

Calendar No. 555

115TH CONGRESS  
2D SESSION**H. R. 1222**

IN THE SENATE OF THE UNITED STATES

FEBRUARY 27, 2018

Received; 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*]**AN ACT**

To amend the Public Health Service Act to coordinate Federal congenital heart disease research efforts and to improve public education and awareness of congenital heart disease, and for other purposes.

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 “Congenital Heart Fu-~~  
5       ~~tures Reauthorization Act of 2017”.~~

1 **SEC. 2. NATIONAL CONGENITAL HEART DISEASE SURVEIL-**  
 2 **LANCE SYSTEM.**

3 Section 399V-2 of the Public Health Service Act (42  
 4 U.S.C. 280g-13) is amended to read as follows:

5 **“SEC. 399V-2. NATIONAL CONGENITAL HEART DISEASE RE-**  
 6 **SEARCH, SURVEILLANCE, AND AWARENESS.**

7 “(a) IN GENERAL.—The Secretary shall—

8 “(1) enhance and expand research and surveil-  
 9 lance infrastructure to study and track the epidemi-  
 10 ology of congenital heart disease (in this section re-  
 11 ferred to as ‘CHD’); and

12 “(2) award grants to eligible entities to under-  
 13 take the activities described in this section.

14 “(b) NATIONAL CONGENITAL HEART DISEASE  
 15 STUDY.—

16 “(1) IN GENERAL.—The Secretary shall plan,  
 17 develop, implement, and submit one or more reports  
 18 to the Congress on a study to improve under-  
 19 standing of the epidemiology of CHD across the life-  
 20 span, from birth to adulthood, with particular inter-  
 21 est in the following:

22 “(A) Health care utilization of those af-  
 23 fected by CHD.

24 “(B) Demographic factors associated with  
 25 CHD, such as age, race, ethnicity, gender, and

1 family history of individuals who are diagnosed  
2 with the disease.

3 ~~“(C) Outcome measures, such that analysis~~  
4 ~~of the outcome measures will allow derivation of~~  
5 ~~evidence-based best practices and guidelines for~~  
6 ~~CHD patients.~~

7 ~~“(2) PERMISSIBLE CONSIDERATIONS.—The~~  
8 ~~study under this subsection may—~~

9 ~~“(A) gather data on the health outcomes of~~  
10 ~~a diverse population of those affected by CHD;~~

11 ~~“(B) consider health disparities among~~  
12 ~~those affected by CHD, which may include the~~  
13 ~~consideration of prenatal exposures; and~~

14 ~~“(C) incorporate behavioral, emotional,~~  
15 ~~and educational outcomes of those affected by~~  
16 ~~CHD.~~

17 ~~“(3) PUBLIC ACCESS.—Data generated from~~  
18 ~~the study under this subsection shall be made avail-~~  
19 ~~able—~~

20 ~~“(A) for purposes of CHD research, sub-~~  
21 ~~ject to appropriate protections of personal pri-~~  
22 ~~vacy, including protections required by para-~~  
23 ~~graph (4); and~~

1           “(B) to the public, subject to paragraph  
2           (4) and with appropriate exceptions for protec-  
3           tion of personal privacy.

4           “~~(4) PATIENT PRIVACY.—~~The Secretary shall  
5           ensure that the study under this subsection is ear-  
6           ried out in a manner that complies with the require-  
7           ments applicable to a covered entity under the regu-  
8           lations promulgated pursuant to section 264(e) of  
9           the Health Insurance Portability and Accountability  
10          Act of 1996.

11          “~~(e) ELIGIBILITY FOR GRANTS.—~~To be eligible to re-  
12          ceive a grant under subsection (a)(2), an entity shall—

13                “~~(1)~~ be a public or private nonprofit entity with  
14                specialized experience in CHD; and

15                “~~(2)~~ submit to the Secretary an application at  
16                such time, in such manner, and containing such in-  
17                formation as the Secretary may require.

