I

117TH CONGRESS
2D SESSION

H. R. 8855

To establish a program to address sickle cell disease and other heritable hemoglobinopathies.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 2022

Ms. LEE of California (for herself, Mr. DANNY K. DAVIS of Illinois, and Ms. ADAMS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To establish a program to address sickle cell disease and other heritable hemoglobinopathies.

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 ''Sickle Cell Disease Treatment Centers Act of 2022''.

SEC. 2. ESTABLISHMENT OF SICKLE CELL DISEASE AND OTHER HERITABLE HEMOGLOBINOPATHIES TREATMENT CENTERS.

Subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by inserting after section 330P (42 U.S.C. 254c–22) the following:

"SEC. 330Q. SICKLE CELL DISEASE AND OTHER HERITABLE HEMOGLOBINOPATHIES TREATMENT CENTERS.

"(a) DEFINITIONS.—In this section:

"(1) COMMUNITY-BASED ORGANIZATION.—The term 'community-based organization' means a community-based organization working in partnership under at least one collaborative agreement with a medical hub and spoke network.

"(2) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that is a sickle cell disease treatment hub-and-spoke network that is comprised of—

"(A) a hub-and-spoke network that includes—

"(i) a medical hub that is a hospital, clinic, or university health center; and

"(ii) at least 1 spoke working in partnership with the medical hub; and

''(B) at least 1 community-based organization working in a partnership with the hub-and-spoke network, or the medical hub, or at least one spoke of such network.

''(3) HUB-AND-SPOKE NETWORK.—The term 'hub-and-spoke network' means a framework for delivery of health care services—

''(A) recommended by the National Academies of Sciences, Engineering, and Medicine in its 2020 report titled, 'Addressing Sickle Cell Disease: A Strategic Plan and Blueprint for Action';

''(B) in which a medical hub identifies and manages a medical spoke or network of spokes, or other subsidiary entities, to provide comprehensive sickle cell disease care;

''(C) in which such subsidiary entities serving as spokes—

''(i) may initially provide limited sickle cell disease care services; and

''(ii) may evolve into hubs and connect with new spokes; and

''(D) in which the medical hub and spoke collaborate with a community-based organization to extend services and outreach to the sickle cell disease community.

“(4) MEDICAL HUB.—The term ‘medical hub’ means a hospital, clinic, or university health center that—

“(A) has an outpatient treatment clinic, infusion capabilities, telehealth capability, and experience serving individuals living with sickle cell disease; and

“(B) follows widely acceptable clinical practice guidelines.

“(5) SPOKE.—The term ‘spoke’ means an entity—

“(A) that is—

“(i) a Federally-qualified health center, as defined in section 1861(aa) of the Social Security Act;

“(ii) a Federally-qualified health center, as defined in section 1905(l)(2)(B) of the Social Security Act; or

“(iii) a hospital, clinic, or university health center that provides clinical care and has telehealth capability;

“(B) that has at least 1 collaborative agreement with a medical hub and a community-based organization; and

“(C) that incorporates a community health worker into the care team.

“(b) PROGRAM ESTABLISHED.—The Secretary shall award grants to eligible entities to establish treatment centers using a hub-and-spoke framework (referred to in this section as ‘Sickle Cell Disease Treatment Centers’), for the purposes of—

“(1) promoting access to coordinated longitudinal health care for all patients with sickle cell disease and individuals with sickle cell trait;

“(2) providing support to establish integrated health care teams for patients with sickle cell disease;

“(3) improving the health and well-being of children, youth, and adults with sickle cell disease;

“(4) increasing reporting on quality and other public health measures with respect to sickle cell disease treatment;

“(5) accurately compiling all applicable State sickle cell newborn screening data;

“(6) integrating sickle cell newborn screening data with longitudinal follow-up data on sickle cell disease health outcomes and associated complications, in collaboration with the Sickle Cell Disease Data Collection Program of the Centers for Disease Control and Prevention; and

''(7) conducting significant public health activities with respect to sickle cell disease.

''(c) USE OF FUNDS BY ELIGIBLE ENTITIES.—An eligible entity shall use grant funds received under this section as follows:

''(1) MEDICAL HUB.—The medical hub of the eligible entity shall carry out the following:

''(A) Operating and administrating costs of operating a hub-and-spoke framework.

''(B) Complying with published sickle cell disease treatment guidelines, as identified by the Secretary.

''(C) Educating providers on sickle cell disease treatment standards and protocols.

''(D) Providing integrated care management, which may include—

''(i) primary care;

''(ii) care management; and

''(iii) mental health services.

''(E) Coordinating specialty care services, whether provided at the medical hub or spoke.

“(F) Coordinating reproductive health services for sickle cell disease patients.

