

118TH CONGRESS
2D SESSION

S. 5226

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 25, 2024

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 2024”.

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 nonprofit organization.

14 “(2) HUB-AND-SPOKE NETWORK.—The term
 15 ‘hub-and-spoke network’ means a system for delivery
 16 of health care services—

17 “(A) in which a medical hub identifies and
 18 manages a medical spoke or network of spokes,
 19 to provide comprehensive sickle cell disease
 20 care;

21 “(B) in which such entities serving as
 22 spokes—

23 “(i) may provide sickle cell disease
 24 care services; and

1 “(ii) may increase services over time
2 to meet the definition of medical hubs and
3 connect with new spokes; and

4 “(C) in which the medical hub and spoke
5 has a partnership with one or more community-
6 based organizations to extend services and out-
7 reach to the sickle cell disease community.

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

11 “(A) provides comprehensive sickle cell dis-
12 ease treatment, which may include medical and
13 surgical treatment, such as provision of stem
14 cell transplants and cell and gene therapies, an
15 outpatient treatment clinic led by a board-cer-
16 tified hematologist, infusion capability, tele-
17 health capability, genetic counseling, access to
18 home care, and a pharmacy;

19 “(B) has experience serving individuals liv-
20 ing with sickle cell disease or other
21 hemoglobinopathies;

22 “(C) follows consensus-based clinical prac-
23 tice guidelines; and

1 “(D) may be a grantee or coordinate with
 2 grantees of the Sickle Cell Disease Treatment
 3 Demonstration Program under section 1106(b).

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

6 “(A) that provides health care services, in-
 7 cluding—

8 “(i) a Federally-qualified health cen-
 9 ter, as defined in section 1905(l)(2)(B) of
 10 the Social Security Act;

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

14 “(iii) a primary care provider;

15 “(iv) an outpatient treatment clinic;

16 “(v) an infusion center; or

17 “(vi) other health care providers;

18 “(B) that has at least 1 collaborative
 19 agreement with a medical hub and one or more
 20 community-based organization; and

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

23 “(b) PROGRAM ESTABLISHED.—The Secretary shall
 24 award grants to eligible entities to establish treatment
 25 centers using a hub-and-spoke framework (referred to in

1 this section as ‘Sickle Cell Disease Treatment Centers’),
2 for the purposes of—

3 “(1) promoting access to coordinated, lifelong
4 health care for all patients with sickle cell disease;

5 “(2) providing support to establish integrated
6 health care teams for patients with sickle cell disease
7 over a patient’s lifetime;

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

10 “(4) improving the pediatric-to-adult health
11 care transition;

12 “(5) collecting and contributing clinical data
13 from States participating in the Sickle Cell Data
14 Collection program of the Centers for Disease Con-
15 trol and Prevention, including the collection of
16 health outcomes and associated complications re-
17 ported pursuant to such program;

18 “(6) ensuring that reporting with respect to
19 sickle cell disease includes reporting on all patients
20 with sickle cell disease, including migrating and for-
21 eign-born patients; and

22 “(7) conducting significant public health aware-
23 ness and education activities with respect to sickle
24 cell disease and sickle cell trait.

1 “(c) ELIGIBLE ENTITY.—The term ‘eligible entity’
 2 means any entity that is comprised of—

3 “(1) a hub-and-spoke network that includes—

4 “(A) a medical hub that is a hospital, clin-
 5 ic, or university health center; and

6 “(B) at least 1 spoke working in partner-
 7 ship with the medical hub; and

8 “(2) at least 1 community-based nonprofit or-
 9 ganization working in a partnership with the hub-
 10 and-spoke network.

11 “(d) USE OF FUNDS BY ELIGIBLE ENTITIES.—An
 12 eligible entity shall use grant funds received under this
 13 section as follows:

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

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

18 “(B) Complying with consensus-based sick-
 19 le cell disease treatment guidelines, as identified
 20 by the Secretary.

21 “(C) Educating health care providers on
 22 sickle cell disease treatment standards and pro-
 23 tocols.

