

Calendar No. 553

115TH CONGRESS
2D SESSION

S. 2465

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.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2018

Mr. SCOTT (for himself, Mr. BOOKER, Mr. JONES, Mr. CASSIDY, Ms. STABENOW, Ms. WARREN, and Mr. BROWN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

AUGUST 15, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
 3 “Sickle Cell Disease Research, Surveillance, Prevention,
 4 and Treatment Act of 2018”.

5 (b) **TABLE OF CONTENTS.**—The table of contents of
 6 this Act is as follows:

Sec. 1. Short title; table of contents.
 Sec. 2. Sense of the Senate.
 Sec. 3. Sickle cell disease surveillance.
 Sec. 4. Sickle cell disease prevention and treatment.
 Sec. 5. Collaboration with community-based entities.

7 **SEC. 2. SENSE OF THE SENATE.**

8 It is the Sense of the Senate that further research
 9 should be undertaken to expand the understanding of the
 10 cause of, and to find a cure for, sickle cell disease.

11 **SEC. 3. SICKLE CELL DISEASE SURVEILLANCE.**

12 Part P of title III of the Public Health Service Act
 13 is amended by inserting after section 399V–6 (42 U.S.C.
 14 280g–17) the following:

15 **“SEC. 399V–7. NATIONAL SICKLE CELL DISEASE SURVEIL-**
 16 **LANCE, PREVENTION, AND TREATMENT PRO-**
 17 **GRAM.**

18 **“(a) SURVEILLANCE.—**

19 **“(1) GRANTS.**—The Secretary may, for each
 20 fiscal year for which appropriations are available to
 21 carry out this subsection, make grants to not more
 22 than 20 eligible entities for the following purposes:

1 “(A) To conduct surveillance and maintain
2 data on the prevalence and distribution of sickle
3 cell disease and its associated health outcomes,
4 complications, and treatments.

5 “(B) To conduct public health initiatives
6 with respect to sickle cell disease, including one
7 or more of the following:

8 “(i) Increasing efforts to improve ac-
9 cess to high-quality sickle cell disease-re-
10 lated health care, including the use of
11 treatments approved under section 505 of
12 the Federal Food, Drug, and Cosmetic Act
13 or licensed under section 351 of this Act.

14 “(ii) Working with partners to im-
15 prove health outcomes of people with sickle
16 cell disease over the lifespan by promoting
17 guidelines for sickle cell disease screening,
18 prevention, and treatment, including man-
19 agement of sickle cell disease complica-
20 tions.

21 “(iii) Providing support to commu-
22 nity-based organizations and State and
23 local health departments in conducting
24 sickle cell disease education and training

activities for patients, communities, and health care providers.

~~“(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.~~

~~“(C) To identify and evaluate promising strategies for prevention and treatment of sickle cell disease complications, including through one or more of the following:~~

~~“(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.~~

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

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

6 “(3) APPLICATION.—To seek a grant under this
7 subsection, an eligible entity shall submit an applica-
8 tion to the Secretary at such time, in such manner,
9 and containing such information as the Secretary
10 may require.

11 “(4) ELIGIBLE ENTITY.—In this subsection, the
12 term ‘eligible entity’ includes the 50 States, the Dis-
13 trict of Columbia, the Commonwealth of Puerto
14 Rico, the United States Virgin Islands, the Com-
15 monwealth of the Northern Mariana Islands, Amer-
16 ican Samoa, Guam, the Federated States of Micro-
17 nesia, the Republic of Marshall Islands, the Republic
18 of Palau, a State health or public health depart-
19 ment, an institution of higher education, or a non-
20 profit entity.”.

