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Kevin M. Rodkey

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MEDICAL TECHNOLOGY MEETS THE MARYLAND GENERAL ASSEMBLY:
A CASE STUDY IN HANDLING ADVANCES IN AUTOMATED EXTERNAL DEFIBRILLATOR TECHNOLOGY

KEVIN M. RODKEY*

INTRODUCTION

Automated external defibrillators (AEDs) are medical devices that have the capability to save the lives of victims of sudden cardiac arrest.\(^1\) While AEDs have been available for over two decades,\(^2\) medical and technological advances over the past decade have resulted in AEDs becoming more publicly accessible.\(^3\) The growing availability of AEDs means they are increasingly used to treat victims of sudden cardiac arrest.\(^4\) While questions about who should use AEDs have been addressed extensively, there is still uncertainty as to whether AEDs should be required at public and private facilities.\(^5\) This Comment reviews the dangers of

\(1\) Tom Aufderheide et al., Community Lay Rescuer Automated External Defibrillation Programs: Key State Legislative Components and Implementation Strategies: A Summary of a Decade of Experience for Healthcare Providers, Policymakers, Legislators, Employers, and Community Leaders From the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy, 113 CIRCULATION 1260, 1260-61 (2006).


\(3\) Dawn B. Jorgenson et al., AED Use in Businesses, Public Facilities and Homes by Minimally Trained First Responders, 59 RESUSCITATION 225, 226 (2003).

\(4\) Aufderheide et al., supra note 1, at 1263.

sudden cardiac arrest and how AEDs function.\(^6\) It then examines the effectiveness of AEDs\(^7\) and the consequences of their widespread use.\(^8\) This Comment will also review the response of courts\(^9\) and legislatures\(^10\) to advances in AED technology to provide context for the legislation considered and enacted by the Maryland General Assembly.\(^11\) Next, this Comment uses Maryland as a case study to examine how one state responded to developments in AED technology and the scientific community’s understanding of the effectiveness of AEDs.\(^12\) Finally, this Comment critiques Maryland’s treatment of AEDs and recommends that Maryland continue to exercise prudence before imposing a duty on businesses to have AEDs on-site.\(^13\)

I. SUDDEN CARDIAC ARREST AND THE LIFE-SAVING POTENTIAL OF AEDS

A. How AEDs Combat the Dangers of Sudden Cardiac Arrest

Every year in the United States, more than 250,000 incidents of sudden cardiac arrest occur outside of hospitals.\(^14\) Many victims of sudden cardiac arrest experience ventricular fibrillation, an abnormal heart rhythm that prevents the heart from pumping blood effectively.\(^15\) Treatment of ventricular fibrillation requires delivery of a shock with a defibrillator, which stops the ventricular fibrillation and allows the heart rhythm to return to normal.\(^16\) For victims of ventricular fibrillation, "the single greatest determinant of survival is the time from collapse to defibrillation."\(^17\)

AEDs are "designed for use by lay rescuers and first responders to reduce time to defibrillation for victims of VF [ventricular fibrillation] sudden cardiac arrest."\(^18\) The user turns the AED on and places the pads on the victim’s chest.\(^19\) The AED analyzes the victim’s heart rhythm and determines whether a shock is

\(^6\) See infra Part I.A.
\(^7\) See infra Parts I.B, I.D.
\(^8\) See infra Part I.C.
\(^9\) See infra Part II.A.
\(^10\) See infra Part II.B.
\(^11\) See infra Parts III.A–B.
\(^12\) See infra Part III.
\(^13\) See infra Part IV.
\(^14\) Aufderheide et al., supra note 1, at 1261; Mary Ann Peberdy et al., Adverse Events Associated With Lay Emergency Response Programs: The Public Access Defibrillation Trial Experience, 70 RESUSCITATION 59, 60 (2006).
\(^15\) Aufderheide et al., supra note 1, at 1261.
\(^16\) Id.
\(^17\) Gary J. Balady et al., Automated External Defibrillators in Health/Fitness Facilities: Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities, 105 CIRCULATION 1147, 1147 (2002).
\(^18\) Aufderheide et al., supra note 1, at 1261.
\(^19\) Id.
needed to treat sudden cardiac arrest. If a shock is needed, a fully automated AED "can deliver the shock without further action by the user." "AEDs will deliver a shock only when VF [ventricular fibrillation] or its precursor, rapid ventricular tachycardia, is present and will not deliver a shock to a person with a normal heart rhythm."