24 “(D) Providing integrated care manage-
 25 ment, which may include—

- 1 “(i) primary care;
- 2 “(ii) specialty care;
- 3 “(iii) pain management;
- 4 “(iv) mental health services;
- 5 “(v) genetic counseling services; and
- 6 “(vi) other providers.

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

9 “(F) Coordinating reproductive health and
10 family planning services for patients with sickle
11 cell disease, trait, or other hemoglobinopathies.

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

16 “(H) Educating health care providers on
17 social determinants of health and implicit bias
18 that may affect quality of care and life for pa-
19 tients with sickle cell disease, trait, or other
20 hemoglobinopathies.

21 “(I) Providing telehealth appointments to
22 patients when appropriate and facilitating ac-
23 cess to telehealth services for sickle cell disease
24 patients to the extent feasible.

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

5 “(K) Providing social work services or
6 community health worker services in coordina-
7 tion with one or more community-based organi-
8 zations.

9 “(L) Collecting and distributing data as
10 required by the National Sickle Cell Disease
11 Coordinating Center established under sub-
12 section (f) or otherwise required by the Sec-
13 retary.

14 “(M) Engaging in quality improvement
15 with respect to such standards of care for
16 health and quality of life outcomes among sickle
17 cell disease patients as the Secretary may re-
18 quire.

19 “(2) COMMUNITY-BASED ORGANIZATION.—The
20 community-based organization of the eligible entity
21 shall provide or coordinate services to patients and
22 families, which may include the following:

23 “(A) Providing education and outreach to
24 individuals at-risk for sickle cell trait, individ-

1 uals with sickle cell trait, sickle cell disease pa-
2 tients, caregivers, and health care providers.

3 “(B) Providing support in addressing so-
4 cial determinants of health, such as food insecu-
5 rity, housing insecurity, and access to education
6 and transportation.

7 “(C) Providing social work services or com-
8 munity health worker services in coordination
9 with a medical hub or spoke.

10 “(D) Testing or coordinating testing for
11 individuals at-risk for sickle cell trait and indi-
12 viduals with sickle cell trait that increase the
13 likelihood of having a child with sickle cell dis-
14 ease, including through coordination with a ge-
15 netic counselor.

16 “(E) Engaging in quality improvement
17 with respect to standards of care or health and
18 quality of life outcomes among sickle cell dis-
19 ease patients, as identified by the Secretary.

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

23 “(A) Collaborating with a medical hub to
24 coordinate and support care for sickle cell dis-
25 ease patients.

1 “(B) Providing standards of care as devel-
2 oped in coordination with the medical hub.

3 “(C) Providing primary care services, ge-
4 netic counseling, or specialty care.

5 “(D) Providing telehealth appointments, as
6 appropriate.

7 “(E) Providing medical or surgical treat-
8 ment.

9 “(F) Implementing individual care plans.

10 “(G) Providing social work services or
11 community health worker services in coordina-
12 tion with one or more community-based organi-
13 zations.

14 “(H) Collecting and distributing data as
15 required by the National Sickle Cell Disease
16 Coordinating Center established under sub-
17 section (f).

18 “(4) ADDITIONAL USES OF FUNDS.—In addi-
19 tion to the uses of funds described in paragraphs
20 (1), (2), and (3), an eligible entity selected to receive
21 a grant under this section may use funds received
22 through the grant—

23 “(A) to identify and secure resources for
24 ensuring reimbursement under, for the State in-
25 volved, the State plan under title XIX of the

1 Social Security Act (or a waiver of such plan),
2 State child health plan under title XXI of such
3 Act (or a waiver of such plan), and other health
4 programs for the prevention and treatment of
5 sickle cell disease, including by working with
6 community-based sickle cell disease organiza-
7 tions and other nonprofit entities;

8 “(B) to assist sickle cell disease patients
9 with accessing appropriate health insurance, in-
10 cluding—

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

15 “(ii) by working with community-
16 based sickle cell disease organizations and
17 other nonprofit entities; and

18 “(iii) by helping sickle cell disease pa-
19 tients know their rights with insurance
20 programs;

