

117TH CONGRESS
2D SESSION

S. 4866

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 15, 2022

Mr. VAN HOLLEN (for himself and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

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 “Sickle Cell Disease
5 Treatment Centers Act of 2022”.

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

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

7 **“SEC. 330Q. SICKLE CELL DISEASE AND OTHER HERITABLE**
 8 **HEMOGLOBINOPATHIES TREATMENT CEN-**
 9 **TERS.**

10 “(a) DEFINITIONS.—In this section:

11 “(1) COMMUNITY-BASED ORGANIZATION.—The
 12 term ‘community-based organization’ means a com-
 13 munity-based organization working in partnership
 14 under at least one collaborative agreement with a
 15 medical hub and spoke network.

16 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-
 17 tity’ means any entity that is a sickle cell disease
 18 treatment hub-and-spoke network that is comprised
 19 of—

20 “(A) a hub-and-spoke network that in-
 21 cludes—

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

24 “(ii) at least 1 spoke working in part-
 25 nership with the medical hub; and

1 “(B) at least 1 community-based organiza-
 2 tion working in a partnership with the hub-and-
 3 spoke network, or the medical hub or at least
 4 one spoke of such network.

5 “(3) HUB-AND-SPOKE NETWORK.—The term
 6 ‘hub-and-spoke network’ means a framework for de-
 7 livery of health care services—

8 “(A) recommended by the National Acad-
 9 emies of Sciences, Engineering, and Medicine in
 10 its 2020 report titled, ‘Addressing Sickle Cell
 11 Disease: A Strategic Plan and Blueprint for Ac-
 12 tion’;

13 “(B) in which a medical hub identifies and
 14 manages a medical spoke or network of spokes,
 15 or other subsidiary entities, to provide com-
 16 prehensive sickle cell disease care;

17 “(C) in which such subsidiary entities serv-
 18 ing as spokes—

19 “(i) may initially provide limited sickle
 20 cell disease care services; and

21 “(ii) may evolve into hubs and connect
 22 with new spokes; and

23 “(D) in which the medical hub and spoke
 24 collaborate with a community-based organiza-

1 tion to extend services and outreach to the sick-
 2 le cell disease community.

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

6 “(A) has an outpatient treatment clinic, in-
 7 fusion capabilities, telehealth capability, and ex-
 8 perience serving individuals living with sickle
 9 cell disease; and

10 “(B) follows widely acceptable clinical
 11 practice guidelines.

12 “(5) SPOKE.—The term ‘spoke’ means an enti-
 13 ty—

14 “(A) that is—

15 “(i) a Federally-qualified health cen-
 16 ter, as defined in section 1861(aa) of the
 17 Social Security Act;

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

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

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

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

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

11 “(1) promoting access to coordinated longitu-
12 dinal health care for all patients with sickle cell dis-
13 ease and individuals with sickle cell trait;

14 “(2) providing support to establish integrated
15 health care teams for patients with sickle cell dis-
16 ease;

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

19 “(4) increasing reporting on quality and other
20 public health measures with respect to sickle cell dis-
21 ease treatment;

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

24 “(6) integrating sickle cell newborn screening
25 data with longitudinal follow-up data on sickle cell

1 disease health outcomes and associated complica-
 2 tions, in collaboration with the Sickle Cell Disease
 3 Data Collection Program of the Centers for Disease
 4 Control and Prevention; and

5 “(7) conducting significant public health activi-
 6 ties with respect to sickle cell disease.

7 “(c) USE OF FUNDS BY ELIGIBLE ENTITIES.—An el-
 8 igible entity shall use grant funds received under this sec-
 9 tion as follows:

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

12 “(A) Operating and administrating costs of
 13 operating a hub-and-spoke framework.

14 “(B) Complying with published sickle cell
 15 disease treatment guidelines, as identified by
 16 the Secretary.

17 “(C) Educating providers on sickle cell dis-
 18 ease treatment standards and protocols.

19 “(D) Providing integrated care manage-
 20 ment, which may include—

21 “(i) primary care;

22 “(ii) care management; and

23 “(iii) mental health services.

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

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

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

7 “(H) Educating providers on social deter-
8 minants of health and implicit bias that may af-
9 fect quality of care and life for patients with
10 sickle cell disease, trait, or other
11 hemoglobinopathies.

12 “(I) Providing telehealth appointments to
13 patients when appropriate and facilitating ac-
14 cess to telehealth services for sickle cell disease
15 patients to the extent feasible.

16 “(J) Providing medical and surgical treat-
17 ment to sickle cell disease patients.

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

22 “(L) Providing social work services in co-
23 ordination with a community-based organiza-
24 tion.

1 “(M) Collecting and distributing data as
2 required by the National Sickle Cell Disease
3 Coordinating Center established under this sec-
4 tion or otherwise required by the Director of
5 the Centers for Disease Control and Prevention.

6 “(N) Engaging in quality improvement
7 with respect to standards of care for health and
8 quality of life outcomes among sickle cell dis-
9 ease patients as identified by the Secretary.