21 **SEC. 4. SICKLE CELL DISEASE PREVENTION AND TREAT-**
22 **MENT.**

23 (a) REAUTHORIZATION.—Section 712(c) of the
24 American Jobs Creation Act of 2004 (Public Law 108–
25 357; 42 U.S.C. 300b–1 note) is amended—

1 (1) by striking “Sickle Cell Disease” each place
2 it appears and inserting “sickle cell disease”;

3 (2) in paragraph (1)(A), by striking “grants to
4 up to 40 eligible entities for each fiscal year in which
5 the program is conducted under this section for the
6 purpose of developing and establishing systemic
7 mechanisms to improve the prevention and treat-
8 ment of Sickle Cell Disease” and inserting “grants
9 to up to 25 eligible entities for each fiscal year in
10 which the program is conducted under this section
11 for the purpose of developing and establishing sys-
12 temic mechanisms to improve the prevention and
13 treatment of sickle cell disease in populations with
14 a high density of sickle cell disease patients”;

15 (3) in paragraph (1)(B)—

16 (A) by striking clause (ii) (relating to pri-
17 ority); and

18 (B) by striking “GRANT AWARD REQUIRE-
19 MENTS” and all that follows through “The Ad-
20 ministrators shall” and inserting “GEOGRAPHIC
21 DIVERSITY.—The Administrator shall”;

22 (4) in paragraph (2), by adding the following
23 new subparagraph at the end:

24 “(E) To expand, coordinate, and imple-
25 ment transition services for adolescents with

1 sickle cell disease making the transition to adult
2 health care.”; and

3 ~~(5) in paragraph (6), by striking “\$10,000,000~~
4 ~~for each of fiscal years 2005 through 2009” and in-~~
5 ~~serting “\$4,455,000 for each of fiscal years 2018~~
6 ~~through 2022”.~~

7 (b) ~~TECHNICAL CHANGES.~~—Subsection (c) of section
8 712 of the American Jobs Creation Act of 2004 (Public
9 Law ~~108–357~~; 42 U.S.C. ~~300b–1~~ note), as amended by
10 subsection (a), is—

11 (1) transferred to the Public Health Service Act
12 ~~(42 U.S.C. 201 et seq.);~~

13 (2) redesignated as subsection (b); and

14 (3) inserted at the end of section ~~399V–7~~ of
15 such Act, as added by section 2 of this Act.

16 **SEC. 5. COLLABORATION WITH COMMUNITY-BASED ENTI-**
17 **TIES.**

18 Section ~~399V–7~~ of the Public Health Service Act, as
19 amended by section ~~3~~, is further amended by adding at
20 the end the following:

21 ~~“(c) COLLABORATION WITH COMMUNITY-BASED EN-~~
22 ~~TITIES.—To be eligible to receive a grant or other assist-~~
23 ~~ance under subsection (a) or (b), an eligible entity must~~
24 ~~have in effect a collaborative agreement with a commu-~~

1 nity-based organization with five or more years of experi-
 2 ence in providing services to sickle cell disease patients.”.

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Sickle Cell Disease and*
 5 *Other Heritable Blood Disorders Research, Surveillance,*
 6 *Prevention, and Treatment Act of 2018”.*

7 **SEC. 2. DATA COLLECTION ON CERTAIN BLOOD DIS-**
 8 **ORDERS.**

9 *Part A of title XI of the Public Health Service Act*
 10 *is amended by inserting after section 1105 (42 U.S.C. 300b-*
 11 *4) the following:*

12 **“SEC. 1106. SICKLE CELL DISEASE AND OTHER HERITABLE**
 13 **BLOOD DISORDERS RESEARCH, SURVEIL-**
 14 **LANCE, PREVENTION, AND TREATMENT.**

15 **“(a) GRANTS.—**

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

20 **“(A) To collect and maintain data on such**
 21 *diseases and conditions, including subtypes as*
 22 *applicable, and their associated health outcomes*
 23 *and complications, including for the purpose*
 24 *of—*

1 “(i) improving national incidence and
2 prevalence data;

3 “(ii) identifying health disparities, in-
4 cluding the geographic distribution, related
5 to such diseases and conditions;

6 “(iii) assessing the utilization of thera-
7 pies and strategies to prevent complications;
8 and

9 “(iv) evaluating the effects of genetic,
10 environmental, behavioral, and other risk
11 factors that may affect such individuals.