21 “(C) to facilitate access to telehealth serv-
22 ices for sickle cell disease patients and individ-
23 uals with sickle cell trait, to the extent feasible;

24 “(D) to fund evidence-based programs that
25 provide education to health care providers,

1 teachers and school personnel, and correctional
 2 institutional personnel, on the care of individ-
 3 uals with sickle cell disease or trait in health
 4 care settings and other appropriate settings, in-
 5 cluding schools and prisons;

6 “(E) to develop a system of social and
 7 community supports, including transportation
 8 services or travel reimbursement for sickle cell
 9 disease patients who do not have, but who need
 10 access to, in-person care with the Sickle Cell
 11 Disease Treatment Centers; and

12 “(F) to facilitate access to sickle cell trait
 13 testing and genetic counseling.

14 “(e) APPLICATION; SELECTION.—

15 “(1) APPLICATION.—An eligible entity desiring
 16 a grant under this section shall submit an applica-
 17 tion to the Secretary at such time, in such manner,
 18 and containing such information as the Secretary
 19 may require, including a description of how the hub-
 20 and-spoke entity and community-based organization
 21 will collaborate in carrying out the activities de-
 22 scribed in subsection (c).

23 “(2) GEOGRAPHIC DISTRIBUTION.—The Sec-
 24 retary shall award grants under this section, to the
 25 extent practicable, to eligible entities, with a focus

on regions where a disproportionate number of patients with sickle cell disease, individuals with sickle cell trait, or other heritable hemoglobinopathy patients per capita reside, and to eligible entities 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, nursing school, nurse practitioner or physician assistant program, genetic counseling program, or school of social work;

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

“(C) serve a rural area.

“(f) NATIONAL SICKLE CELL DISEASE COORDINATING CENTER.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish, or enter a cooperative agreement with an entity
3 to establish, the National Sickle Cell Disease Coordi-
4 nating Center, which shall coordinate the activities
5 conducted by grantees under this section and carry
6 out the activities described in paragraph (2).

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

10 “(A) Advise the Secretary on the design
11 and implementation of, and coordinate the in-
12 frastructure of, the Sickle Cell Disease Treat-
13 ment Centers established under subsection (b),
14 including with respect to administrative require-
15 ments and ensuring that sickle cell health care
16 is available across the United States.

17 “(B) Develop a national strategy for the
18 practice of equitable care, coordinated com-
19 prehensive quality care, research and resources
20 for patients and health care providers, and
21 treatment modality options to improve patient
22 outcomes, and submit such national strategy to
23 the Secretary.

24 “(C) Coordinate with Federal agencies to
25 improve data collection over the lifespan of pa-

1 tients and routinely update a national needs as-
2 sessment to improve care for individuals im-
3 pacted by sickle cell disease.

4 “(D) Coordinate with hub-and-spoke net-
5 works, patients, researchers, and health care
6 providers to maintain a comprehensive sickle
7 cell research, treatment, and national care
8 strategy.

9 “(E) Establish a rotating panel of stake-
10 holders, including health care providers, pa-
11 tients, individuals impacted by sickle cell dis-
12 ease, allied health professionals, care coordina-
13 tors, social workers, community health workers,
14 and sickle cell community-based and advocacy
15 organizations to advise the Center, provide up-
16 to-date information and forecasts on status and
17 plans for improving sickle cell care, treatment,
18 and access to treatment modalities for individ-
19 uals and families living with sickle cell disease.

20 “(F) Coordinate and support hub-and-
21 spoke frameworks.

22 “(G) Support improvement in patient and
23 family-centered care, health outcomes, and care
24 affordability by improving access to care.

1 “(H) Provide or coordinate technical as-
 2 sistance and support to health care providers,
 3 family members and advocates, public health
 4 professionals, policymakers, and patients that
 5 want to improve access to quality care, tele-
 6 medicine, family planning, health care transi-
 7 tion, and family and community engagement.

8 “(I) Inform and educate the public about
 9 sickle cell disease, sickle cell trait, and options
 10 for quality care.