“(G) Providing a dedicated sickle cell expert at the medical hub to assist in overseeing care of sickle cell disease patients at spokes and to advise the community-based organization.

“(H) Educating providers on social determinants of health and implicit bias that may affect quality of care and life for patients with sickle cell disease, trait, or other hemoglobinopathies.

“(I) Providing telehealth appointments to patients when appropriate and facilitating access to telehealth services for sickle cell disease patients to the extent feasible.

“(J) Providing medical and surgical treatment to sickle cell disease patients.

“(K) Implementing pediatric-to-adult health care transition programs for purposes of ensuring coordinated patient graduation from pediatric to adult providers for all patients.

“(L) Providing social work services in coordination with a community-based organization.

“(M) Collecting and distributing data as required by the National Sickle Cell Disease Coordinating Center established under this section or otherwise required by the Director of the Centers for Disease Control and Prevention.

“(N) Engaging in quality improvement with respect to standards of care for health and quality of life outcomes among sickle cell disease patients as identified by the Secretary.

“(2) COMMUNITY-BASED ORGANIZATION.—The community-based organization of the eligible entity shall provide or coordinate each of the following:

“(A) Providing education and outreach to sickle cell disease patients, caregivers, and health providers.

“(B) Providing support in addressing social determinants of health.

“(C) Providing social work services in coordination with a medical hub or spoke.

“(D) Testing or coordinating testing for sickle cell conditions and for carrier states that put a family at risk for having a child with sickle cell disease.

“(E) Engaging in quality improvement with respect to standards of care or health and quality of life outcomes among sickle cell disease patients, as identified by the Secretary.

"(3) SPOKE.—The spokes of the eligible entity shall provide or coordinate each of the following services:

"(A) Collaborating with a medical hub to coordinate and support care for sickle cell disease patients.

"(B) Providing the approved standards of care for such patients.

"(C) Providing primary care services or specialty care.

"(D) Providing telehealth appointments, as appropriate.

"(E) Providing medical or surgical treatment.

"(F) Implementing individual care plans.

"(G) Providing social work services in coordination with a community-based organization.

"(H) Collecting and distributing data required by the National Sickle Cell Disease Coordinating Center established under this section and the Sickle Cell Disease Data Collection

Program of the Centers for Disease Control and Prevention.

"(4) ADDITIONAL USES OF FUNDS.—In addition to the uses of funds described in paragraphs (1), (2), and (3), an eligible entity selected to receive a grant under this section may use funds received through the grant—

"(A) to identify and secure resources for ensuring reimbursement under, for the State involved, the State plan under title XIX of the Social Security Act (or a waiver of such plan), State child health plan under title XXI of such Act (or a waiver of such plan), and other health programs for the prevention and treatment of sickle cell disease, including by working with community-based sickle cell disease organizations and other nonprofit entities;

"(B) to assist sickle cell disease patients with accessing appropriate health care insurance, including—

"(i) through the payment of insurance premiums and cost-sharing amounts, to the extent otherwise permitted under State and Federal law;

''(ii) by working with community-based sickle cell disease organizations and other nonprofit entities; and

''(iii) by helping sickle cell disease patients know their rights with insurance programs;

''(C) to facilitate access to telehealth services for sickle cell disease patients to the extent feasible;

''(D) to fund evidence-based programs that provide education to teachers and school personnel, correctional institution personnel, and health care professionals on the care of individuals with sickle cell disease in health care settings and other appropriate settings, including schools and prisons;

''(E) to offer transportation services for sickle cell disease patients who do not have, but who need access to in-person care with the Sickle Cell Disease Treatment Centers; and

''(F) to facilitate access to sickle cell trait testing and genetic counseling.

''(d) APPLICATION; SELECTION.—

''(1) APPLICATION.—An eligible entity desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a description of how the hub-and-spoke entity and community-based organization will collaborate in carrying out the activities described in subsection (c). Such an application may be submitted on behalf of the eligible entity by a hub-and-spoke network or by the community-based organization.

"(2) GEOGRAPHIC DISTRIBUTION.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall award grants under this section, to the extent practicable, to eligible entities located across the United States, with a focus on regions where a disproportionate number of patients with sickle cell disease or other heritable hemoglobinopathy patients per capita reside, and with the intention of awarding grants nationwide so that patients can access more comprehensive sickle cell disease treatment services no matter where they reside.

"(3) PRIORITIES IN MAKING AWARDS.—In awarding grants under this section, the Secretary may give priority to eligible entities that—

"(A) include at least one historically black college or university (defined as a part B institution under section 322 of the Higher Education Act of 1965 (20 U.S.C. 1061)) or minority serving institution (defined as an eligible institution under section 371 of such Act (20 U.S.C. 1067q)) that has a medical school;

"(B) serve an area with a prevalence of sickle cell disease; or

"(C) serve a rural area.

