

SICKLE CELL DISEASE AND OTHER HERITABLE BLOOD
DISORDERS RESEARCH, SURVEILLANCE, PREVENTION,
AND TREATMENT ACT OF 2023

AUGUST 25, 2023.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and
Commerce, submitted the following

R E P O R T

[To accompany H.R. 3884]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3884) to amend title XI of the Public Health Service Act to reauthorize the program providing for sickle cell disease and other heritable blood disorders research, surveillance, prevention, and treatment, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2023”.

SEC. 2. REAUTHORIZATION OF SICKLE CELL DISEASE AND OTHER HERITABLE BLOOD DISORDERS RESEARCH, SURVEILLANCE, PREVENTION, AND TREATMENT.

Section 1106(b) of the Public Health Service Act (42 U.S.C. 300b–5(b)) is amended—

(1) in paragraph (3)(A), by inserting “, grant, or cooperative agreement” after “contract”; and

(2) in paragraph (6), by striking “\$4,455,000 for each of fiscal years 2019 through 2023” and inserting “\$8,205,000 for each of fiscal years 2024 through 2028”.

PURPOSE AND SUMMARY

H.R. 3884 would reauthorize the programs and activities under the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) aimed to support research, prevention, and treatment for sickle cell disease and other heritable blood disorders for fiscal years 2024–2028.

BACKGROUND AND NEED FOR LEGISLATION

The programs reauthorized under the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2023 support states’ efforts to provide services, education, training, and best practices related to identification, prevention, and treatment of sickle cell disease. Sickle cell disease (SCD) is the most common inherited blood disorder in the United States, affecting an estimated 100,000 Americans.¹ People with SCD are born with it, though most newborns who have SCD do not have symptoms until they are about 5 or 6 months old. SCD is a lifelong disease, though there are several innovative new treatments for the disease, and one cure through a bone marrow or stem cell transplant. This legislation will continue funding for these programs with the goal of continuing to improve health outcomes.

COMMITTEE ACTION

On June 14, 2023, the Subcommittee on Health held a hearing on H.R. 3884. The Subcommittee received testimony from:

- Dr. Elizabeth Cherot, MD, MBA, Senior Vice President and Chief Medical Health Officer, March of Dimes;
 - Dr. Alexis A. Thompson, MD, MPH, Chief of Division of Hematology, Elias Schwartz MD Endowed Chair in Hematology, Children’s Hospital of Philadelphia, Professor of Pediatrics, University of Pennsylvania Perelman School of Medicine;
 - Dr. Meredith McNamara, MD, MS, FAAP, Assistant Professor, Yale School of Medicine;
 - Dr. Miriam Grossman, MD, Child, Adolescent, and Adult Psychiatrist;
 - Mr. George Manahan, Parkinson’s Advocate and Patient;
- and,

¹Centers for Disease Control and Prevention, Data & Statistics on Sickle Cell Disease, July 6, 2023.

- Mr. Kevin O'Connor, Assistant to the General President for Government Affairs and Political Action, International Association of Fire Fighters.

On July 13, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 3884, as amended, to the full Committee by a record vote of 28 yeas and 0 nays. On July 19, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 3884, as amended, favorably reported to the House by a record vote of 50 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE # 5**

BILL: H.R. 3884, the Sickle Cell Disease and Other Heritable Disorders Research, Surveillance, Prevention, and Treatment Act of 2023

AMENDMENT: A motion by Mrs. Rodgers to order H.R. 3884 favorably reported to the House, as amended (Final Passage).

DISPOSITION: **AGREED TO**, by a roll call vote of 50 yeas to 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone	X		
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette	X		
Rep. Guthrie	X			Rep. Schakowsky	X		
Rep. Griffith	X			Rep. Matsui	X		
Rep. Bilirakis	X			Rep. Castor	X		
Rep. Johnson	X			Rep. Sarbanes	X		
Rep. Bucshon	X			Rep. Tonko	X		
Rep. Hudson	X			Rep. Clarke	X		
Rep. Walberg	X			Rep. Cárdenas	X		
Rep. Carter	X			Rep. Ruiz	X		
Rep. Duncan	X			Rep. Peters	X		
Rep. Palmer	X			Rep. Dingell	X		
Rep. Dunn	X			Rep. Veasey	X		
Rep. Curtis	X			Rep. Kuster	X		
Rep. Lesko	X			Rep. Kelly	X		
Rep. Pence	X			Rep. Barragán	X		
Rep. Crenshaw	X			Rep. Blunt Rochester			
Rep. Joyce	X			Rep. Soto	X		
Rep. Armstrong	X			Rep. Craig	X		
Rep. Weber	X			Rep. Schrier	X		
Rep. Allen	X			Rep. Trahan	X		
Rep. Balderson	X			Rep. Fletcher	X		
Rep. Fulcher	X						
Rep. Pfluger							
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte	X						