B. The Effectiveness of AEDs in Improving Survival Rates for Sudden Cardiac Arrest Victims

Timely use of an AED significantly increases the chance of surviving sudden cardiac arrest. On average, only 6.4 percent of people who experience sudden cardiac arrest in the presence of a bystander survive to hospital discharge. The survival rate falls 7 percent to 10 percent for every minute that passes from collapse caused by ventricular fibrillation sudden cardiac arrest if no cardiopulmonary resuscitation (CPR) is provided. In most communities, the time between collapse from sudden cardiac arrest and the arrival of emergency medical service (EMS) personnel is seven to eight minutes or longer. If defibrillation is achieved within the first minutes for the victim of sudden cardiac arrest, the survival rate can be as high as 90 percent. When a victim of sudden cardiac arrest receives immediate bystander CPR and defibrillation within three to five minutes of collapse, rate of survival to hospital discharge ranges from 49 percent to 74 percent. However, AED programs that fail to shorten time to defibrillation and bystander CPR have not documented any improvement in survival rates.

Coordinated public access defibrillator (PAD) programs have proven successful in increasing the survival rate of victims of sudden cardiac arrest. PAD programs provide a way for the general public to provide early defibrillation using AEDs while awaiting the arrival of traditional EMS personnel.

20. See Balady et al., supra note 17, at 1147.
21. Aufderheide et al., supra note 1, at 1261.
23. See Aufderheide et al., supra note 1, at 1261–62; see also Hazinski et al., supra note 22, at 3337.
24. Aufderheide et al., supra note 1, at 1261.
25. Hazinski et al., supra note 22, at 3337. "When bystander CPR is provided, the fall in survival is more gradual and averages 3% to 4% per minute from collapse to defibrillation." Id.
26. Id.
27. Balady et al., supra note 17, at 1147.
28. Aufderheide et al., supra note 1, at 1261. These survival rates were reported by airports, commercial airlines, casinos, and community police AED programs. Id.
29. Id.
30. See Balady et al., supra note 17, at 1147–48; Hazinski et al., supra note 22, at 3337.
31. Peberdy et al., supra note 14, at 60.
programs were implemented in casinos and airlines, the sudden cardiac arrest survival rates to discharge from the hospital were 53 percent and 40 percent, respectively.\textsuperscript{32} Moreover, a PAD trial found that where only CPR was provided, 15 of 107 individuals experiencing definite cardiac arrest survived to hospital discharge whereas when CPR and defibrillation via an AED was provided, 30 of 128 victims survived to discharge.\textsuperscript{33} The increase in the number of survivors of sudden cardiac arrest who received CPR plus AED treatment compared with the number of survivors who received CPR alone was statistically significant.\textsuperscript{34}

C. Consequences of Widespread Use of AEDs

AEDs have been described as "highly accurate, user-friendly computerized devices with voice and audio prompts that guide the user through the critical steps of operation."\textsuperscript{35} Despite this description, as AEDs were deployed in more areas, concern grew about the potential negative consequences of widespread use of AEDs by lay people in emergency situations.\textsuperscript{36} One PAD trial, involving trained lay responders, found that "[a]dverse events were rare and consisted chiefly of stolen AEDs and transient psychological stress among rescuers."\textsuperscript{37} Another study of AED use by lay individuals who completed an AED training course found there were no patient- or volunteer-related adverse events.\textsuperscript{38} The study concluded that "trained lay rescuers can use modern generation shock-advisory AEDs effectively and safely."\textsuperscript{39}

Additional studies showed that minimally trained lay responders can also use AEDs safely and effectively. A study that compared AED usage by EMS personnel with untrained sixth grade students found that all participants properly and safely used the AED, with the sixth graders taking only modestly longer to deliver the shock than their EMS counterparts.\textsuperscript{40} In another study, AED use at businesses and public facilities by minimally trained first responders resulted in no instances of

\begin{itemize}
\item \textsuperscript{32} See Balady et al., supra note 17, at 1148.
\item \textsuperscript{33} Hazinski et al., supra note 22, at 3337.
\item \textsuperscript{34} \textit{Id.}
\item \textsuperscript{35} Aufderheide et al., supra note 1, at 1261.
\item \textsuperscript{36} See Jorgenson et al., supra note 3, at 226 (noting the lack of testing on the success of lay responders in using AEDs in public settings and hypothesizing that there would be no safety problems with their use).
\item \textsuperscript{37} Hazinski et al., supra note 22, at 3337–38.
\item \textsuperscript{38} Peberdy et al., supra note 14, at 60–62.
\item \textsuperscript{39} \textit{Id.}
\item \textsuperscript{40} See John W. Gundry et al., \textit{Comparison of Naïve Sixth-Grade Children with Trained Professionals in the Use of an Automated External Defibrillator}, 100 CIRCULATION 1703, 1706–07 (1999). The only instruction given to the sixth-graders was direction to identify the electrode pads, the necessity of peeling them from the packaging, and to place the pads on the mannequin’s chest. \textit{Id.} at 1704. The study found that it took the EMS personnel an average of sixty-seven seconds to setup the AED and apply a shock to a mannequin while it took the schoolchildren an average of ninety seconds. \textit{Id.} at 1705.
\end{itemize}
AED use causing harm or injuries to the patient, rescuer, or bystanders.\textsuperscript{41} The study noted two instances where AED pads were improperly applied to responsive patients, but the AED correctly assessed each patient's situation and did not deliver a shock.\textsuperscript{42} As indicated by research, AEDs are devices that can be used by lay responders to increase the survival rate for a victim of sudden cardiac arrest while not posing a significant risk to the user or the victim.