11 “(g) 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, in coordination with the Na-
 15 tional Sickle Cell Coordinating Center established under
 16 subsection (f), shall carry out the following:

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

21 “(2) Collecting and maintaining up-to-date data
 22 on sickle cell disease, including subtypes as applica-
 23 ble, and their associated health outcomes and com-
 24 plications, in consultation with States participating
 25 in the Sickle Cell Data Collection of the Centers for

1 Disease Control and Prevention, including for the
2 purpose of—

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

6 “(B) identifying health disparities impact-
7 ing individuals born with sickle cell disease, in-
8 cluding subtypes as applicable, and other
9 hemoglobinopathies;

10 “(C) assessing the utilization of therapies,
11 comprehensive complication risk screening, and
12 strategies to prevent complications resulting
13 from sickle cell disease and to increase quality
14 of life; and

15 “(D) evaluating the effects of genetic, envi-
16 ronmental, behavioral, and other risk factors
17 that may affect individuals with sickle cell dis-
18 ease.

19 “(3) Developing educational materials, public
20 awareness campaigns, or other outreach programs
21 regarding the inheritance pattern, treatment of, and
22 prevention of complications from sickle cell disease
23 and prevalence of sickle cell trait, as well as pro-
24 grams and activities that will enhance the lives of in-

1 dividuals living with sickle cell disease and sickle cell
2 disease trait.

3 “(h) REQUEST FOR INFORMATION.—Not later than
4 180 days after the date of enactment of the Sickle Cell
5 Disease Treatment Centers Act of 2024, and in advance
6 of each new grant cycle thereafter, the Secretary shall
7 publish in the Federal Register a request for information
8 seeking feedback from stakeholders on—

9 “(1) best practices with respect to the establish-
10 ment and implementation of Sickle Cell Disease
11 Treatment Centers; and

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

14 “(i) REPORT TO CONGRESS.—

15 “(1) IN GENERAL.—Not later than 3 years
16 after the date of the enactment of the Sickle Cell
17 Disease Treatment Centers Act of 2024 and every 5
18 years thereafter, the Secretary shall submit to the
19 Committee on Health, Education, Labor, and Pen-
20 sions and the Committee on Appropriations of the
21 Senate and the Committee on Energy and Com-
22 merce and the Committee on Appropriations of the
23 House of Representatives a report on the impact of
24 the Sickle Cell Disease Treatment Centers estab-

1 lished under this section on health outcomes for
 2 sickle cell disease patients.

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

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

8 “(B) information about the specific activi-
 9 ties supported by grant funds awarded under
 10 this section with respect to each eligible entity;

11 “(C) the number of sickle cell disease pa-
 12 tients served by grant programs funded under
 13 this section and demographic information about
 14 those patients, including race, sex, gender, geo-
 15 graphic location, and age; and

16 “(D) information about patient experiences
 17 with the hub-and-spoke system and community-
 18 based organizations.

19 “(j) SUPPLEMENT, NOT SUPPLANT.—The activities
 20 under this section shall supplement, not supplant, other-
 21 wise authorized activities of the Department of Health and
 22 Human Services relating to sickle cell disease.

23 “(k) AUTHORIZATION OF APPROPRIATIONS.—

24 “(1) IN GENERAL.—To carry out this section,
 25 there are authorized to be appropriated such sums

1 as may be necessary for fiscal year 2025 and each
2 fiscal year thereafter.

3 “(2) ALLOCATION TO ACTIVITIES.—Of the
4 amount appropriated under paragraph (1) for a fis-
5 cal year—

6 “(A) 70 percent may be awarded to eligible
7 entities for purposes of supporting the activities
8 of hub and spoke networks that are a part of
9 such eligible entities;

10 “(B) 20 percent may be awarded to eligible
11 entities for purposes of supporting the activities
12 of community-based organizations that are a
13 part of such eligible entities;

14 “(C) 5 percent may be used for the estab-
15 lishment and maintenance of the National Sick-
16 le Cell Disease Coordinating Center described
17 in subsection (f); and

18 “(D) 5 percent may be used for the activi-
19 ties of the Sickle Cell Data Collection program
20 of the Centers for Disease Control and Preven-
21 tion described in subsection (g).”.

○