

Legislative Strategies for Modernizing U.S. AED Laws

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EXECUTIVE SUMMARY

Sudden Cardiac Arrest and the Public Health Imperative

- Sudden cardiac arrest (SCA) strikes approximately 350,000 victims per year in the U.S. (the equivalent of three full 747 aircraft per day). 95 percent of SCA victims die, even though the condition is treatable with rapid defibrillation.
- Automated external defibrillators (AEDs), which treat SCA by delivering an electric pulse (shock) to the heart, are easy to use medical devices that, if widely deployed and rapidly used by bystanders, can save thousands of lives per year.

Current AED Public Policy is Antiquated and Impedes Widespread AED Deployment

- Current AED laws do not protect every AED program participant who should be protected. Even though AEDs are easy to use and untrained AED users are often involved in helping SCA victims, in many cases untrained users are not protected under Good Samaritan immunity laws.
- Current AED laws vary in all 50 states creating a complex quagmire of often conflicting AED program “standards” that serve as a barrier to widespread AED deployment and make it nearly impossible for willing bystanders to know whether they have Good Samaritan immunity protection, thus creating a risk they might not retrieve and use publicly placed AEDs.
- In contrast to common perceptions, many states do not technically offer AED Good Samaritan protection to anyone.
- Contrary to their intended goal, current AED laws actually increase rather than decrease liability risk facing AED program participants because they include complex and burdensome operational requirements as conditions of immunity.

Modernizing AED Good Samaritan Immunity

- Modernizing AED Good Samaritan immunity laws requires simplification, removal of AED program operational requirements, and offering meaningful coverage to all AED program participants.
- Modernizing AED Good Samaritan laws will reduce liability barriers and encourage more organizations to more rapidly deploy AEDs.

Enhancing 911 Agency Role in AED Response

- The U.S. currently has less than 5 percent of the total number of AEDs needed to cover all urbanized areas, and publicly placed AEDs are used in only about 2 percent of all SCA incidents.
- Integrating 911 agencies into community AED response systems has the potential to at least double the utilization rates for all existing and newly deployed public access AEDs and save more lives.

AED Deployment Mandates

- Legislative AED deployment mandates represent the primary tool policymakers have to directly control the number and location of AEDs placed in defined public settings.
- Targeted AED deployment mandates, such as those requiring AEDs in schools and health clubs, necessarily offer a very limited overall public health benefit because they result in only a small, incremental increase in the number of AEDs deployed within a community, cover only a very limited response area, and impact a very small percent of a community’s population.
- General mandates, such as those that might require AEDs at all locations with 100 or more persons on site per day, have the potential to significantly increase a community’s sudden cardiac arrest survival rates by more rapidly adding a large number of AEDs over a wide area and thus covering a much larger population base.
- Because sudden cardiac arrest is the leading cause of adult death in the U.S., and it’s treatable with rapid defibrillation, the subject of general AED mandates is worthy of serious public policy consideration.

SUDDEN CARDIAC ARREST – A SIGNIFICANT PUBLIC HEALTH THREAT

Sudden cardiac arrest (SCA) strikes approximately 350,000 people per year in the U.S. Affecting nearly 1,000 victims per day (the equivalent of three full 747 aircraft), SCA is the leading cause of adult death in the U.S. SCA impacts people of all ages, including many outwardly healthy individuals with no known heart conditions. Predicting who, when and where SCA will strike is virtually impossible. The only definitive emergency treatment for sudden cardiac arrest is defibrillation which involves the rapid delivery of an electric pulse (shock) to the heart. Though a treatable condition, approximately 95 percent of SCA victims die annually in the U.S., generally because treatment with a defibrillator is delayed or unavailable.

Rapid defibrillation significantly increases the chances of survival for SCA victims. Defibrillation therapy delivered within 1 minute of SCA can result in a 90 percent probability of survival. Chances of survival decline by 7-10 percent for every minute defibrillation therapy is delayed. After 8-10 minutes, when traditional emergency medical services personnel generally arrive, the survival probability is less than 10 percent.

AUTOMATED EXTERNAL DEFIBRILLATORS – A PUBLIC HEALTH IMPERATIVE

An automated external defibrillator (AED) is a medical device designed to quickly, safely and effectively deliver a defibrillation shock to SCA victims. AEDs are easy to use because they offer voice, text and graphics prompts – even minimally trained or non-trained individuals are able to use AEDs to save lives.