\subsection{D. Cost-Effectiveness of AEDs and Recommendations for Placement of AEDs}

While studies over the past decade have shown the benefits of AEDs and alleviated concerns about the potential hazards of lay people using AEDs, studies have also considered the cost-effectiveness of AEDs. As recently as 2003, the need for data on the cost-effectiveness of AEDs to determine where AEDs should be placed to save the most lives existed.\textsuperscript{43} Whether AEDs are cost-effective depends on society's willingness to pay for each quality-adjusted life year (QALY) gained from successful use of an AED and the relative benefit that AED deployment provides over improving traditional EMS response.\textsuperscript{44} A cost less than $50,000 per QALY may be accepted as cost-effective, but AEDs could also be considered cost-effective at $100,000 per QALY.\textsuperscript{45} The studies that address cost-effectiveness involve a number of variables including: the probability of AED use on arrest victim; the probability of surviving unimpaired; the life expectancy for arrest survivors; and the costs of AED purchase, maintenance, and training.\textsuperscript{46}

Research indicates that it is cost-effective to deploy AEDs in certain targeted public locations, but placing AEDs in all public facilities may not be justified.\textsuperscript{47} Early studies from the 1990s estimated that use of AEDs in urban centers "is

\begin{footnotes}
\footnote{41. Jorgenson et al., supra note 3, at 230.}
\footnote{42. Id. at 230–31.}
\footnote{43. See Andrew Walker et al., Cost Effectiveness and Cost Utility Model of Public Place Defibrillators in Improving Survival After Prehospital Cardiopulmonary Arrest, 327 BRIT. MED. J. 1316 (2003); Robert Davis, Young Spread the Word on Defibrillators, USA TODAY, Nov. 6, 2003, at 1OD.}
\footnote{44. Kristian B. Filion et al., Cost Effectiveness of Drug Eluting Stents Including the Economic Impact of Late Stent Thrombosis, 103 AM. J. CARDIOLOGY 338, 339 (2009); see also Peter Cram et al., Cost-effectiveness of Automated External Defibrillator Deployment in Selected Public Locations, 18 J. GEN. INTERNAL MED. 745, 750–51 & tbl.2 (2003). Quality-adjusted life years (QALY) are "utility measurements that compare health-related welfare based on quality and length of life . . . . A QALY is one life year weighted by the estimated quality of life after receiving a particular health care service." Ani B. Satz, The Limits of Health Care Reform, 59 ALA. L. REV. 1451, 1480–81 (2008). A QALY of $50,000 means that society would spend $50,000 installing and maintaining AEDs in a particular type of public forum (e.g., golf courses) for each quality year of life saved.}
\footnote{45. Filion et al., supra note 44, at 339.}
\footnote{46. Cram et al., supra note 44, at 747, 749 & tbl.3 (noting "key" variables used in cost-effectiveness studies).}
\footnote{47. E.g., id. at 751–52.}
\end{footnotes}
potentially economically attractive." Subsequent studies demonstrated that use of AEDs by lay responders could be cost-effective where sudden cardiac arrest is frequent and lay responders provide prompt treatment. The studies also concluded that deploying public access AEDs in areas with low cardiac arrest rates or where there is little difference in time to defibrillation between EMS personnel and on-the-scene responders is unlikely to be cost-effective. More than one study indicates that it would be cost-effective to place AEDs at international airports and it may be cost-effective to place AEDs at public sports venues, golf courses, and jails. Health clubs and large shopping malls are at the outer limits of what could be considered cost-effective for having an AED on-site, while having an AED at a hotel, restaurant, or industrial site generally would not be cost-effective.

Based on the available research, the American Heart Association, in collaboration with the International Liaison Committee on Resuscitation, developed guidelines to recommend where public access AEDs should be located. Current guidelines recommend a public access AED program if (1) a sudden cardiac arrest is likely to occur within five years, (2) there is a population present that has an elevated risk of sudden cardiac arrest, or (3) a low likelihood that EMS can provide defibrillation within five minutes. Further, the American Heart Association encourages all health and fitness facilities to have AEDs, but only strongly encourages placement at facilities with more than 2,500 members or where EMS response time is anticipated to be greater than five minutes. Likewise, academic literature recommends that public access AEDs should be considered for some schools but that "blanket coverage of all schools would not meet traditional levels of cost-effectiveness."

