115TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
115–329

CONGENITAL HEART FUTURES REAUTHORIZATION ACT OF 2017

SEPTEMBER 25, 2017.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 1222]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1222) 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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

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 "Congenital Heart Futures Reauthorization Act of 2017".

SEC. 2. NATIONAL CONGENITAL HEART DISEASE SURVEILLANCE SYSTEM.

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

"SEC. 399V–2. NATIONAL CONGENITAL HEART DISEASE RESEARCH, SURVEILLANCE, AND AWARENESS.

"(a) IN GENERAL.—The Secretary shall—

"(1) enhance and expand research and surveillance infrastructure to study and track the epidemiology of congenital heart disease (in this section referred to as 'CHD'); and

"(2) award grants to eligible entities to undertake the activities described in this section.

"(b) NATIONAL CONGENITAL HEART DISEASE STUDY.—

"(1) IN GENERAL.—The Secretary shall plan, develop, implement, and submit one or more reports to the Congress on a study to improve understanding of the epidemiology of CHD across the lifespan, from birth to adulthood, with particular interest in the following:

"(A) Health care utilization of those affected by CHD.

"(B) Demographic factors associated with CHD, such as age, race, ethnicity, gender, and family history of individuals who are diagnosed with the disease.

"(C) Outcome measures, such that analysis of the outcome measures will allow derivation of evidence-based best practices and guidelines for CHD patients.

"(2) PERMISSIBLE CONSIDERATIONS.—The study under this subsection may—

"(A) gather data on the health outcomes of a diverse population of those affected by CHD;

"(B) consider health disparities among those affected by CHD, which may include the consideration of prenatal exposures; and

"(C) incorporate behavioral, emotional, and educational outcomes of those affected by CHD.

"(3) PUBLIC ACCESS.—Data generated from the study under this subsection shall be made available—

"(A) for purposes of CHD research, subject to appropriate protections of personal privacy, including protections required by paragraph (4); and

"(B) to the public, subject to paragraph (4) and with appropriate exceptions for protection of personal privacy.

"(4) PATIENT PRIVACY.—The Secretary shall ensure that the study under this subsection is carried out in a manner that complies with the requirements applicable to a covered entity under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(c) ELIGIBILITY FOR GRANTS.—To be eligible to receive a grant under subsection (a)(2), an entity shall—

"(1) be a public or private nonprofit entity with specialized experience in CHD; and

"(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $4,000,000 for each of fiscal years 2018 through 2022.".

SEC. 3. CONGENITAL HEART DISEASE RESEARCH.

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

"SEC. 425. CONGENITAL HEART DISEASE.

"(a) IN GENERAL.—The Director of the Institute may expand, intensify, and coordinate research and related activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

"(1) causation of congenital heart disease, including genetic causes;

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

"(3) diagnosis, treatment, and prevention;

"(4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and

"(5) identifying barriers to lifelong care for individuals with congenital heart disease.

"(b) COORDINATION OF RESEARCH ACTIVITIES.—The Director of the Institute may coordinate research efforts related to congenital heart disease among multiple research institutions and may develop research networks.

"(c) MINORITY AND MEDICALLY UNDERSERVED COMMUNITIES.—In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.

"(d) REPORT FROM NIH.—Not later than one year after the date of the enactment of the Congenital Heart Futures Reauthorization Act of 2017, the Director of NIH, acting through the Director of the Institute, shall provide a report to Congress—

"(1) outlining the ongoing research efforts of the National Institutes of Health regarding congenital heart disease; and

"(2) identifying—

"(A) future plans for research regarding congenital heart disease; and

"(B) the areas of greatest need for such research.".

PURPOSE AND SUMMARY

H.R. 1222 was introduced on May 11, 2017, by Rep. Gus Bilirakis (R–FL). The bill reauthorizes research and surveillance efforts to study and track congenital heart disease (CHD). It enhances current activities at the Centers for Disease Control and Prevention, awards grants to further study CHD, and directs the National Institutes of Health to report on their ongoing research efforts in this space.

BACKGROUND AND NEED FOR LEGISLATION

Congenital heart diseases (CHDs) are defects in the structure and function of the heart that disrupt the flow of blood through the heart. These defects range from simple to severe and life threatening. CHDs are the most common birth defect and the leading cause of infant mortality. Although the causes of CHDs among most infants are unknown, according to the CDC, at least 15 percent of all CHDs are associated with genetic conditions. Indeed, CHD is prevalent in individuals with Down syndrome; approximately half of all infants born with Down syndrome have cardiovascular defects.