To address the public health threat of SCA, the American Heart Association and other interested groups actively promote the widespread deployment and use of AEDs by people without medical training. As a result, AEDs are now found in many public settings. Examples include airports, shopping malls, schools, health clubs, sports arenas, manufacturing facilities, office buildings, and more. As many as 425,000 AEDs are estimated to be located in U.S. public settings as of the end of 2006. While this number is expected to grow to over 1 million by 2010, it is still well below the number needed to have a significant impact on overall SCA survival rates. Well crafted public policy initiatives can accelerate the rate of AED growth.

CURRENT AED PUBLIC POLICY – AN ANTIQUATED APPROACH

Generally, immunity laws are enacted by policymakers to encourage particular types of conduct. For example, the first Good Samaritan law, enacted in California during the 1950s, offered immunity to physicians who voluntarily stopped to render aid to accident victims. The goal of this approach was to encourage physicians to act by reducing the risk of negligence lawsuits.

Similarly, starting in the mid-1990s, legislatures throughout the U.S. began enacting AED-related Good Samaritan laws presumably with the intent that such laws would reduce liability risks and therefore encourage more organizations and individuals to buy, deploy and use AEDs in public settings. Such laws now exist in every state and vary widely in structure, content, complexity, and scope of coverage. Unfortunately, for reasons discussed below, the current first-generation of AED laws actually increases rather than decreases liability risk and is a barrier to those organizations considering the deployment of AEDs.

Gaps in the Scope of Current AED Law Coverage

Public policy goals associated with existing AED laws are not well-articulated in the statutes themselves or in the current literature surrounding AED public policy. These laws were originally intended to reduce legal liability risks facing organizations deploying, and bystanders using, AEDs in public settings. It is also widely perceived, and often stated in published materials, that the existing universe of AED Good Samaritan laws offers broad liability protection to all AED program participants. In stark contrast to these widespread perceptions, current AED Good Samaritan laws **do not** protect everyone who should be protected. Consider the following selected highlights:

- **49% of states do not offer immunity protection to untrained AED users:** Despite the growing presence of AEDs in public settings and the advances in AED-guided instructions for lay-users, 25 states fail to offer immunity protection to untrained AED users.
- **24% of states technically do not offer immunity protection to anyone — rather, they offer only placebo immunity:** Though they possess so-called AED Good Samaritan immunity laws, at least 12 states fail to offer immunity protection to anyone. Placebo laws incorporate language that protects only reasonable, non-negligent conduct. Conduct amounting to ordinary negligence — expected to be included within meaningful Good Samaritan laws — is not protected.
- **20% of states do not offer immunity protection to AED acquirers or those responsible for AED program sites:** As illogical as it seems, 10 states fail to offer immunity protection to those responsible for purchasing and deploying AEDs in public settings.
- **One state does not offer any immunity protection to trained AED users:** Surprisingly, one state fails to offer immunity protection to trained AED users though AED acquirers, trainers, and physicians are offered protection.

While well intentioned, current AED laws are not well crafted. As a result, significant gaps now exist in the scope of AED Good Samaritan coverage.

First-Generation AED Law Approach Increases Rather Than Decreases Liability Risk

Contrary to their perceived purpose, first-generation AED laws generally increase rather than decrease liability risk. This is because they pursue two distinct AED program objectives, only one of which is appropriately addressed through legislation. The first objective, clearly within the province of legislatures, was to offer qualified immunity protection to certain AED program constituents with the goal of encouraging widespread AED deployment. The second objective, more appropriately addressed outside the legislative arena, was to incorporate AED program design and operational requirements as conditions of immunity. Unfortunately, including this second objective increases liability risks facing organizations with AEDs and is an ill-suited method for creating effective AED programs.

AEDs themselves do not save lives. Rather, people quickly retrieving and using AEDs save lives. An AED program is the framework within which people, systems, methods, equipment, and actions are configured to prepare for and respond to suspected sudden cardiac arrest emergencies prior to the arrival of traditional emergency medical services resources. While AEDs are quite easy to use, designing and operating an effective AED program is a complicated process. As with any complex health and safety program, AED programs must be customized to the particular organization acquiring AEDs.

