

116TH CONGRESS  
2D SESSION

# H. R. 6166

To amend the Public Health Service Act to authorize and support the creation and dissemination of cardiomyopathy education, awareness, and risk assessment materials and resources to identify more at-risk families, to authorize research and surveillance activities relating to cardiomyopathy, and for other purposes.

---

## IN THE HOUSE OF REPRESENTATIVES

MARCH 10, 2020

Mr. KIM (for himself and Mr. BARR) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## A BILL

To amend the Public Health Service Act to authorize and support the creation and dissemination of cardiomyopathy education, awareness, and risk assessment materials and resources to identify more at-risk families, to authorize research and surveillance activities relating to cardiomyopathy, 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 “Cardiomyopathy  
5 Health Education, Awareness, Research, and Training in  
6 the Schools Act of 2020” or the “HEARTS Act of 2020”.

1 **SEC. 2. MATERIALS AND RESOURCES TO INCREASE EDU-**  
2 **CATION AND AWARENESS OF CARDIO-**  
3 **MYOPATHY AMONG SCHOOL ADMINISTRA-**  
4 **TORS, EDUCATORS, AND FAMILIES.**

5 Part P of title III of the Public Health Service Act  
6 (42 U.S.C. 280g et seq.) is amended by adding at the end  
7 the following new section:

8 **“SEC. 399V-7. MATERIALS AND RESOURCES TO INCREASE**  
9 **EDUCATION AND AWARENESS OF CARDIO-**  
10 **MYOPATHY AMONG SCHOOL ADMINISTRA-**  
11 **TORS, EDUCATORS, AND FAMILIES.**

12 “(a) MATERIALS AND RESOURCES.—Not later than  
13 18 months after the date of the enactment of this section,  
14 the Secretary, in conjunction with the Director of the Cen-  
15 ters for Disease Control and Prevention (in this section  
16 referred to as the ‘Director’) shall develop public education  
17 materials and resources to be disseminated to school ad-  
18 ministrators, educators, school health professionals, coach-  
19 es, families, guardians, caregivers, and other appropriate  
20 individuals. The materials and resources shall include—

21 “(1) background information to increase edu-  
22 cation and awareness of cardiomyopathy among  
23 school administrators, educators, and families;

24 “(2) guidelines regarding the placement of  
25 automated external defibrillators in schools, early

1 childhood education programs, and child care cen-  
2 ters;

3 “(3) training information on automated exter-  
4 nal defibrillators and cardiopulmonary resuscitation;  
5 and

6 “(4) recommendations for how schools, early  
7 childhood education programs, and child care centers  
8 can develop and implement a cardiac emergency re-  
9 sponse plan.

10 “(b) DISSEMINATION OF MATERIALS AND RE-  
11 SOURCES.—Not later than 30 months after the date of  
12 the enactment of this section, the Secretary, through the  
13 Director, shall disseminate the materials and resources de-  
14 veloped under subsection (a) in accordance with the fol-  
15 lowing:

16 “(1) DISTRIBUTION BY STATE EDUCATIONAL  
17 AGENCIES.—The Secretary shall make available such  
18 materials and resources to State educational agen-  
19 cies to distribute—

20 “(A) to school administrators, educators,  
21 school health professionals, coaches, families,  
22 guardians, caregivers, and other appropriate in-  
23 dividuals, the cardiomyopathy education and  
24 awareness materials and resources developed  
25 under subsection (a)(1);

1           “(B) to parents, guardians, or other care-  
2           givers, the risk assessment for individuals with  
3           or at risk for cardiomyopathy developed pursu-  
4           ant to section 399V–8(b)(1); and

5           “(C) to school administrators, educators,  
6           school health professionals, and coaches—

7                   “(i) the guidelines described in sub-  
8                   section (a)(2);

9                   “(ii) the training information de-  
10                  scribed in subsection (a)(3); and

11                  “(iii) the recommendations described  
12                  in subsection (a)(4).

13           “(2) DISSEMINATION TO HEALTH DEPART-  
14           MENTS AND PROFESSIONALS.—The Secretary shall  
15           make available the materials and resources devel-  
16           oped under subsection (a) to State and local health  
17           departments, pediatricians, hospitals, and other  
18           health professionals, such as nurses and first re-  
19           sponders.

20           “(3) POSTING ON WEBSITE.—

21                   “(A) CDC.—

22                           “(i) IN GENERAL.—The Secretary,  
23                           through the Director, shall post the mate-  
24                           rials and resources developed under sub-  
25                           section (a) on the public internet website

1 of the Centers for Disease Control and  
2 Prevention.