49. Graham Nichol et al., Cost Effectiveness of Defibrillation by Targeted Responders in a Public Setting, 108 CIRCULATION 697, 700 (2003); see Cram et al., supra note 44, at 751.
50. Nichol et al., supra note 49, at 700; see Cram et al., supra note 44, at 751.
51. See Cram et al., supra note 44, at 748 & tbl.2; Nichol et al., supra note 49, at 701 tbl.3 (stating the corrected starting estimates for the statistics for table three as below $100,000 per QALY for every location except one, see Corrections, 109 CIRCULATION 3256, 3256 (2004)).
52. Cram et al., supra note 44, at 748 & tbl.2; Nichol et al., supra note 49, at 701 tbl.3 (modified by Corrections, supra note 51, at 3256).
54. Id.; Katayoun Lotfi et al., Cardiac Arrest in Schools, 116 CIRCULATION 1374, 1378 (2007).
55. Balady et al., supra note 17, at 1148.
56. Lotfi et al., supra note 54, at 1378.
II. NATIONAL LEGAL RESPONSE TO THE DEVELOPMENT OF AEDS

A. Courts Are Reluctant to Impose a Legal Duty on Facilities to Provide Automated External Defibrillators

While the benefits of AEDs are documented, courts have generally refused to impose a common law duty on the owners of facilities to obtain and use AEDs. A Kansas court held that a company is not obligated to use an AED as part of rendering emergency care to an employee when a company nurse or emergency medical technician was not available.57 Ohio’s intermediate appellate court held that the managers of a swimming pool did not have a duty to have an AED nearby, despite expert testimony that having an AED on site would make the swimming pool area safer.58 Similarly, Florida’s intermediate appellate court held that there was “no common law or statutory duty that a business have an AED on its premises” and that a fitness center was not liable for failing to provide an AED.59 The court noted that even if there was a duty to provide first aid to business invitees, the obligation required no more assistance than could be provided by an untrained person and did not include CPR or using an AED.60

As justification for not imposing a duty on businesses, courts have deferred to the decisions of state legislatures.61 In Atcovitz v. Gulph Mills Tennis Club, a 2002 case before the Pennsylvania Supreme Court, the appellee claimed that the

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60. See id. at 559. The Court referred to the American Red Cross and American Heart Association’s Guidelines for First Aid, which include:
   calling for help: positioning a victim; administering medications to an acute asthma or anaphylactic reaction sufferer; ensuring that a seizure victim has an open airway; controlling a victim’s bleeding by applying pressure; irrigating and applying antibiotic ointment to wounds and abrasions; cooling thermal burns, covering blisters; assessing victims of electrocution; manually stabilizing the head of a blunt trauma victim so the head, neck and spine do not move and are kept in line; applying cold packs to soft-tissue injuries such as sprains and muscle contusions; rinsing an avulsed tooth with water and placing it in milk for transport to the dentist; snugly bandaging an elapid snakebite, immobilizing the bitten extremity and immediately getting medical help; warming a victim of hypothermia; removing a drowning victim from the water; calling the poison control center, safely removing chemicals, and irrigating a chemical burn site with water.
   Id.
61. See id. at 561–62 (noting that Florida’s Cardiac Arrest Survival Act does not require an AED to be placed in any building and holding that there is no common law or statutory duty that a business must have an AED); Rotolo v. San Jose Sports & Entm’t, LLC, 59 Cal. Rptr. 3d 770, 774–75 (Cal. Ct. App. 2007) (holding that the legislature has occupied the field of AED regulation and that imposing a duty to inform the public of the presence of AED would defeat the legislature’s purpose of promoting the widespread availability of AEDs); Atcovitz v. Gulph Mills Tennis Club, Inc., 812 A.2d 1218, 1223–24 (Pa. 2002) (holding that appellant did not have a duty to own an AED when the state legislature restricted who could own and operate an AED).
appellant, a tennis club, was negligent in failing to have an AED on hand because prompt use of an AED would have lessened his injuries from sudden cardiac arrest. In determining whether a duty existed, the court's analysis turned on "the overall public interest in the proposed solution." The court noted that AED training and use was highly regulated by statutes and regulations, and the court "must refrain from imposing additional requirements upon that legislation" where the legislature has "so thoroughly considered the statewide application and implications of a subject." The court based its ruling on the state law, which prohibited untrained individuals from using an AED.

In addition, the court discussed civil immunity for AED use under state law. Subsequent to plaintiff's incident at the tennis club, Pennsylvania enacted the AED Good Samaritan Act, which provides civil immunity for trained users of AEDs and requires expected users to complete training in the use of an AED. The court stated that "as an exception to that general rule, the AED Good Samaritan Act also provided immunity for untrained individuals who, in good faith, use an AED in an emergency as an ordinary, reasonably prudent individual would do under the same or similar circumstances." Notably, the court still held that "the existence of a civil immunity provision for Good Samaritans who use an AED in an emergency situation cannot impose a duty on a business establishment to acquire, maintain, and use such a devise on its premises."