In their current form, most AED laws incorporate numerous AED program design and operational requirements as conditions of immunity. Examples include maintenance, agency notification, training, medical oversight, documentation, and many others. While these are important AED program components, they represent only a subset of all factors to be considered in designing and operating an effective AED program (see, for example, *AED Program Specifications: Planning Guidelines for the Placement, Retrieval and Use of AEDs in Public Settings* available at www.AEDRiskInsights.com). Further, states impose a widely varying mix of AED program operational requirements reflecting differing internally and externally influenced priorities. No two states take an identical approach.

Standards defining what constitutes a “reasonable” AED program are only now emerging. Notwithstanding significant complexities associated with AED program design and operations, requirements embedded within AED laws impose mandatory “standards” and operational burdens on every AED program site regardless of size, scope, or unique characteristics. This unusual mix of often conflicting legislation, and the unrealistic one-size-fits-all approach, creates significant risk that AED

immunity law requirements will be viewed as establishing a “standard of care” resulting in increased rather than decreased liability exposure for organizations with AEDs.

Put another way, the inherent and growing risk of the current approach is that immunity protection will be lost because an organization is unable to understand what constitutes compliance, and thus fails to fully act in accordance with an AED law’s terms. An organization might also lose immunity protection by failing to comply with stated operational requirements having no impact on an SCA incident or outcome. These risks are now materializing in AED-related litigation.

Efforts to use AED immunity laws as a tool to design AED programs has led to significantly increased confusion and legal liability risk. Current laws vary in all 50 states, meaning in effect that program design standards vary in all 50 states. This AED law quagmire often makes it difficult for organizations potentially interested in deploying AEDs to say “yes” since “yes” frequently means increased confusion, burdens, and risk. The current state of U.S. AED laws also creates a situation in which it is nearly impossible for willing bystanders to know whether they have Good Samaritan immunity protection, and thus they might not retrieve and use publicly placed AEDs.

MODERN APPROACH TO AED GOOD SAMARITAN IMMUNITY

The primary goal of AED Good Samaritan immunity laws should be to simply and meaningfully offer qualified liability protection to all AED program constituents with the objective of encouraging more organizations to deploy AEDs. AED program requirements should be addressed outside of the legislative arena. This is similar to the approach used for cardiopulmonary resuscitation (CPR). OSHA laws requiring CPR training typically do not incorporate CPR training requirements directly into, or as conditions to, general Good Samaritan immunity laws. Rather, they rely upon CPR training guidelines published by third-party organizations. AED immunity laws can better encourage widespread AED deployment and reduce liability risk by following this model.

Model AED Good Samaritan Immunity Law

The model AED Good Samaritan immunity law (Model AED Law) provided below is founded on the following principles:

- Positively influence behavior: The law must effectively reduce liability risk in order to encourage more organizations to acquire AEDs.
- Be understandable: The law must be easy to read and understand.
- Provide broad coverage: The law must protect all AED program participants.
- Provide meaningful liability protection: The law must meaningfully protect all but grossly negligent or willful or wanton misconduct.
- Eliminate burdensome and complex immunity conditions: The law must not include AED program design or operational requirements as conditions of immunity.
- Achieve uniformity: When widely adopted, the law must make AED Good Samaritan immunity standards uniform throughout the U.S.

Model AED Good Samaritan Immunity Law
(AED Good Samaritan Immunity Modernization Act)

An act to repeal [insert statutory references] and enact new provisions relating to AED Good Samaritan immunity.

Section 1. [Insert statutory references] are hereby repealed and replaced with the following:

Section 2. The following persons and entities are immune from civil liability for damages arising out of acts or omissions relating to preparing for and responding to suspected sudden cardiac arrest emergencies absent gross negligence or willful or wanton misconduct:

- (a) Any person or entity that acquires an automated external defibrillator;
- (b) Any person or entity that owns, manages or is otherwise responsible for the premises on which an automated external defibrillator is located;
- (c) Any person who retrieves an automated external defibrillator in response to a perceived sudden cardiac arrest emergency;
- (d) Any person who uses, attempts to use, or fails to use an automated external defibrillator in response to a perceived sudden cardiac arrest emergency;
- (e) Any physician or other authorized person who issues a prescription for the purchase of an automated external defibrillator;
- (f) Any person or entity that is involved with the design, management or operation of an AED program; and
- (g) Any person or entity that provides instruction in the use of an automated external defibrillator.