07/19/2023

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND
TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 3884 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to reauthorize sickle cell programs and activities under CDC and HRSA to support efforts to provide services, education, training, and best practices related to identification, prevention, and treatment of sickle cell disease.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3884 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 3884:

- On June 14, 2023, the Subcommittee on Health held a hearing on H.R. 3884. The Subcommittee received testimony from:
 - Dr. Elizabeth Cherot, MD, MBA, Senior Vice President and Chief Medical Health Officer, March of Dimes;
 - Dr. Alexis A. Thompson, MD, MPH, Chief of Division of Hematology, Elias Schwartz MD Endowed Chair in Hematology, Children’s Hospital of Philadelphia, Professor of Pediatrics, University of Pennsylvania Perelman School of Medicine;
 - Dr. Meredith McNamara, MD, MS, FAAP, Assistant Professor, Yale School of Medicine;

- Dr. Miriam Grossman, MD, Child, Adolescent, and Adult Psychiatrist;
- Mr. George Manahan, Parkinson’s Advocate and Patient; and,
- Mr. Kevin O’Connor, Assistant to the General President for Government Affairs and Political Action, International Association of Fire Fighters.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

earmark, limited tax benefits, and limited tariff benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 3884 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides a short title of “Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2023”.

Section 2. Reauthorization of sickle cell disease and other heritable blood disorders research, surveillance, prevention, and treatment

Section 2 amends Title XI of the Public Health Service Act to reauthorize the program providing for sickle cell disease and other heritable blood disorders research, surveillance, prevention, and treatment, for fiscal years 2024 through 2028.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

PART A—GENETIC DISEASES

* * * * * * *

SEC. 1106. SICKLE CELL DISEASE AND OTHER HERITABLE BLOOD DIS- ORDERS RESEARCH, SURVEILLANCE, PREVENTION, AND TREATMENT.

(a) GRANTS.—

(1) IN GENERAL.—The Secretary may award grants related to heritable blood disorders, including sickle cell disease, for one or more of the following purposes:

(A) To collect and maintain data on such diseases and conditions, including subtypes as applicable, and their associated health outcomes and complications, including for the purpose of—

- (i) improving national incidence and prevalence data;
- (ii) identifying health disparities, including the geographic distribution, related to such diseases and conditions;
- (iii) assessing the utilization of therapies and strategies to prevent complications; and
- (iv) evaluating the effects of genetic, environmental, behavioral, and other risk factors that may affect such individuals.

(B) To conduct public health activities with respect to such conditions, which may include—

- (i) developing strategies to improve health outcomes and access to quality health care for the screening for, and treatment and management of, such diseases and conditions, including through public-private partnerships;
- (ii) providing support to community-based organizations and State and local health departments in conducting education and training activities for patients, communities, and health care providers concerning such diseases and conditions;
- (iii) supporting State health departments and regional laboratories, including through training, in testing to identify such diseases and conditions, including specific forms of sickle cell disease, in individuals of all ages; and
- (iv) the identification and evaluation of best practices for treatment of such diseases and conditions, and prevention and management of their related complications.

(2) POPULATION INCLUDED.—The Secretary shall, to the extent practicable, award grants under this subsection to eligible entities across the United States to improve data on the incidence and prevalence of heritable blood disorders, including sickle cell disease, and the geographic distribution of such diseases and conditions.

(3) APPLICATION.—To seek a grant under this subsection, an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(4) PRIORITY.—In awarding grants under this subsection, the Secretary may give priority, as appropriate, to eligible entities that have a relationship with a community-based organization that has experience in, or is capable of, providing services to individuals with heritable blood disorders, including sickle cell disease.

(5) ELIGIBLE ENTITY.—In this subsection, the term “eligible entity” includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of Marshall Islands, the Republic of Palau, Indian tribes, a State or local health department, an institution of higher education, or a nonprofit entity with appropriate experience to conduct the activities under this subsection.