B. State Legislatures and Congress Are Actively Regulating the Use of Automated External Defibrillators

With courts exercising deference, state legislatures control public policy regarding AEDs. By 2001, all 50 states had enacted AED laws or regulations. As of 2008, twelve states require AED placement in schools and eight states and the

63. Id. at 1223. The court focused on "the overall public interest in the proposed solution" as one of five factors the courts are to balance in determining whether a common law duty exists; the other four are "(1) the relationship between the parties; (2) the social utility of the actor's conduct; (3) the nature of the risk imposed and the foreseeability of the harm incurred; [and] (4) the consequences of imposing a duty upon the actor . . . ." Id. (citing Althaus ex rel. Althaus v. Cohen, 756 A.2d 1166, 1169 (Pa. 2000)).
64. Id.
65. Id.
66. Id. at 1224.
68. Atcovitz, 812 A.2d at 1224. The AED Good Samaritan Act defines "good faith" as including "a reasonable opinion that the immediacy of the situation is such that the use of an AED should not be postponed until emergency medical services personnel arrive or the person is hospitalized." 42 PA. CONS. STAT. ANN. § 8331.2(f).
69. Atcovitz, 812 A.2d at 1224.
District of Columbia require AED placement in health clubs.\textsuperscript{71} Forty-six states and the District of Columbia provide some form of civil immunity to trained users of AEDs.\textsuperscript{72} States that have enacted AED laws, either allowing lay persons to use AEDs or regulating the terms and conditions of AED use, tend to also have laws expanding the civil immunity protections for lay users of AEDs.\textsuperscript{73}

At the federal level, in 2000, President Clinton signed into law the Cardiac Arrest Survival Act, which required that the Secretary of Health and Human Services establish guidelines with respect to placing AEDs in federal buildings.\textsuperscript{74} It also provides civil immunity for authorized users of AEDs, but does not preempt state immunity laws.\textsuperscript{75} Congress then enacted the Community Access to Emergency Defibrillation Act of 2002, which authorized $25 million in federal grants for fiscal year 2003 for states and localities to purchase AEDs for public places where sudden cardiac arrest is likely to occur.\textsuperscript{76} States and localities may use the federal grant money to encourage private companies to purchase AEDs and to train employees in CPR and emergency defibrillation.\textsuperscript{77}

III. MARYLAND ALLOWS PUBLIC ACCESS TO AEDS AND CONSIDERS MANDATORY AED PLACEMENT AT PUBLIC FACILITIES

A. Maryland Law Evolved to Allow Greater Access to AEDs

The Maryland General Assembly first considered legislation on AEDs a decade ago. In 1999, Maryland enacted the Emergency Medical Services—Automated External Defibrillator Program Act ("Maryland AED Act").\textsuperscript{78} The Maryland AED Act allowed facilities to operate an AED if the facility met certain stringent requirements.\textsuperscript{79} The law required the facility to have a sponsoring physician, to register with the agency responsible for emergency medical services in the jurisdiction, and to comply with written protocols developed by an oversight

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\textsuperscript{71} Id. Colorado, Florida, Georgia, Illinois, Maryland, Michigan, Nevada, New York, Ohio, Pennsylvania, South Carolina, and Virginia require AEDs in school. Id. California, Illinois, Indiana, Massachusetts, Michigan, New Jersey, New York, Rhode Island and the District of Columbia require that health clubs have at least one AED. Id.

\textsuperscript{72} Id. The only states to not provide limited immunity for trained users in Good Samaritan statutes are Delaware, Maine, New Jersey, and Rhode Island. Id.

\textsuperscript{73} See generally id. (describing the AED laws, none of which have reduced immunity protections).


\textsuperscript{75} § 404, 114 Stat. at 2339.


\textsuperscript{77} § 312(a)(6), 116 Stat. at 635.


\textsuperscript{79} 1999 Md. Laws at 1719–20.
The Maryland AED Act also required the facility to ensure that each person who used an AED successfully completed a training course. If a facility met these statutory requirements, the Maryland AED Act protected the facility from civil liability “for any act or omission in the provision of automated external defibrillation.” The law also provided civil immunity to trained users over the age of eighteen who used an AED in good faith. The law did not provide immunity for acts that amounted to “gross negligence, willful or wanton misconduct, or intentionally tortious conduct.”

When the General Assembly considered the Maryland AED Act in 1999, the legislation had significant support. The Maryland State Medical Society, Maryland State Police, and the Maryland Institute for Emergency Medical Services Systems (MIEMSS) all supported the proposed legislation and saw it as a way to increase public access to AEDs. However, by 2005, these groups expressed frustration that current law did not make AEDs accessible enough. The Maryland State Police noted that the original legislation permitting public use of AEDs “was deliberately restrictive to prevent misuse and abuse of the units,” but the value of AEDs have been proven over time and “fears of misuse and abuse have not been realized.” In testimony before the General Assembly, the Maryland Institute for Emergency Medical Services stated that “Maryland’s AED law should be modified to remove restrictions that currently impede wider public access to AEDs for use in a sudden cardiac arrest.” In response, the General Assembly amended the Maryland AED Act when it enacted the Automated External Defibrillator Program Act (“AED

80. Id. at 1719.
81. Id. at 1720.
82. Id. at 1721.
83. Id. at 1720-21.
84. Id. at 1722.
Program Act") in 2005. The AED Program Act removed the prohibition against minors using an AED and removed the provision restricting the use of AEDs to authorized facilities. The legislation was supported by the Maryland Institute for Emergency Medical Services, the Maryland State Police, and the Professional Fire Fighters of Maryland because it expanded accessibility to AEDs "without greatly increasing the risk in their use." However, the General Assembly did not amend the civil immunity provision, which still required the individual to complete an AED training course and only provided immunity if the act or omission occurred at an authorized facility.

