

SICKLE CELL DISEASE RESEARCH, SURVEILLANCE,  
PREVENTION, AND TREATMENT ACT OF 2017

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OCTOBER 19, 2017.—Committed to the Committee of the Whole House on the State  
of the Union and ordered to be printed

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Mr. WALDEN, from the Committee on Energy and Commerce,  
submitted the following

R E P O R T

[To accompany H.R. 2410]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2410) to amend the Public Health Service Act to reauthorize a sickle cell disease prevention and treatment demonstration program and to provide for sickle cell disease research, surveillance, prevention, and treatment, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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## PURPOSE AND SUMMARY

H.R. 2410 was introduced on May 11, 2017, by Rep. Danny K. Davis (D–IL). H.R. 2410 reauthorizes the Sickle Cell Disease Treatment Demonstration Program under the Public Health Service Act. The bill increases sickle cell disease (SCD) research and surveillance. It also authorizes grants for improving outreach and treatment in populations with a high density of SCD patients, emphasizing collaboration with community-based entities with experience in providing services to patients with this disease.

## BACKGROUND AND NEED FOR LEGISLATION

Sickle Cell Disease is a group of inherited blood cell disorders that results in misshapen blood cells, creating blockages in small blood vessels, leading to various health care complications ranging from mild discomfort to death. The exact number of those living with SCD in the United States is unknown, but the Centers for Disease Control and Prevention estimate that SCD affects approximately 100,000 Americans, occurring in about one out of every 365 African-American births.

Treatments for this disease are limited and focus on relieving symptoms, reducing pain, and avoiding crises and complications. At this time, hematopoietic stem cell transplantation is the only cure. Enhancing research and surveillance efforts will improve current understanding of this life-long disease and potentially lead to a cure. Collaboration with community-based organizations treating SCD patients provides an opportunity to reduce costs while enhancing health outcomes.

## COMMITTEE ACTION

During the 114th Congress, on September 8, 2016, the Subcommittee on Health held a hearing on H.R. 1807, which was substantially similar to H.R. 2410. The hearing was entitled “Examining Legislation to Improve Public Health.” The Subcommittee received testimony from:

- Sonja L. Banks, President and COO, Sickle Cell Disease Association of America, Inc.;
- General Arthur Dean, Chairman and CEO, Community Anti-Drug Coalitions of America;
- Jonathan Leffert, President-Elect, American Association of Clinical Endocrinologists;
- Brad Marino, Chair, Pediatric Congenital Heart Association; and
- R. Sean Morrison, Director, National Palliative Care Research Center.

On May 18, 2017, the Subcommittee on Health met in open markup session and forwarded H.R. 2410, without amendment, to the full Committee by a voice vote. On June 7, 2017, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2410, without amendment, favorably reported to the House by a voice vote.

## 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. There were no record votes taken in connection with ordering H.R. 2410 reported.

## OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee has not held hearings on this legislation.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 2410 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, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC. September 22, 2017.*

Hon. GREG WALDEN,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Rebecca Yip.

Sincerely,

KEITH HALL,  
*Director.*

Enclosure.

*H.R. 2410—Sickle Cell Disease Research, Surveillance, Prevention,  
and Treatment Act of 2017*

H.R. 2410 would authorize the Secretary of Health and Human Services, through the Centers for Disease Control and Prevention (CDC), to conduct surveillance and collect data on the prevalence of sickle cell disease (SCD). In addition, the bill would authorize the Secretary to develop public health initiatives that support community-based organizations in education activities and to support regional and state health departments in testing to identify SCD. H.R. 2410 would authorize the appropriation of about \$4.5 million a year for fiscal years 2018 through 2022 to carry out those activities.

The bill would require CDC to build upon past activities related to SCD by conducting surveillance and developing public health initiatives through grants to States. Previous funding from the Amer-

ican Jobs Creation Act of 2004 of \$10 million a year for SCD expired in 2009. There has been no explicit funding for SCD since 2009. However, CDC has continued to conduct activities related to SCD and other blood disorders. Based on historical spending for similar activities, CBO estimates that implementing H.R. 2410 would cost \$18 million over the 2018–2022 period, primarily for additional staff and other administrative costs; the remaining amounts would be spent after 2022. Enacting H.R. 2410 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

H.R. 2410 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Rebecca Yip. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.