Although advances in medical care permit adults and children with CHD to lead longer and healthier lives, disease management—especially in critical cases—still requires a lifetime of specialized cardiac care. Accurately tracking the prevalence, further understanding the causes, and identifying novel treatments will improve the lives of those living with CHD and decrease the risk of birth defects in the future.

COMMITTEE ACTION

During the 114th Congress, on September 8, 2016, the Subcommittee on Health held a hearing on H.R. 3952, which was substantially similar to H.R. 1222. 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. 1222, as amended, 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. 1222, as amended, 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. 1222 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. 1222 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. 1222, the Congenital Heart Futures Reauthorization 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.

Enclosure.

H.R. 1222—Congenital Heart Futures Reauthorization Act of 2017

Summary: H.R. 1222 would direct the Secretary of Health and Human Services (HHS), through the Centers for Disease Control and Prevention (CDC), to enhance surveillance capabilities to track the epidemiology of congenital heart disease (CHD) and to provide grants to study the epidemiology of CHD across the lifespan. In addition, the legislation would require the Secretary to produce a report to Congress on CHD that includes information on the demographics and health care utilization of individuals with the disease. H.R. 1222 would authorize the appropriation of a total of $20 million for fiscal years 2018 through 2022 to carry out those activities. Additionally, the bill would reauthorize research on CHD at the National Institutes of Health (NIH) and would require NIH to produce a report on its research efforts on CHD. CBO estimates that implementing all the provisions in H.R. 1222 would cost $131 million over the 2018–2022 period, assuming appropriation of the necessary and specified amounts. Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

CBO estimates that enacting H.R. 1222 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

H.R. 1222 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 1222 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—						
	2017	2018	2019	2020	2021	2022	2017–2022
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
Estimated Authorization Level	0	4	4	4	115	118	246
Estimated Outlays	0	2	4	4	30	93	131

Note: Components may not add to totals because of rounding.

Basis of estimate: H.R. 1222 would direct the Secretary of HHS to enhance surveillance capabilities, create a public education campaign, and provide grants to study congenital heart disease. In 2017, $4 million was authorized for those activities at CDC related to CHD. The bill would require CDC to build upon current activities by expanding surveillance activities and providing a report to Congress that examines CHD epidemiology focusing on demographics, healthcare utilization, and outcome measures. H.R. 1222 would authorize $4 million for each of fiscal years 2018 through 2022 to carry out those activities. Based on historical spending for similar activities, CBO estimates that implementing those provisions would cost $17 million over the 2018–2022 period, primarily for additional staff and other administrative costs.

The bill would also reauthorize NIH to conduct research on CHD and would require NIH to report on those efforts. Under current law, research at NIH is authorized through fiscal year 2020. In fiscal year 2016, NIH supported about $111 million in research on CHD. Although H.R. 1222 does not specify an authorized amount

for that research, CBO expects that NIH would devote similar amounts of resources in fiscal years 2021 and 2022. Based on historical spending for similar activities, CBO estimates that subject to appropriation of the necessary amounts, implementing those provisions would cost $115 million over the 2018–2022 period, primarily for research on CHD in 2021 and 2022.

Pay-As-You-Go Considerations: None.

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 1222 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

Intergovernmental and private-sector impact: H.R. 1222 contains no intergovernmental or private-sector mandates as defined in UMRA.

Estimate prepared by: Federal Costs: Rebecca Yip, Ellen Werble; Impact on state, local, and tribal governments: Zachary Byrum; Impact on the private sector: Amy Petz.

Estimate 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 enhance and further coordinate CHD research, surveillance, and outreach initiatives in order to better understand the epidemiology of CHD from birth to adulthood and to identify CHD causes, outcomes, treatments, and barriers to care.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 1222 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. 1222 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. 1222 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

Section 1 provides that the Act may be cited as the "Congenital Heart Futures Reauthorization Act of 2017."

Section 2. National Congenital Heart Disease Surveillance System

Section 2 authorizes the appropriation of $4 million for each of fiscal years 2018 to 2022 for the Secretary to enhance and expand research and surveillance efforts in order to study and track the epidemiology, health disparities, and health outcomes of congenital heart disease.

Section 3. Congenital heart disease research

Section 3 authorizes the Director of the National Institutes of Health to expand, intensify, and coordinate research with respect to congenital heart disease.

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 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–2. NATIONAL CONGENITAL HEART DISEASE SURVEILLANCE SYSTEM.