Continuing the trend of allowing greater access to AEDs, in 2008, Maryland overhauled its regulation of AEDs and civil immunity for AED users. The Public Access Automated External Defibrillator Program Act ("PAD Program Act") allowed widespread use of AEDs, while the Immunity from Liability Act extended the civil immunity provisions. The PAD Program Act removed the requirement that a facility must have a sponsoring physician but still required facilities to register with a regulatory board and to use an AED cleared for market by the Food and Drug Administration. The Immunity from Liability Act removed the requirements that the AED user must have successfully completed an AED training course and that the AED be used only at a registered facility. Thus, as of March 2009, Maryland law grants civil immunity to a person who (1) acts "in

89. 2005 Md. Laws at 1929, 1931.
91. Schwartz et al. Testimony, supra note 90.
97. During the 2009 Maryland legislative session, Delegate Lee introduced House Bill 1117 in the House of Delegates. H.D. 1117, 2009 Leg., 425th Sess. (Md. 2009). The bill proposed removing the requirement that a person using AED provide assistance in a reasonably prudent manner. Id. It also attempted to extend civil immunity to an individual who witnesses a sudden cardiac arrest emergency but fails to use an AED on the victim. Id. While the bill passed in the House of Delegates, the Senate did not vote on the bill; therefore, it failed during this session. Md. General Assembly, House Bill 1117 (2009), available at http://mlis.state.md.us/2009rs/billfile/hb1117.htm.
good faith while rendering automated external defibrillation to a person who is a victim or reasonably believed by the individual to be a victim of a sudden cardiac arrest”; (2) the aid “is provided in a reasonably prudent manner”; and (3) the aid is provided without compensation.  

B. The Maryland General Assembly Rejected Most Attempts to Require AEDs at Public Facilities

In addition to considering who may use AEDs, the General Assembly has also considered who must have AEDs. For example, in 2000, legislation was introduced in the House of Delegates to require an AED and a trained operator at certain facilities. The bill would have mandated AEDs be available at sports stadiums and horse race tracks where attendance exceeded 3,000 persons. Moreover, it would have required indoor concert halls, museums, shopping malls, train stations, health clubs, and correctional facilities to have an AED and trained operator regardless of the number of persons on the premises. Despite support from the Maryland Department of Health and Mental Hygiene and the Maryland Institute for Emergency Medical Services Systems, the House Committee on Environmental Matters issued an unfavorable report on the bill, which in effect guaranteed that the legislation would not be enacted. In part, the Committee was concerned about how state and local governments as well as small businesses would pay for providing AEDs and trained operators at the over 1,500 affected public and private facilities across Maryland.

In 2006, the debate on the High Schools—Automated External Defibrillator Program Act (“High Schools AED Act”) captured the tension between providing potentially life-saving medical equipment and recognizing that limited funding

100. Id.
101. Id.
should be used in a cost-effective manner. The High Schools AED Act requires each high school in Maryland to provide an AED on-site with a trained operator present at all school-sponsored athletic events. By 2006, eight of Maryland’s twenty-four counties had enacted AED programs in all high schools. The legislation requires the other sixteen jurisdictions to provide AEDs at a combined 142 public high schools at a cost of $2,000 to $4,000 per school. The Maryland Institute for Emergency Medical Services Systems supported the legislation, noting that between January 2001 and December 2004, twenty-five cardiac arrests occurred in Maryland schools, including ten at public high schools. However, the Maryland Association of Boards of Education and individual school districts opposed the legislation, calling it an unfunded mandate that eliminated local discretion over the allocation of limited dollars for student safety in favor of one product. Despite the costs associated with implementing an AED program in high schools and the opposition from school boards, the High Schools AED Act became the first legislation enacted in Maryland to require that specific facilities have AEDs.

While the House of Delegates took the lead in requiring AEDs in schools, in 2007, the Maryland Senate moved forward with legislation to require AEDs at swimming pools. As introduced, the Swimming Pools—Automated External Defibrillator Programs Study Act (“Swimming Pools AED Act”) would have required AEDs at all public pools, pools open for general admission to the public, or pools used by a camp, college, country club, or amusement park. However, this bill ignited the same debate over the costs versus benefits of AEDs. In support of the measure, the American Heart Association encouraged the establishment of AED programs, particularly in areas with high occupancy or a


109. Id. at 3.

110. 2006 Hearing on High Schools AED Act, supra note 106.