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

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

16 “(B) Providing support in addressing so-
17 cial determinants of health.

18 “(C) Providing social work services in co-
19 ordination with a medical hub or spoke.

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

24 “(E) Engaging in quality improvement
25 with respect to standards of care or health and

1 quality of life outcomes among sickle cell dis-
2 ease patients, as identified by the Secretary.

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

6 “(A) Collaborating with a medical hub to
7 coordinate and support care for sickle cell dis-
8 ease patients.

9 “(B) Providing the approved standards of
10 care for such patients.

11 “(C) Providing primary care services or
12 specialty care.

13 “(D) Providing telehealth appointments, as
14 appropriate.

15 “(E) Providing medical or surgical treat-
16 ment.

17 “(F) Implementing individual care plans.

18 “(G) Providing social work services in co-
19 ordination with a community-based organiza-
20 tion.

21 “(H) Collecting and distributing data re-
22 quired by the National Sickle Cell Disease Co-
23 ordinating Center established under this section
24 and the Sickle Cell Disease Data Collection

1 Program of the Centers for Disease Control
2 and Prevention.

3 “(4) ADDITIONAL USES OF FUNDS.—In addi-
4 tion to the uses of funds described in paragraphs
5 (1), (2), and (3), an eligible entity selected to receive
6 a grant under this section may use funds received
7 through the grant—

8 “(A) to identify and secure resources for
9 ensuring reimbursement under, for the State in-
10 volved, the State plan under title XIX of the
11 Social Security Act (or a waiver of such plan),
12 State child health plan under title XXI of such
13 Act (or a waiver of such plan), and other health
14 programs for the prevention and treatment of
15 sickle cell disease, including by working with
16 community-based sickle cell disease organiza-
17 tions and other nonprofit entities;

18 “(B) to assist sickle cell disease patients
19 with accessing appropriate health care insur-
20 ance, including—

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

1 “(ii) by working with community-
2 based sickle cell disease organizations and
3 other nonprofit entities; and

4 “(iii) by helping sickle cell disease pa-
5 tients know their rights with insurance
6 programs;

7 “(C) to facilitate access to telehealth serv-
8 ices for sickle cell disease patients to the extent
9 feasible;

10 “(D) to fund evidence-based programs that
11 provide education to teachers and school per-
12 sonnel, correctional institution personnel, and
13 health care professionals on the care of individ-
14 uals with sickle cell disease in health care set-
15 tings and other appropriate settings, including
16 schools and prisons;

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

21 “(F) to facilitate access to sickle cell trait
22 testing and genetic counseling.

23 “(d) APPLICATION; SELECTION.—

24 “(1) APPLICATION.—An eligible entity desiring
25 a grant under this section shall submit an applica-

1 tion to the Secretary at such time, in such manner,
2 and containing such information as the Secretary
3 may require, including a description of how the hub-
4 and-spoke entity and community-based organization
5 will collaborate in carrying out the activities de-
6 scribed in subsection (c). Such an application may
7 be submitted on behalf of the eligible entity by a
8 hub-and-spoke network or by the community-based
9 organization.

10 “(2) GEOGRAPHIC DISTRIBUTION.—The Sec-
11 retary, acting through the Administrator of the
12 Health Resources and Services Administration, shall
13 award grants under this section, to the extent prac-
14 ticable, to eligible entities located across the United
15 States, with a focus on regions where a dispropor-
16 tionate number of patients with sickle cell disease or
17 other heritable hemoglobinopathy patients per capita
18 reside, and with the intention of awarding grants
19 nationwide so that patients can access more com-
20 prehensive sickle cell disease treatment services no
21 matter where they reside.

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

1 “(A) include at least one historically black
2 college or university (defined as a part B insti-
3 tution under section 322 of the Higher Edu-
4 cation Act of 1965 (20 U.S.C. 1061)) or minor-
5 ity serving institution (defined as an eligible in-
6 stitution under section 371 of such Act (20
7 U.S.C. 1067q)) that has a medical school;

8 “(B) serve an area with a prevalence of
9 sickle cell disease; or

10 “(C) serve a rural area.

11 “(4) ELIGIBLE PATIENTS.—For purposes of
12 this section, patients who may be treated by Sickle
13 Cell Disease Treatment Centers, or who may be sup-
14 ported by public health activities and other program-
15 ming, shall include patients with sickle cell disease,
16 and may include patients with other heritable
17 hemoglobinopathies.

18 “(e) NATIONAL SICKLE CELL DISEASE COORDI-
19 NATING CENTER.—

20 “(1) IN GENERAL.—The Secretary, acting
21 through the Administrator of the Health Resources
22 and Services Administration, shall enter into a con-
23 tract with an entity to serve as the National Sickle
24 Cell Disease Coordinating Center, which shall co-
25 ordinate the activities conducted by grantees under

1 this section and carry out the activities described in
2 paragraph (2).