3 “(ii) ADDITIONAL INFORMATION.—

4 The Director is encouraged to maintain on  
5 such public internet website such addi-  
6 tional information regarding cardio-  
7 myopathy as deemed appropriate by the  
8 Director.

9 “(B) STATE EDUCATIONAL AGENCIES.—

10 State educational agencies are encouraged to  
11 create public internet webpages dedicated to  
12 cardiomyopathy and post the materials and re-  
13 sources developed under subsection (a) on such  
14 webpages.

15 “(c) DEFINITIONS.—In this section:

16 “(1) The term ‘school administrator’ means a  
17 principal, director, manager, or other supervisor or  
18 leader within an elementary school, secondary  
19 school, State-based early childhood education pro-  
20 gram, or child care center.

21 “(2) The term ‘school health professional’  
22 means a health professional serving at an elemen-  
23 tary school, secondary school, State-based early  
24 childhood education program, or child care center.

1           “(3) The terms ‘early childhood education pro-  
2           gram’, ‘elementary school’, and ‘secondary school’  
3           have the meanings given to those terms in section  
4           8101 of the Elementary and Secondary Education  
5           Act of 1965.

6           “(d) AUTHORIZATION OF APPROPRIATIONS.—For  
7           carrying out this section and section 399V–8, there is au-  
8           thorized to be appropriated \$1,000,000 for each of fiscal  
9           years 2021 through 2025.”.

10 **SEC. 3. RESEARCH AND SURVEILLANCE ACTIVITIES RELAT-**  
11 **ING TO CARDIOMYOPATHY.**

12           (a) CDC RESEARCH AND SURVEILLANCE.—Part P  
13           of title III of the Public Health Service Act (42 U.S.C.  
14           280g et seq.), as amended by section 2, is further amended  
15           by adding at the end the following new section:

16 **“SEC. 399V–8. RESEARCH AND SURVEILLANCE ACTIVITIES**  
17 **RELATING TO CARDIOMYOPATHY.**

18           “(a) REPORTS ON CDC NATIONAL CARDIO-  
19           MYOPATHY SURVEILLANCE RESEARCH ACTIVITIES.—

20           “(1) INITIAL REPORT.—Not later than June 1,  
21           2021, the Secretary, acting through the Director of  
22           the Centers for Disease Control and Prevention,  
23           shall submit to Congress an initial report on find-  
24           ings and data generated from surveillance and re-  
25           search activities conducted by the Centers for Dis-

1 ease Control and Prevention to improve the under-  
2 standing of the prevalence and epidemiology of car-  
3 diomyopathy across the lifespan, from birth to adult-  
4 hood, with particular interest in the following:

5 “(A) The health care costs, utilization, and  
6 natural history of individuals with cardio-  
7 myopathy, in both the pediatric and adult popu-  
8 lation.

9 “(B) The number of adults and children  
10 affected by cardiomyopathy, as well as age-spe-  
11 cific mortality.

12 “(2) FINAL REPORT.—Not later than January  
13 1, 2026, the Secretary, acting through the Director  
14 of the Centers for Disease Control and Prevention,  
15 shall submit to Congress a final report on the con-  
16 tent described in paragraph (1).

17 “(3) PUBLIC ACCESS.—Subject to paragraph  
18 (4), the reports submitted under this subsection  
19 shall be made available to the public.

20 “(4) PATIENT PRIVACY.—The Secretary shall  
21 ensure that this subsection is carried out in a man-  
22 ner that complies with the requirements applicable  
23 to a covered entity under the regulations promul-  
24 gated pursuant to section 264(c) of the Health In-  
25 surance Portability and Accountability Act of 1996.

1       “(b) IMPROVING RISK ASSESSMENTS FOR INDIVID-  
2 UALS WITH CARDIOMYOPATHY.—

3           “(1) IN GENERAL.—The Secretary, acting  
4 through the Director of the Centers for Disease  
5 Control and Prevention, shall develop and make pub-  
6 licly available a risk assessment for individuals with  
7 or at risk for cardiomyopathy. Such risk assessment  
8 shall, at a minimum, include the following:

9           “(A) Background information of the preva-  
10 lence, incidence, and health impact of cardio-  
11 myopathy, including all forms of cardio-  
12 myopathy and their effects on pediatric, adoles-  
13 cent, and adult individuals.

14           “(B) A worksheet with variables and con-  
15 ditions for an individual or health care provider  
16 to use in assessing whether the individual is at  
17 risk for cardiomyopathy.

18           “(C) A worksheet with variables and  
19 stages of progression for an individual or health  
20 care provider to use in assessing whether and to  
21 what extent cardiomyopathy has progressed in  
22 the individual.