(b) DEMONSTRATION PROGRAM FOR THE DEVELOPMENT AND ESTABLISHMENT OF SYSTEMIC MECHANISMS FOR THE PREVENTION AND TREATMENT OF SICKLE CELL DISEASE.—

(1) AUTHORITY TO CONDUCT DEMONSTRATION PROGRAM.—

(A) IN GENERAL.—The Administrator, through the Bureau of Primary Health Care and the Maternal and Child Health Bureau, shall continue efforts, including by awarding grants, to develop or establish mechanisms to improve the treatment of sickle cell disease, and to improve the prevention and treatment of complications of sickle cell disease, in populations with a high proportion of individuals with sickle cell disease, including through—

- (i) the coordination of service delivery for individuals with sickle cell disease;
- (ii) genetic counseling and testing;
- (iii) bundling of technical services related to the prevention and treatment of sickle cell disease;
- (iv) training of health professionals; and
- (v) identifying and establishing other efforts related to the expansion and coordination of education, treatment, and continuity of care programs for individuals with sickle cell disease.

(B) GEOGRAPHIC DIVERSITY.—The Administrator shall, to the extent practicable, award grants under this section to eligible entities located in different regions of the United States.

(2) ADDITIONAL REQUIREMENTS.—An eligible entity awarded a grant under this subsection shall use funds made available under the grant to carry out, in addition to the activities described in paragraph (1)(A), the following activities:

(A) To facilitate and coordinate the delivery of education, treatment, and continuity of care for individuals with sickle cell disease under—

- (i) the entity’s collaborative agreement with a community-based sickle cell disease organization or a non-

profit entity that works with individuals who have sickle cell disease;

(ii) the sickle cell disease newborn screening program for the State in which the entity is located; and

(iii) the maternal and child health program under title V of the Social Security Act (42 U.S.C. 701 et seq.) for the State in which the entity is located.

(B) To train nursing and other health staff who provide care for individuals with sickle cell disease.

(C) To enter into a partnership with adult or pediatric hematologists in the region and other regional experts in sickle cell disease at tertiary and academic health centers and State and county health offices.

(D) To identify and secure resources for ensuring reimbursement under the medicaid program, State children's health insurance program, and other health programs for the prevention and treatment of sickle cell disease.

(E) To provide or coordinate services for adolescents with sickle cell disease making the transition to adult health care.

(3) NATIONAL COORDINATING CENTER.—

(A) ESTABLISHMENT.—The Administrator shall enter into a contract, *grant*, or *cooperative agreement* with an entity to serve as the National Coordinating Center for the demonstration program conducted under this subsection.

(B) ACTIVITIES DESCRIBED.—The National Coordinating Center shall—

(i) collect, coordinate, monitor, and distribute data, best practices, and findings regarding the activities funded under grants made to eligible entities under the demonstration program;

(ii) develop a model protocol for eligible entities with respect to the prevention and treatment of sickle cell disease;

(iii) develop educational materials regarding the prevention and treatment of sickle cell disease; and

(iv) prepare and submit to Congress a final report that includes recommendations regarding the effectiveness of the demonstration program conducted under this subsection and such direct outcome measures as—

(I) 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

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

(4) APPLICATION.—An eligible entity desiring a grant under this subsection shall submit an application to the Administrator at such time, in such manner, and containing such information as the Administrator may require.

(5) DEFINITIONS.—In this subsection:

(A) ADMINISTRATOR.—The term “Administrator” means the Administrator of the Health Resources and Services Administration.

(B) ELIGIBLE ENTITY.—The term “eligible entity” means a Federally-qualified health center, a nonprofit hospital or clinic, or a university health center that provides primary health care, that—

(i) has a collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity with experience in working with individuals who have sickle cell disease; and

(ii) demonstrates to the Administrator that either the Federally-qualified health center, the nonprofit hospital or clinic, the university health center, the organization or entity described in clause (i), or the experts described in paragraph (2)(C), has at least 5 years of experience in working with individuals who have sickle cell disease.

(C) FEDERALLY-QUALIFIED HEALTH CENTER.—The term “Federally-qualified health center” has the meaning given that term in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1396d(l)(2)(B)).

(6) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, **[\$4,455,000 for each of fiscal years 2019 through 2023]** *\$8,205,000 for each of fiscal years 2024 through 2028.*

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