12 “(B) To conduct public health activities
13 with respect to such conditions, which may in-
14 clude—

15 “(i) developing strategies to improve
16 health outcomes and access to quality health
17 care for the screening for, and treatment
18 and management of, such diseases and con-
19 ditions, including through public-private
20 partnerships;

21 “(ii) providing support to community-
22 based organizations and State and local
23 health departments in conducting education
24 and training activities for patients, commu-

1 nities, and health care providers concerning
2 such diseases and conditions;

3 “(iii) supporting State health depart-
4 ments and regional laboratories, including
5 through training, in testing to identify such
6 diseases and conditions, including specific
7 forms of sickle cell disease, in individuals of
8 all ages; and

9 “(iv) the identification and evaluation
10 of best practices for treatment of such dis-
11 eases and conditions, and prevention and
12 management of their related complications.

13 “(2) *POPULATION INCLUDED.*—The Secretary
14 shall, to the extent practicable, award grants under
15 this subsection to eligible entities across the United
16 States to improve data on the incidence and preva-
17 lence of heritable blood disorders, including sickle cell
18 disease, and the geographic distribution of such dis-
19 eases and conditions.

20 “(3) *APPLICATION.*—To seek a grant under this
21 subsection, an eligible entity shall submit an applica-
22 tion to the Secretary at such time, in such manner,
23 and containing such information as the Secretary
24 may require.

1 “(4) *PRIORITY*.—In awarding grants under this
 2 subsection, the Secretary may give priority, as appro-
 3 priate, to eligible entities that have a relationship
 4 with a community-based organization that has expe-
 5 rience in, or is capable of, providing services to indi-
 6 viduals with heritable blood disorders, including sickle
 7 cell disease.

8 “(5) *ELIGIBLE ENTITY*.—In this subsection, the
 9 term ‘eligible entity’ includes the 50 States, the Dis-
 10 trict of Columbia, the Commonwealth of Puerto Rico,
 11 the United States Virgin Islands, the Commonwealth
 12 of the Northern Mariana Islands, American Samoa,
 13 Guam, the Federated States of Micronesia, the Repub-
 14 lic of Marshall Islands, the Republic of Palau, Indian
 15 tribes, a State or local health department, an institu-
 16 tion of higher education, or a nonprofit entity with
 17 appropriate experience to conduct the activities under
 18 this subsection.”.

19 **SEC. 3. SICKLE CELL DISEASE PREVENTION AND TREAT-**
 20 **MENT.**

21 (a) *REAUTHORIZATION*.—Section 712(c) of the Amer-
 22 ican Jobs Creation Act of 2004 (Public Law 108–357; 42
 23 U.S.C. 300b–1 note) is amended—

24 (1) by striking “Sickle Cell Disease” each place
 25 it appears and inserting “sickle cell disease”;

(2) in paragraph (1)(A), by striking “shall conduct a demonstration program by making grants to up to 40 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” and inserting “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”;

(3) in paragraph (1)(B)—

(A) by striking clause (ii) (relating to priority); and

(B) by striking “GRANT AWARD REQUIREMENTS” and all that follows through “The Administrator shall” and inserting “GEOGRAPHIC DIVERSITY.—The Administrator shall”;

(4) in paragraph (2), by adding the following new subparagraph at the end:

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

1 (5) *in paragraph (6), by striking “\$10,000,000*
 2 *for each of fiscal years 2005 through 2009” and in-*
 3 *serting “\$4,455,000 for each of fiscal years 2019*
 4 *through 2023”.*

5 (b) *TECHNICAL CHANGES.—Subsection (c) of section*
 6 *712 of the American Jobs Creation Act of 2004 (Public Law*
 7 *108-357; 42 U.S.C. 300b-1 note), as amended by subsection*
 8 *(a), is—*

9 (1) *transferred to the Public Health Service Act*
 10 (42 U.S.C. 201 *et seq.*);

11 (2) *redesignated as subsection (b); and*

12 (3) *inserted at the end of section 1106 of such*
 13 *Act, as added by section 2 of this Act.*

14 **SEC. 4. SENSE OF THE SENATE.**

15 *It is the Sense of the Senate that further research*
 16 *should be undertaken to expand the understanding of the*
 17 *causes of, and to find cures for, heritable blood disorders,*
 18 *including sickle cell disease.*

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