23           “(D) Guidelines on cardiomyopathy  
24 screenings for individuals who are at risk for,  
25 or have a family history of, cardiomyopathy.



1           “(2) STAKEHOLDER INPUT.—In carrying out  
2 paragraph (1), the Director of the Centers for Dis-  
3 ease Control and Prevention shall seek input from  
4 external stakeholders including—

5                   “(A) representatives from national patient  
6 advocacy organizations expert in all forms of  
7 cardiomyopathy;

8                   “(B) representatives from medical profes-  
9 sional societies that specialize in the care of  
10 adults and pediatrics with cardiomyopathy; and

11                   “(C) representatives from other relevant  
12 Federal agencies.

13           “(c) CARDIOMYOPATHY DEFINED.—For purposes of  
14 this section, the term ‘cardiomyopathy’ means a heart dis-  
15 ease that affects the heart’s muscle (myocardium)—

16                   “(1) the symptoms of which may vary from  
17 case to case, including—

18                           “(A) cases in which no symptoms are  
19 present (asymptomatic); and

20                           “(B) cases in which there are symptoms of  
21 a progressive condition that may result from an  
22 impaired ability of the heart to pump blood,  
23 such as fatigue, irregular heartbeats (arrhyth-  
24 mia), heart failure, and, potentially, sudden car-  
25 diac death; and

1           “(2) the recognized types of which include di-  
2           lated, hypertrophic, restrictive, arrhythmogenic right  
3           ventricular dysplasia, and left ventricular non-com-  
4           paction.”.

5           (b) FEDERAL WORKING GROUP.—

6           (1) IN GENERAL.—Not later than one year  
7           after the date of the enactment of this Act, the Sec-  
8           retary of Health and Human Services shall convene  
9           an interdisciplinary working group for the purpose  
10          of expanding cardiomyopathy research.

11          (2) DUTIES.—The working group shall—

12           (A) develop a research strategy to address  
13           the gaps in knowledge on the molecular and ge-  
14           netic causes of cardiomyopathy in children;

15           (B) identify approaches that could result  
16           in the development of preventive and disease-di-  
17           rected therapies specific to pediatric cardiomy-  
18           opathies and heart failure; and

19           (C) explore novel clinical trial methodolo-  
20           gies and end points in an effort to optimize suc-  
21           cessful completion of clinical trials in this rare  
22           patient population.

23          (3) MEMBERSHIP.—The Secretary shall appoint  
24          to the working group members representing a range  
25          of stakeholders outside of the Federal Government

1 with subject matter expertise relating to cardio-  
2 myopathy, including—

3 (A) pediatric cardiologists with expertise in  
4 the diagnosis and treatment of children with  
5 cardiomyopathies and heart failure and clinical  
6 trials related to the pediatric population;

7 (B) geneticists with expertise in pediatric  
8 cardiomyopathy and heart failure;

9 (C) cardiovascular molecular biologists;

10 (D) pharmacologists;

11 (E) research scientists with expertise in  
12 cardiomyopathy and heart failure; and

13 (F) other stakeholders with relevant exper-  
14 tise, as determined by the Secretary.

15 (4) REPORT TO CONGRESS.—Not later than 2  
16 years after the date of the enactment of this Act, the  
17 Working Group shall publish and submit to Con-  
18 gress a report that contains—

19 (A) a description of the activities of the  
20 working group;

21 (B) the findings and recommendations of  
22 the working group with respect to each of the  
23 topics described in paragraph (2); and

24 (C) the recommendations of the working  
25 group relating to actions that Federal agencies

1 and Congress can take to implement the rec-  
2 ommendations described in subparagraph (B).

3 (5) NO COMPENSATION.—A member of the  
4 working group shall serve without compensation.

5 (6) TERMINATION.—The working group shall  
6 terminate on the date on which the working group  
7 submits the report under paragraph (4).

8 (7) CARDIOMYOPATHY DEFINED.—For pur-  
9 poses of this subsection, the term “cardiomyopathy”  
10 means a heart disease that affects the heart’s muscle  
11 (myocardium)—

12 (A) the symptoms of which may vary from  
13 case to case, including—

14 (i) cases in which no symptoms are  
15 present (asymptomatic); and

16 (ii) cases in which there are symptoms  
17 of a progressive condition that may result  
18 from an impaired ability of the heart to  
19 pump blood, such as fatigue, irregular  
20 heartbeats (arrhythmia), heart failure,  
21 and, potentially, sudden cardiac death; and

22 (B) the recognized types of which include  
23 dilated, hypertrophic, restrictive, arrhythmogen-

- 1 ic right ventricular dysplasia, and left ventric-
- 2 ular non-compactation.

○