111. Id. (testimony of John R. Woolums, Esq., Maryland Association of Boards of Education).


114. Id. The bill would not have applied to a pool located “at a facility intended for the use of individuals staying at the facility, including a hotel or motel pool” or on residential property. Id.

large number of visitors.\footnote{Id. (testimony of Michaeleine Fedder, American Heart Association).} Similar to the concerns the school boards raised with the High Schools AED Act, the Maryland Association of Counties opposed the Swimming Pools AED Act, saying it imposed an unfunded mandate on county government and dictated how counties spend scarce resources for public safety.\footnote{Id. (testimony of the Maryland Association of Counties).} Yet, unlike the High Schools AED Act, the Swimming Pools AED Act was amended to only require a study of whether AEDs should be required at swimming pools.\footnote{Md. Gen. Assembly, Senate Bill 742 (2007), available at http://mlis.state.md.us/2007rs/billfile/sb0742.htm.} Thus, while it was enacted by the General Assembly, the Swimming Pools AED Act did not mandate AEDs be placed at particular facilities.\footnote{Act of May 8, 2007, 2007 Md. Laws at 2197, 2200–01 (requiring that a study of AED programs for swimming pools occur).}

Before the start of the 2008 legislative session, the Maryland Institute for Emergency Medical Services Systems conducted the study required by the Swimming Pools AED Act.\footnote{See DEP’T OF LEGISLATIVE SERVS., MD. GEN. ASSEMBLY, FISCAL AND POLICY NOTE: SWIMMING POOLS: AUTOMATED EXTERNAL DEFIBRILLATOR PROGRAMS: SENATE BILL 330, at 3 (2008), available at http://mlis.state.md.us/2008rs/fnotesfbil_0000/sb0330.pdf.} The study, conducted by a strong proponent of AED programs,\footnote{See supra notes 85, 87, 90, 102 and accompanying text (detailing MIEMSS support of AED programs).} characterized swimming pools as low-risk locations and only recommended voluntary placements of AEDs at swimming pools.\footnote{See DEP’T OF LEGISLATIVE SERVS., supra note 120, at 3.} Based in part on the recommendation that AED placement at swimming pools be voluntary, legislation to require AEDs at swimming pools died in the Senate Finance Committee.\footnote{See S.B. 330, 2008 Leg., 425th Sess. (Md. 2008); Md. Gen. Assembly, Senate Bill 330 (2008), available at http://mlis.state.md.us/2008rs/billfile/sb0330.htm.}

In addition to a second attempt to require AEDs at swimming pools, the 2008 session also saw legislation to require AEDs at all Maryland courthouses.\footnote{H.B. 1556, 2008 Leg., 425th Sess. (Md. 2008).} However, the bill was withdrawn by its sponsor before it had a committee hearing.\footnote{Md. Gen. Assembly, House Bill 1556 (2008), available at http://mlis.state.md.us/2008rs/billfile/hb1556.htm.} For the 2009 session, no legislation was introduced to require AEDs at additional public or private facilities.\footnote{See Md. Gen. Assembly, Status of all House Legislation Introduced As of 8:56 AM on 6/25/2009 (2009), available at http://mlis.state.md.us/ (under the heading “Bill Indexes,” follow “House Legislation” hyperlink); Md. Gen. Assembly, Status of all Senate Legislation Introduced As of 8:56 AM on 6/25/2009 (2009), available at http://mlis.state.md.us/ (under the heading “Bill Indexes,” follow “Senate Legislation” hyperlink).}
IV. ANALYSIS OF MARYLAND’S RESPONSE TO ADVANCES IN AED TECHNOLOGY

Over the past decade, Maryland legislators responsibly responded to changes in AED technology to promote public health. When the General Assembly enacted the Maryland AED Act in 1999 to allow trained lay persons to use AEDs and provided them with civil immunity, Maryland eventually allowed wider use of AEDs in 2005 and 2008, after other states expanded their AED programs and studies established that AEDs could save lives while not posing a threat from misuse.

In each case, the legislation to allow greater public access to AEDs was strongly supported by the medical and EMS community. In the case of determining who may use AEDs, the General Assembly took a measured approach in weighing the benefits against the potential harms before following the weight of the available evidence and actions of other states to create a public access defibrillation program.

Like its approach to permitting public access to AEDs, Maryland has generally avoided rushing into mandating public access to AEDs. In 2000, the General Assembly rejected the first attempt to require AEDs at stadiums, shopping malls, and other public facilities. At that time, the cost-effectiveness of AEDs


128. See Nat'l Conference of State Legislatures, supra note 70.


131. See Nat'l Conference of State Legislatures, supra note 70.

132. E.g., Balady, supra note 17, at 1147–48 (stating that prompt AED use could result in sudden cardiac arrest survival rates of 40 percent to 53 percent).

133. E.g., Jorgensen, supra note 3, at 230–31 (noting that AED use by minimally trained first responders did not present safety concerns).


