may use funds received through such agree-
4 ment or grant—

5 “(1) to cover patient care costs required to con-
6 duct research described in subsection (a)(2)(A);

7 “(2) to provide, for the purpose described in
8 subsection (a)(2)(B)—

9 “(A) clinical training and continuing edu-
10 cation for health professionals and related per-
11 sonnel with respect to rare kidney diseases; and

12 “(B) information programs for the public,
13 with respect to rare kidney diseases; and

14 “(3) to provide, for the purpose described in
15 subsection (a)(2)(B)—

16 “(A) for education of members of the pub-
17 lic, particularly through outreach to rural and
18 underserved communities, on the diagnosis (in-
19 cluding through routine urinalysis and through
20 genetic testing), prevention, control, and treat-
21 ment of rare kidney diseases; and

22 “(B) for education of individuals diagnosed
23 with rare kidney diseases on renal diet and life-
24 style, genetic testing, and programs to promote
25 urinalysis, and on mental and emotional health

1 resources for families of rare kidney disease pa-
2 tients.

3 “(d) RESEARCH FUNDED.—Research conducted
4 using funds awarded through a cooperative agreement or
5 grant under this section—

6 “(1) shall include study of genotype-phenotype
7 relation to disease progression; and

8 “(2) with respect the populations studied in
9 such research, may not include any consideration of
10 quality-adjusted life years or disability adjusted life
11 years, or other similar mechanisms that discriminate
12 against individuals with disabilities in value and
13 cost-effectiveness assessments.

14 “(e) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—
15 The period of support for a center of excellence under sub-
16 section (a) may not exceed 5 years, except that such period
17 may be extended by the Director of the Institute for addi-
18 tional periods of not more than 5 years for each center
19 if—

20 “(1) the operations of such center have been re-
21 viewed by an appropriate technical and scientific
22 peer review group established by the Director of the
23 Institute; and

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

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
5 carry out this section, there are authorized to be appro-
6 priated \$6,000,000 for each of fiscal years 2024 through
7 2028.”.

8 **SEC. 3. UNDERSTANDING AND SLOWING THE PROGRES-**
9 **SION OF RARE KIDNEY DISEASE THROUGH**
10 **EARLY INTERVENTION, TESTING, AND TREAT-**
11 **MENT.**

12 (a) IN GENERAL.—The Secretary shall conduct a
13 study on testing, preventative care, precision medicine,
14 and treatment, with respect to rare kidney disease. Such
15 study shall review—

16 (1) the impact of routine urinalysis on the time-
17 ly diagnosis of rare kidney disease and on the qual-
18 ity of patient care following a diagnosis of such dis-
19 ease;

20 (2) the quality and reliability of kidney biopsy
21 in the diagnosis of rare kidney disease;

22 (3) the utility and appropriate use of genetic
23 and genomic tests in detecting kidney disease, in-
24 cluding—

1 (A) advances in genetic and genomic test-
2 ing, and in particular testing of the APOL1
3 gene, and whether such testing may improve
4 the diagnosis and treatment of rare kidney dis-
5 ease;

6 (B) barriers to genetic and genomic test-
7 ing, such as diagnostic, predictive, presymp-
8 tomatic testing, and DNA sequencing clinical
9 services, including an analysis of any existing
10 barriers related to health insurance coverage of
11 such testing and access to genetic counselors,
12 pathologists, and other relevant professions;
13 and

14 (C) strategies to increase routine urinalysis
15 and other diagnostic testing and to improve
16 technologies to diagnose such disease, including
17 genetic testing, and to improve access to health
18 insurance coverage of such diagnostic testing
19 and technologies;

20 (4) the social, behavioral, and biological factors
21 leading to rare kidney disease;

22 (5) treatment patterns associated with pro-
23 viding care, under the Medicare program under title
24 XVIII of the Social Security Act (42 U.S.C. 1395 et
25 seq.), the Medicaid program under title XIX of such

1 Act (42 U.S.C. 1396 et seq.), and through private
2 health insurance, to populations that are dispropor-
3 tionately affected by such disease;

4 (6) access to nephrologists among populations
5 that are disproportionately affected by such disease;

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

10 (8) patient trust of treating providers among
11 populations that are disproportionately affected by
12 such disease.

13 (b) REPORT.—

14 (1) IN GENERAL.—Not later than 18 months
15 after the date of the enactment of this Act, the Sec-
16 retary shall submit to the Congress a report on the
17 results of the study under subsection (a), together
18 with such recommendations as the Secretary deter-
19 mines to be appropriate.

20 (2) CONSULTATION.—In conducting the study
21 under subsection (a) and developing the report re-
22 quired by paragraph (1), the Secretary shall consult
23 with relevant stakeholders, including health care
24 providers, medical professional societies, State-based
25 societies, public health experts, health educators,

1 health professional organizations, drug and device
2 manufacturers, patient organizations, pharmacists,
3 payors, State and local public health departments,
4 State medical boards, and other entities with experi-
5 ence in health care, public health, nephrology, and
6 rare disease, as appropriate.

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

14 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
15 out this section, there is authorized to be appropriated
16 \$1,000,000 for each of fiscal years 2024 through 2028.

17 **SEC. 4. PROVIDER EDUCATION.**

18 (a) PRIMARY CARE TRAINING.—Section
19 747(b)(3)(E) of the Public Health Service Act (42 U.S.C.
20 293k(b)(3)(E)) is amended—

21 (1) by striking “and individuals” and inserting
22 “, individuals”; and

23 (2) by inserting “, and individuals with kidney
24 disease (including rare kidney disease)” after “dis-
25 abilities”.

1 (b) NEPHROLOGY FELLOWSHIPS.—Section 736(b) of
2 the Public Health Service Act (42 U.S.C. 293) is amend-
3 ed—

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

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

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

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

13 “(A) increasing providers’ knowledge of
14 issues related to prevention, diagnosis, and
15 treatment of rare kidney disease for populations
16 disproportionately impacted by the disease, in-
17 cluding the prevalence of the gene APOL1;

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

21 “(C) increasing the number of
22 nephrologists trained to provide care to such
23 populations; and”.

1 **SEC. 5. DELAYING KIDNEY DISEASE IMPACT.**

2 Section 1881(f) of the Social Security Act (42 U.S.C.
3 1395rr(f)) is amended by adding at the end the following
4 new paragraph:

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

9 “(B) The Secretary shall conduct a comprehensive
10 study of methods to increase public awareness of rare kid-
11 ney disease.

12 “(C) The Secretary shall submit to Congress, not
13 later than 24 months after the date of the enactment of
14 the New Era of Preventing End-Stage Kidney Disease
15 Act, a report on the experiments and study conducted
16 under subparagraphs (A) and (B). Such report shall in-
17 clude recommendations for legislative changes that the
18 Secretary finds necessary or desirable as a result of such
19 experiments and study.”.

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