18          “~~(d) AUTHORIZATION OF APPROPRIATIONS.—~~To  
19          carry out this section, there is authorized to be appro-  
20          priated \$4,000,000 for each of fiscal years 2018 through  
21          2022.”.

22   **SEC. 3. CONGENITAL HEART DISEASE RESEARCH.**

23          Section 425 of the Public Health Service Act (42  
24          U.S.C. 285b–8) is amended to read as follows:

1 **“SEC. 425. CONGENITAL HEART DISEASE.**

2       “(a) IN GENERAL.—The Director of the Institute  
3 may expand, intensify, and coordinate research and re-  
4 lated activities of the Institute with respect to congenital  
5 heart disease, which may include congenital heart disease  
6 research with respect to—

7           “(1) causation of congenital heart disease, in-  
8 cluding genetic causes;

9           “(2) long-term outcomes in individuals with  
10 congenital heart disease, including infants, children,  
11 teenagers, adults, and elderly individuals;

12          “(3) diagnosis, treatment, and prevention;

13          “(4) studies using longitudinal data and retro-  
14 spective analysis to identify effective treatments and  
15 outcomes for individuals with congenital heart dis-  
16 ease; and

17          “(5) identifying barriers to lifelong care for in-  
18 dividuals with congenital heart disease.

19       “(b) COORDINATION OF RESEARCH ACTIVITIES.—

20 The Director of the Institute may coordinate research ef-  
21 forts related to congenital heart disease among multiple  
22 research institutions and may develop research networks.

23       “(c) MINORITY AND MEDICALLY UNDERSERVED  
24 COMMUNITIES.—In carrying out the activities described in  
25 this section, the Director of the Institute shall consider

1 the application of such research and other activities to mi-  
 2 nority and medically underserved communities.

3 “(d) ~~REPORT FROM NIH.~~—Not later than 1 year  
 4 after the date of the enactment of the Congenital Heart  
 5 Futures Reauthorization Act of 2017, the Director of  
 6 NIH, acting through the Director of the Institute, shall  
 7 provide a report to Congress—

8 “(1) outlining the ongoing research efforts of  
 9 the National Institutes of Health regarding con-  
 10 genital heart disease; and

11 “(2) identifying—

12 “(A) future plans for research regarding  
 13 congenital heart disease; and

14 “(B) the areas of greatest need for such  
 15 research.”.

16 **SECTION 1. SHORT TITLE.**

17 *This Act may be cited as the “Congenital Heart Fu-*  
 18 *tures Reauthorization Act of 2017”.*

19 **SEC. 2. NATIONAL CONGENITAL HEART DISEASE RE-**  
 20 **SEARCH, SURVEILLANCE, AND AWARENESS.**

21 *Section 399V–2 of the Public Health Service Act (42*  
 22 *U.S.C. 280g–13) is amended to read as follows:*

1 **“SEC. 399V-2. NATIONAL CONGENITAL HEART DISEASE RE-**  
2 **SEARCH, SURVEILLANCE, AND AWARENESS.**

3 “(a) *IN GENERAL.*—*The Secretary shall, as appro-*  
4 *priate—*

5 “(1) *enhance and expand research and data col-*  
6 *lection efforts related to congenital heart disease, in-*  
7 *cluding to study and track the epidemiology of con-*  
8 *genital heart disease to understand health outcomes*  
9 *for individuals with congenital heart disease across*  
10 *all ages;*

11 “(2) *conduct activities to improve public aware-*  
12 *ness of, and education related to, congenital heart dis-*  
13 *ease, including care of individuals with such disease;*  
14 *and*

15 “(3) *award grants to entities to undertake the*  
16 *activities described in this section.*