#### 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 improve SCD research, surveillance and outreach initiatives that enhance the treatment of SCD, emphasizing collaboration with community-based entities with experience in providing services to patients with this disease.

#### DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2410 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.

#### 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.

#### 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. 2410 contains no earmarks, limited tax benefits, or limited tariff benefits.

#### DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 2410 contains no directed rule makings.

## 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; table of contents*

Section 1 provides that the Act may be cited as the “Sickle Cell Disease Research, Surveillance, Prevention and Treatment Act of 2017.”

*Section 2. Sickle cell disease research*

Section 2 authorizes the Secretary to conduct and support research to further understand the causes of sickle cell disease and to find a cure for sickle cell disease.

*Section 3. Sickle cell disease surveillance*

Section 3 authorizes the Secretary to make grants to States to conduct surveillance on the epidemiology of sickle cell disease, implement public health initiatives, and identify and evaluate sickle cell disease prevention and treatment strategies.

*Section 4. Sickle cell disease prevention and treatment*

Section 4 reauthorizes the Sickle Cell Disease Treatment Demonstration Program under the Public Health Service Act, providing for grants to 25 eligible entities to develop and establish mechanisms to improve prevention and treatment in populations with a high density of sickle cell disease patients.

*Section 5. Collaboration with community-based entities*

Section 5 requires eligible grantees to have a collaborative agreement with a community-based organization with at least five years of experience in providing services to sickle cell disease patients.

## 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 (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

**PUBLIC HEALTH SERVICE ACT**

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**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE**

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## PART P—ADDITIONAL PROGRAMS

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### SEC. 399V-7. NATIONAL SICKLE CELL DISEASE RESEARCH, SURVEILLANCE, PREVENTION, AND TREATMENT PROGRAM.

(a) *RESEARCH.*—The Secretary may conduct or support research to expand the understanding of the cause of, and to find a cure for, sickle cell disease.

(b) *SURVEILLANCE.*—

(1) *GRANTS.*—The Secretary may, for each fiscal year for which appropriations are available to carry out this subsection, make grants to not more than 20 States—

(A) to conduct surveillance and maintain data on the prevalence and distribution of sickle cell disease and its associated health outcomes, complications, and treatments;

(B) to conduct public health initiatives with respect to sickle cell disease, including—

(i) increasing efforts to improve access to, and receipt of, high-quality sickle cell disease-related health care, including the use of treatments approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

(ii) working with partners to improve health outcomes of people with sickle cell disease over the lifespan by promoting guidelines for sickle cell disease screening, prevention, and treatment, including management of sickle cell disease complications;

(iii) providing support to community-based organizations and State and local health departments in conducting sickle cell disease education and training activities for patients, communities, and health care providers; and

(iv) supporting and training State health departments and regional laboratories in comprehensive testing to identify specific forms of sickle cell disease in people of all ages; and

(C) to identify and evaluate promising strategies for prevention and treatment of sickle cell disease complications, including through—

(i) improving estimates of the national incidence and prevalence of sickle cell disease, including estimates about the specific types of sickle cell disease;

(ii) identifying health disparities related to sickle cell disease;

(iii) assessing the utilization of therapies and strategies to prevent complications related to sickle cell disease; and

(iv) evaluating the impact of genetic, environmental, behavioral, and other risk factors that may affect sickle cell disease health outcomes.

(2) *POPULATION INCLUDED.*—The Secretary shall, to the extent practicable, award grants under this subsection to States across the United States so as to include data on the majority of the United States population with sickle cell disease.

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

(4) *DEFINITIONS.*—In this subsection:

(A) The term “Secretary” means the Secretary of Health and Human Services, acting through the Director of the National Center on Birth Defects and Developmental Disabilities.

(B) The term “State” 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 the Marshall Islands, and the Republic of Palau.

(c) *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 conduct a demonstration program by making grants to up to 25 eligible entities for each fiscal year in which the program is conducted under this section for the purpose of developing and establishing systemic mechanisms to improve the prevention and treatment of sickle cell disease in populations with a high density of sickle cell disease patients, 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 expand, coordinate, and implement transition 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 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 2018 through 2022.

(d) *COLLABORATION WITH COMMUNITY-BASED ENTITIES.*—To be eligible to receive a grant or other assistance under subsection (b) or (c), an entity must have in effect a collaborative agreement with a community-based organization with 5 or more years of experience in providing services to sickle cell disease patients.

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