On December 23, 2024, President Biden signed H.R. 6829, the Cardiomyopathy Health Education, Awareness, and Research, and AED Training in the Schools Act of 2024 (the HEARTS Act) of 2024 into law. The new law establishes a series of programs and requirements relating to sudden heart issues, with a particular focus on children and youth.

269 Mill Road

Chelmsford, MA 01824

978.421.9655 (main)

978.421.0015 (fax)

zoll.com

Specifically, the law requires the Department of Health and Human Services (HHS) to disseminate information about cardiomyopathy and the use of automated external defibrillators (AEDs) to certain school professionals, families, and others, and it must develop specified risk assessment tools for cardiomyopathy for clinicians and individuals. In addition, the Centers for Disease Control and Prevention (CDC) is required to report on certain research and surveillance activities, and the National Institutes of Health (NIH) must report on its research relating to cardiomyopathy. The act also establishes a grant program to provide cardiopulmonary resuscitation (CPR) training and AEDs in public schools.

The implementation timeline for the new law is largely over the next 18 – 30 months and will have an organizational period that will be driven by internal HHS planning, and then increasingly engaging outside stakeholders, such as the American Heart Association, the Smart Hearts Sports Coalition, the American College of Cardiology, the American Academy of Pediatrics, and others. During this time, Congress will also be working on annual funding bills for the entire government, in which they may include funding that will provide an indication of the level of financial support that HHS will have for implementing the provisions of the new law.

**HEARTS Act Overview:**

* Within 18 months (June of 2026), the Secretary of HHS, working with the Director of the CDC will develop educational materials and resources to be disseminated to school administrators, educators, school health professionals, coaches, families, guardians, caregivers, and other people. The materials will include:
  + Information on the signs, symptoms, and risk factors associated with high-risk cardiac conditions and genetic heart rhythm abnormalities that may cause sudden cardiac arrest in children, adolescents, and young adults. This includes cardiomyopathy; long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, and Wolff-Parkinson-White syndrome; and other high-risk cardiac conditions.
  + Guidelines regarding the placement of AEDs in schools, early childhood education programs, and childcare centers.
  + Training information on AEDs and CPR.
  + Recommendations for how schools, early childhood education programs, and childcare centers can develop and implement a cardiac emergency response plan.
* Within 30 months (June 2027), the Secretary of HHS will disseminate the materials and resources to State education agencies, so that they can distribute them to school administrators, educators, school health professionals, coaches, families, guardians, caregivers, and other appropriate individuals. This includes the cardiomyopathy risk assessment materials, the guidelines and training information, and the cardiac response plan recommendations.
* The Secretary of HHS will make the materials and resources available to state and local health departments, pediatricians, hospitals, and other health professionals, such as nurses and first responders.
* The Director of the CDC will post all the materials and resources on its public-facing website, and keep it updated with additional relevant cardiomyopathy information.
* State educational agencies are also encouraged to create public webpages dedicated to cardiomyopathy and post the materials and resources.

**Reporting**

* The law also requires the government to develop and issue a number of reports, including:
  + Within 18 months (June 2026), the CDC will submit a report to Congress (and make it publicly available) on the findings based on its existing activities to improve the understanding of the prevalence and epidemiology of cardiomyopathy across the lifespan, from birth to adulthood, with particular focus on the history of people with cardiomyopathy, in both pediatric and adult populations; and estimates of cardiomyopathy-related emergency department (ED) visits and hospitalizations, in both pediatric and adult populations.
  + Within 18 months (June 2026), the Secretary of HHS, along with the Director of the NIH, will submit a report to Congress and the public outlining the ongoing research efforts of the NIH regarding cardiomyopathy, and identifying a research agenda regarding adult forms of cardiomyopathy, plans for researching cardiomyopathy affecting the pediatric population, and the areas of greatest need for research.

**Risk Assessment and Screening**

* The Secretary of HHS will develop and make publicly available a cardiomyopathy risk assessment for health care providers and individuals. The risk assessment will include:
  + Background information on the prevalence, incidence, and health impact of cardiomyopathy, including all forms of cardiomyopathy and their effects on pediatric, adolescent, and adult populations.
  + A worksheet with variables and conditions for an individual or health care provider to use in assessing whether a person is at risk for cardiomyopathy.
  + A worksheet with variables and stages of progression for an individual or health care provider to use in assessing whether and to what extent cardiomyopathy has progressed in a person.
  + Guidelines on cardiomyopathy screenings for individuals who are at risk for, or have a family history of, cardiomyopathy.
* In developing the risk assessments and screening material, the Director of the CDC will seek input from external stakeholders, including representatives from national patient advocacy organizations, representatives from medical professional societies that specialize in the care of adults and pediatrics with cardiomyopathy; and representatives from other relevant Federal agencies.

**Research**

* The Secretary of HHS, in consultation with the Director of the NIH, may expand and coordinate research and related activities of the NIH with respect to cardiomyopathy, which may include research related to the causation of cardiomyopathy, including genetic causes and molecular biomarkers; long-term health outcomes in individuals with cardiomyopathy, including infants, children, teenagers, adults, and elderly people; and studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for people with cardiomyopathy. The Secretary will also try to ensure there is not duplication of research activities as a result of the new law.

**Grants for AEDs and CPR Training**

* The Secretary of HHS may award grants to eligible entities to develop and implement a comprehensive program to promote student access to AEDs and CPR in public elementary schools and secondary schools. An eligible entity receiving a grant may use funds to carry out any of the following activities:
  + Developing and providing comprehensive materials to establish AED and CPR programs in public elementary schools and secondary schools.
  + Providing support for CPR and AED training programs in those schools for students, staff, and related sports volunteers.
  + Providing support for developing a cardiac emergency response plan within schools.
  + Purchasing AEDs that have been approved by the Food and Drug Administration (FDA).
  + Purchasing necessary AED batteries and performing necessary AED maintenance (such as by replacing AED pads) in accordance with the labeling of the AED involved.
  + Replacing old and outdated AED and CPR equipment, machinery, and educational materials.
* To be eligible for a grant the requesting entity must be a local educational agency, (including a public charter school operating as a local educational agency under State law) in consultation with a qualified health care entity.
  + The term ‘qualified health care entity’ means a health care entity that is a public entity; or a nonprofit (there are specific sections of the IRS Code where this is defined, but in general sections 501(c) and 501(a) apply here); demonstrates an ability to develop, train, and implement a comprehensive program to promote student access to AEDs and CPR in public elementary and secondary schools; and is qualified in providing technical assistance in AED and CPR training.
* The new law does not expressly provide additional funding for any of these activities, nor does it “authorize” new funds. However, that is largely a legislative term of art in order to ensure that the bill did not come with an associated cost that would increase government spending and make passage more difficult politically. However, it does allow the Secretary of HHS to issue grants utilizing existing funding in other areas, or discretionary funding within HHS, the CDC, or other agencies and programs under its jurisdiction.