[(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

[(1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into a nationally-representative, population-based surveillance system that compiles data concerning actual occurrences of congenital heart disease, to be known as the "National Congenital Heart Disease Surveillance System"; or

[(2) award a grant to one eligible entity to undertake the activities described in paragraph (1).

[(b) PURPOSE.—The purpose of the Congenital Heart Disease Surveillance System shall be to facilitate further research into the types of health services patients use and to identify possible areas for educational outreach and prevention in accordance with standard practices of the Centers for Disease Control and Prevention.

[(c) CONTENT.—The Congenital Heart Disease Surveillance System—

[(1) may include information concerning the incidence and prevalence of congenital heart disease in the United States;

[(2) may be used to collect and store data on congenital heart disease, including data concerning—

[(A) demographic factors associated with congenital heart disease, such as age, race, ethnicity, sex, and family history of individuals who are diagnosed with the disease;

[(B) risk factors associated with the disease;

[(C) causation of the disease;

[(D) treatment approaches; and

[(E) outcome measures, such that analysis of the outcome measures will allow derivation of evidence-based best practices and guidelines for congenital heart disease patients; and

[(3) may ensure the collection and analysis of longitudinal data related to individuals of all ages with congenital heart disease, including infants, young children, adolescents, and adults of all ages.

[(d) PUBLIC ACCESS.—The Congenital Heart Disease Surveillance System shall be made available to the public, as appropriate, including congenital heart disease researchers.

[(e) PATIENT PRIVACY.—The Secretary shall ensure that the Congenital Heart Disease Surveillance System is maintained in a manner that complies with the regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996.

[(f) ELIGIBILITY FOR GRANT.—To be eligible to receive a grant under subsection (a)(2), an entity shall—

[(1) be a public or private nonprofit entity with specialized experience in congenital heart disease; and

[(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.]

SEC. 399V–2. NATIONAL CONGENITAL HEART DISEASE RESEARCH, SURVEILLANCE, AND AWARENESS.

(a) IN GENERAL.—The Secretary shall—

(1) enhance and expand research and surveillance infrastructure to study and track the epidemiology of congenital heart disease (in this section referred to as "CHD"); and

(2) award grants to eligible entities to undertake the activities described in this section.

(b) NATIONAL CONGENITAL HEART DISEASE STUDY.—

(1) IN GENERAL.—The Secretary shall plan, develop, implement, and submit one or more reports to the Congress on a study to improve understanding of the epidemiology of CHD across the lifespan, from birth to adulthood, with particular interest in the following:

(A) Health care utilization of those affected by CHD.

(B) Demographic factors associated with CHD, such as age, race, ethnicity, gender, and family history of individuals who are diagnosed with the disease.

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

(2) PERMISSIBLE CONSIDERATIONS.—The study under this subsection may—

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

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

(C) incorporate behavioral, emotional, and educational outcomes of those affected by CHD.

(3) PUBLIC ACCESS.—Data generated from the study under this subsection shall be made available—

(A) for purposes of CHD research, subject to appropriate protections of personal privacy, including protections required by paragraph (4); and

(B) to the public, subject to paragraph (4) and with appropriate exceptions for protection of personal privacy.

(4) PATIENT PRIVACY.—The Secretary shall ensure that the study under this subsection is carried out in a manner that complies with the requirements applicable to a covered entity under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

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

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $4,000,000 for each of fiscal years 2018 through 2022.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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Subpart 2—National Heart, Lung, and Blood Institute

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[SEC. 425. CONGENITAL HEART DISEASE.

[(a) IN GENERAL.—The Director of the Institute may expand, intensify, and coordinate research and related activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

[(1) causation of congenital heart disease, including genetic causes;

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

[(3) diagnosis, treatment, and prevention;

[(4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and

[(5) identifying barriers to life-long care for individuals with congenital heart disease.

[(b) COORDINATION OF RESEARCH ACTIVITIES.—The Director of the Institute may coordinate research efforts related to congenital heart disease among multiple research institutions and may develop research networks.

[(c) MINORITY AND MEDICALLY UNDERSERVED COMMUNITIES.—In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.]

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the Institute shall consider the application of such research and other activities to minority and medically underserved communities.

(d) REPORT FROM NIH.—Not later than one year after the date of the enactment of the Congenital Heart Futures Reauthorization Act of 2017, the Director of NIH, acting through the Director of the Institute, shall provide a report to Congress—

(1) outlining the ongoing research efforts of the National Institutes of Health regarding congenital heart disease; and

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

(B) the areas of greatest need for such research.

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