135. See supra Part III.A.

136. See supra notes 99–104 and accompanying text.
was not widely known and no other state had enacted legislation requiring public facilities to have AEDs. Hence, the General Assembly refrained from setting new policy on the use of AEDs in the absence of data to support its decision.

However, when the General Assembly considered legislation to require AEDs at high schools, it was no longer being asked to legislate in the dark. By 2006, one state had enacted legislation requiring or encouraging the placement of AEDs in schools and several other states were considering similar legislation. Moreover, studies were available that evaluated the cost-effectiveness of AEDs and determined that AEDs could be a worthwhile investment at high schools. Thus, the General Assembly had the ability to make an informed decision.

The General Assembly demonstrated that it would take a prudent approach to mandating AED placement when it commissioned its own study of the effectiveness of AEDs instead of requiring AEDs at swimming pools. The Maryland Institute for Emergency Medical Services Systems' report recommended that high-risk locations, like BWI Marshall Airport and enclosed malls, have AEDs available on-site. It further recommended that intermediate-risk locations, like sports stadiums, golf courses, and health clubs, be considered as locations for AEDs. Finally, the report recommended only voluntary placement of AEDs at low-risk locations like swimming pools, hotels, and restaurants. Following the recommendations of the report, the General Assembly rejected legislation the following year to require AEDs at swimming pools and courthouses. Consequently, the actions of the General Assembly suggest that it carefully weighed the costs and advantages of AEDs before making decisions on requiring their use.

137. See Davis, supra note 43 (quoting the Director of the Maryland Institute for Emergency Medical Services Systems as saying that as of 2003, more data is needed on the cost-effectiveness of AEDs).

138. See Nat'l Conference of State Legislatures, supra note 70.

139. Id. Florida required AEDs at certain schools. Id. Michigan and Ohio appropriated state funds to procure AEDs for schools, while New York and Nevada both considered similar legislation. Id.


141. See supra notes 113–123 and accompanying text.

142. DEP'T OF LEGISLATIVE SERVS., supra note 120, at 3.

143. Id.

144. Id.


Going forward, the General Assembly should continue to exercise the prudence it has already displayed in determining whether AEDs should be required at certain locations. In so doing, the General Assembly will give businesses and public facilities the opportunity to decide for themselves whether to provide AEDs. Even without legislation, in 2008, fifty-three swimming pools in Maryland already had AEDs on-site.\textsuperscript{147} Companies are also taking seriously the decision of whether to have an AED on-site; T. Rowe Price studied the issue for close to a year before deciding to install AEDs at its facilities.\textsuperscript{148} As of 2008, T. Rowe Price had been joined by over 365 businesses in the greater Baltimore area that decided to participate in Maryland’s AED program.\textsuperscript{149} The number of businesses that have AEDs is growing\textsuperscript{150} and will likely continue to increase because Maryland recently enhanced the civil immunity protections of owners and operators of AEDs.\textsuperscript{151} Consequently, Maryland may be able to achieve widespread placement of AEDs by allowing businesses and facilities to make the decision for themselves instead of having the decision made for them by the General Assembly.\textsuperscript{152} If the General Assembly decides that the individual decisions of business owners do not meet the public health needs, then the General Assembly has the information, in the form of the report by the Maryland Institute for Emergency Medical Services and other published studies, to require AEDs only where the cost-effectiveness of the device is established.\textsuperscript{153}

\textbf{CONCLUSION}

AEDs are beneficial life-saving tools that are easy to use and present a low risk of adverse events. Maryland, like many other states, developed a public policy of promoting AED use by expanding the scope of who can use AEDs and granting civil immunity to untrained lay users of AEDs. While promoting AED use is important, the General Assembly has been reluctant to adopt statutes requiring facilities to have AEDs on-site. However, even in the absence of a mandate, an increasing number of facilities are acquiring AEDs. Maryland should continue to allow private actors to make individualized decisions about whether the potential

\textsuperscript{147} DEP’T OF LEGISLATIVE SERVS., supra note 120, at 3.
\textsuperscript{149} Id. The greater Baltimore area includes Anne Arundel County, Baltimore City, Baltimore County, Harford County, and Howard County. Id. In addition to T. Rowe Price, Northrop Grumman, Under Armour, and the law firm Whiteford, Taylor, & Preston all have AEDs at their facilities. Id.
\textsuperscript{150} Id.
\textsuperscript{151} See Jeffrey Lubin et al., An Assessment of Public Attitudes Toward Automated External Defibrillators, 62 RESUSCITATION 43, 45 (2007) (finding that the second greatest obstacle to public access defibrillation was fear of legal liability); supra note 94 and accompanying text.
\textsuperscript{152} See generally Sernovitz, supra note 148.
\textsuperscript{153} See DEP’T OF LEGISLATIVE SERVS., supra note 120, at 3; see also supra Part I.D.
value of an AED outweighs its costs. If this approach does not sufficiently protect the public's health, then the General Assembly should rely on the established cost-effectiveness research to determine whether AEDs should be required.