17 “(b) *ACTIVITIES.*—

18 “(1) *IN GENERAL.*—*The Secretary shall carry*  
19 *out activities, including, as appropriate, through a*  
20 *national cohort study and a nationally-representative,*  
21 *population-based surveillance system, to improve the*  
22 *understanding of the epidemiology of congenital heart*  
23 *disease in all age groups, with particular attention*  
24 *to—*

25 “(A) *the incidence and prevalence of con-*  
26 *genital heart disease in the United States;*

1           “(B) causation and risk factors associated  
2           with, and natural history of, congenital heart  
3           disease;

4           “(C) health care utilization by individuals  
5           with congenital heart disease;

6           “(D) demographic factors associated with  
7           congenital heart disease, such as age, race, eth-  
8           nicity, sex, and family history of individuals  
9           who are diagnosed with the disease; and

10          “(E) evidence-based practices related to care  
11          and treatment for individuals with congenital  
12          heart disease.

13          “(2) *PERMISSIBLE CONSIDERATIONS.*—In car-  
14          rying out the activities under this section, the Sec-  
15          retary may, as appropriate—

16               “(A) collect data on the health outcomes, in-  
17               cluding behavioral and mental health outcomes,  
18               of a diverse population of individuals of all ages  
19               with congenital heart disease, such that analysis  
20               of the outcomes will inform evidence-based prac-  
21               tices for individuals with congenital heart dis-  
22               ease; and

23               “(B) consider health disparities among in-  
24               dividuals with congenital heart disease, which



1           *may include the consideration of prenatal expo-*  
2           *sure.*

3           “(c) *AWARENESS CAMPAIGN.—The Secretary may*  
4           *carry out awareness and educational activities related to*  
5           *congenital heart disease in individuals of all ages, which*  
6           *may include information for patients, family members, and*  
7           *health care providers, on topics such as the prevalence of*  
8           *such disease, the effect of such disease on individuals of all*  
9           *ages, and the importance of long-term, specialized care for*  
10          *individuals with such disease.*

11          “(d) *PUBLIC ACCESS.—The Secretary shall ensure*  
12          *that, subject to subsection (e), information collected under*  
13          *this section is made available, as appropriate, to the public,*  
14          *including researchers.*

15          “(e) *PATIENT PRIVACY.—The Secretary shall ensure*  
16          *that the data and information collected under this section*  
17          *are made available in a manner that, at a minimum, pro-*  
18          *tects personal privacy to the extent required by applicable*  
19          *Federal and State law.*

20          “(f) *ELIGIBILITY FOR GRANTS.—To be eligible to re-*  
21          *ceive a grant under subsection (a)(3), an entity shall—*

22                  “(1) *be a public or private nonprofit entity with*  
23                  *specialized experience in congenital heart disease; and*

1           “(2) submit to the Secretary an application at  
2           such time, in such manner, and containing such in-  
3           formation as the Secretary may require.

4           “(g) *AUTHORIZATION OF APPROPRIATIONS.*—To carry  
5 out this section, there are authorized to be appropriated  
6 such sums as may be necessary for each of fiscal years 2019  
7 through 2023.”.

8 **SEC. 3. REPORT.**

9           Not later than 3 years after the date of enactment of  
10 the Congenital Heart Futures Reauthorization Act of 2017,  
11 the Secretary of Health and Human Services shall submit  
12 to the Committee on Health, Education, Labor, and Pen-  
13 sions of the Senate and the Committee on Energy and Com-  
14 merce of the House of Representatives a report summarizing  
15 any activities carried out pursuant to section 399V–2 of  
16 the Public Health Service Act (as amended by section 2),  
17 including planned activities, and a summary of any re-  
18 search findings and ongoing research efforts, gaps, and  
19 areas of greatest need within the Department of Health and  
20 Human Services regarding congenital heart disease in pa-  
21 tients of all ages.



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To amend the Public Health Service Act to coordinate Federal congenital heart disease research efforts and to improve public education and awareness of congenital heart disease, and for other purposes.

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August 15, 2018

Reported with an amendment