"(4) ELIGIBLE PATIENTS.—For purposes of this section, patients who may be treated by Sickle Cell Disease Treatment Centers, or who may be supported by public health activities and other programming, shall include patients with sickle cell disease, and may include patients with other heritable hemoglobinopathies.

"(e) NATIONAL SICKLE CELL DISEASE COORDINATING CENTER.—

"(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall enter into a contract with an entity to serve as the National Sickle Cell Disease Coordinating Center, which shall coordinate the activities conducted by grantees under this section and carry out the activities described in paragraph (2).

"(2) DUTIES.—The National Sickle Cell Disease Coordinating Center shall carry out each of the following activities:

"(A) Coordinate the infrastructure of Sickle Cell Disease Treatment Centers established under subsection (b).

"(B) Coordinate and support hub-and-spoke frameworks.

"(f) CDC SICKLE CELL DISEASE DATA COLLECTION PROGRAM FOR SCD TREATMENT CENTERS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall coordinate the following with respect to eligible entities under this section:

"(1) Collecting, coordinating, monitoring, and distributing data, best practices, and findings regarding the activities funded under grants made to eligible entities under this section.

"(2) Collecting and maintaining up-to-date data on sickle cell disease and sickle cell trait, including subtypes as applicable, and their associated health outcomes and complications, including for the purpose of—

''(A) improving national incidence and prevalence data, including the geographic distribution of affected individuals;

''(B) working with the State newborn screening programs to establish a national registry of sickle cell newborn screening data to serve as a foundation for assessing longevity and the prevalence of complications resulting from sickle cell disease;

''(C) identifying health disparities impacting individuals born with sickle cell disease and sickle cell trait, including subtypes as applicable, and other hemoglobinopathies;

''(D) assessing the utilization of therapies, comprehensive complication risk screening, and strategies to prevent complications resulting from sickle cell disease and to increase quality of life; and

''(E) evaluating the effects of genetic, environmental, behavioral, and other risk factors that may affect individuals with sickle cell disease.

''(3) Developing educational materials, public awareness campaigns, or other outreach programs regarding the prevention and treatment of sickle cell disease and the prevalence of sickle cell trait.

"(4) Preparing and submitting to Congress a final report that includes recommendations regarding the effectiveness of the Sickle Cell Disease Treatment Centers established under subsection (b) and direct outcome measures, including—

"(A) the number and type of health care resources utilized (such as emergency room visits, hospital visits, length of stay, and physician visits for individuals with sickle cell disease); and

"(B) the number of individuals that were tested and subsequently received genetic counseling for the sickle cell trait.

"(g) REQUEST FOR INFORMATION.—Not later than 180 days after the date of enactment of the Sickle Cell Disease Treatment Centers Act of 2022, and in advance of each new grant cycle thereafter, the Secretary shall publish in the Federal Register a request for information seeking feedback from stakeholders on—

"(1) best practices with respect to the establishment and implementation of Sickle Cell Disease Treatment Centers; and

“(2) any other information that the Secretary may require.

“(h) REPORT TO CONGRESS.—

“(1) IN GENERAL.—Not later than 3 years after the date of the enactment of the Sickle Cell Disease Treatment Centers Act of 2022 and every 5 years thereafter, the Secretary shall submit to Congress a report on the impact of the Sickle Cell Disease Treatment Centers established under this section on health outcomes for sickle cell disease patients.

“(2) REPORT ELEMENTS.—The report described in this section shall include—

“(A) a summary and description of eligible entities operating a hub-and-spoke framework that are receiving grant funds under this section;

“(B) information about the specific activities supported by grant funds awarded under this section with respect to each eligible entity; and

“(C) the number of sickle cell disease patients served by grant programs funded under this section and demographic information about those patients, including race, sex, gender, geographic location, and age.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $535,000,000 for fiscal year 2023 and each fiscal year thereafter. Of the amount made available for a fiscal year under the preceding sentence, not less than—

"(1) 70 percent shall be used to award grants to at least 128 eligible entities where the application is submitted by medical hubs or spokes;

"(2) 20 percent shall be used to award grants to at least 100 eligible entities where the application is submitted by community-based sickle cell disease organizations or nonprofit entities that are part of an eligible entity;

"(3) 5 percent shall be used for the establishment and maintenance of the National Sickle Cell Disease Coordinating Center described in subsection (e); and

"(4) 5 percent shall be used for the activities of the Sickle Cell Data Collection program of the Centers for Disease Control and Prevention described in this section.".

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