3 “(2) DUTIES.—The National Sickle Cell Dis-
4 ease Coordinating Center shall carry out each of the
5 following activities:

6 “(A) Coordinate the infrastructure of Sick-
7 le Cell Disease Treatment Centers established
8 under subsection (b).

9 “(B) Coordinate and support hub-and-
10 spoke frameworks.

11 “(f) CDC SICKLE CELL DISEASE DATA COLLECTION
12 PROGRAM FOR SCD TREATMENT CENTERS.—The Sec-
13 retary, acting through the Director of the Centers for Dis-
14 ease Control and Prevention, shall coordinate the following
15 with respect to eligible entities under this section:

16 “(1) Collecting, coordinating, monitoring, and
17 distributing data, best practices, and findings re-
18 garding the activities funded under grants made to
19 eligible entities under this section.

20 “(2) Collecting and maintaining up-to-date data
21 on sickle cell disease and sickle cell trait, including
22 subtypes as applicable, and their associated health
23 outcomes and complications, including for the pur-
24 pose of—

1 “(A) improving national incidence and
2 prevalence data, including the geographic dis-
3 tribution of affected individuals;

4 “(B) working with the State newborn
5 screening programs to establish a national reg-
6 istry of sickle cell newborn screening data to
7 serve as a foundation for assessing longevity
8 and the prevalence of complications resulting
9 from sickle cell disease;

10 “(C) identifying health disparities impact-
11 ing individuals born with sickle cell disease and
12 sickle cell trait, including subtypes as applica-
13 ble, and other hemoglobinopathies;

14 “(D) assessing the utilization of therapies,
15 comprehensive complication risk screening, and
16 strategies to prevent complications resulting
17 from sickle cell disease and to increase quality
18 of life; and

19 “(E) evaluating the effects of genetic, envi-
20 ronmental, behavioral, and other risk factors
21 that may affect individuals with sickle cell dis-
22 ease.

23 “(3) Developing educational materials, public
24 awareness campaigns, or other outreach programs

1 regarding the prevention and treatment of sickle cell
2 disease and the prevalence of sickle cell trait.

3 “(4) Preparing and submitting to Congress a
4 final report that includes recommendations regard-
5 ing the effectiveness of the Sickle Cell Disease
6 Treatment Centers established under subsection (b)
7 and direct outcome measures, including—

8 “(A) the number and type of health care
9 resources utilized (such as emergency room vis-
10 its, hospital visits, length of stay, and physician
11 visits for individuals with sickle cell disease);
12 and

13 “(B) the number of individuals that were
14 tested and subsequently received genetic coun-
15 seling for the sickle cell trait.

16 “(g) REQUEST FOR INFORMATION.—Not later than
17 180 days after the date of enactment of the Sickle Cell
18 Disease Treatment Centers Act of 2022, and in advance
19 of each new grant cycle thereafter, the Secretary shall
20 publish in the Federal Register a request for information
21 seeking feedback from stakeholders on—

22 “(1) best practices with respect to the establish-
23 ment and implementation of Sickle Cell Disease
24 Treatment Centers; and

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

3 “(h) REPORT TO CONGRESS.—

4 “(1) IN GENERAL.—Not later than 3 years
5 after the date of the enactment of the Sickle Cell
6 Disease Treatment Centers Act of 2022 and every 5
7 years thereafter, the Secretary shall submit to Con-
8 gress a report on the impact of the Sickle Cell Dis-
9 ease Treatment Centers established under this sec-
10 tion on health outcomes for sickle cell disease pa-
11 tients.

12 “(2) REPORT ELEMENTS.—The report de-
13 scribed in this section shall include—

14 “(A) a summary and description of eligible
15 entities operating a hub-and-spoke framework
16 that are receiving grant funds under this sec-
17 tion;

18 “(B) information about the specific activi-
19 ties supported by grant funds awarded under
20 this section with respect to each eligible entity;
21 and

22 “(C) the number of sickle cell disease pa-
23 tients served by grant programs funded under
24 this section and demographic information about

1 those patients, including race, sex, gender, geo-
2 graphic location, and age.

3 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section,
5 \$535,000,000 for fiscal year 2023 and each fiscal year
6 thereafter. Of the amount made available for a fiscal year
7 under the preceding sentence, not less than—

8 “(1) 70 percent shall be used to award grants
9 to at least 128 eligible entities where the application
10 is submitted by medical hubs or spokes;

11 “(2) 20 percent shall be used to award grants
12 to at least 100 eligible entities where the application
13 is submitted by community-based sickle cell disease
14 organizations or nonprofit entities that are part of
15 an eligible entity;

16 “(3) 5 percent shall be used for the establish-
17 ment and maintenance of the National Sickle Cell
18 Disease Coordinating Center described in subsection
19 (e); and

20 “(4) 5 percent shall be used for the activities of
21 the Sickle Cell Data Collection program of the Cen-
22 ters for Disease Control and Prevention described in
23 this section.”.

○