Selected Model AED Law Commentary

The following commentary highlights the goals and objectives of this modern legislative approach. It also reviews selected operational requirements commonly found in first-generation AED Good Samaritan immunity laws and the reasons these requirements are omitted from the Model AED Law. Only the most prevalent operational requirements are discussed, though many others exist.

Understandability: The Model AED Law is purposefully crafted to be easy to read and easy to understand. This approach will help organizations with, or considering the purchase of, AEDs to clearly recognize the benefits and scope of available immunity coverage hopefully leading to the more rapid widespread deployment of AEDs.

Scope of coverage: The Model AED Law offers immunity protection to each person and entity involved with AED programs.

Scope of liability protection: The Model AED Law offers immunity protection for all but grossly negligent or willful or wanton misconduct.

Training: The Model AED Law omits any reference to training as a condition of AED Good Samaritan immunity. Based on the following reasons, there is no longer a supportable public policy rationale for imposing training requirements as a condition of immunity:

- The ease-of-use characteristics of modern AEDs: AEDs are now widely recognized as very easy to use. Even untrained 6th graders guided by voice, text and graphics prompts were shown to be able to use AEDs nearly as rapidly as trained paramedics. In effect, AEDs offer real-time training to users.
- The successful use of AEDs by untrained bystanders: A recent Chicago O'Hare Airport study documented that over 60 percent of AED users who successfully saved SCA victims were untrained.
- The critical need to encourage rapid AED use: Because SCA is 100 percent fatal unless quickly treated, every willing rescuer should be enabled and encouraged to respond to SCA emergencies, regardless of formal training status. AEDs can only help SCA victims. AEDs cannot harm a victim since safety features incorporated into the devices allow the delivery of a defibrillation shock only when medically warranted.

While the Model AED Law does not include a training condition, individuals and organizations may still independently choose to obtain formal AED training.

Emergency 911 notification: Nearly half the states now require, as a condition of immunity, that AED users quickly call 911 in the event of a suspected sudden cardiac arrest emergency. The Model AED Law omits this requirement. This is because bystanders volunteering to help SCA victims may or may not immediately call 911 when faced with an actual emergency. Those willing to help SCA victims should not be at risk for the loss of Good Samaritan protection based on a failure to comply with this administrative requirement. This is particularly true since approximately 99 percent of the U.S. population (excluding infants and very young children) are aware of the importance of calling the 911 emergency number when faced with an emergency, and since 911 is typically called quickly when SCA strikes. Any egregious misconduct would constitute gross negligence and would therefore not be protected under the Model AED Law.

Administrative AED placement notification: Approximately two-thirds of the states require that AED owners report the presence and location of AEDs to a state or local agency in order to qualify for immunity. The Model AED Law omits this requirement. This is because 911 agencies are not required to use this information. AED laws containing this requirement therefore create a burden without a benefit. This issue is better addressed via changes to 911 statutes as discussed below under Enhancing 911 Agency Role in AED Response.

ENHANCING 911 AGENCY ROLE IN AED RESPONSE

Approximately two-thirds of the states currently require that AED owners report the presence and location of AEDs to state or local agencies, often 911 agencies. However, there is no concurrent requirement that 911 agencies utilize AED location information to help SCA victims. So this information, even if reported, goes mostly unused. As a result, publicly placed AEDs available both at and nearby SCA victims remain invisible and are only infrequently retrieved and used when needed. This is true notwithstanding the unique position of 911 agencies as **the** central point of contact for those trying to help SCA victims. The lack of readily accessible AED location information within 911 dispatch agencies also contributes to the extremely low utilization rates of publicly placed AEDs. By formally integrating 911 agencies into community-based AED response systems, AEDs will be used more frequently and more lives will be saved.

AED Density and Utilization

With approximately 425,000 AEDs now found in public settings, the U.S. has less than 5 percent of the total number of AEDs needed to effectively cover all urbanized areas (AED density). This is because to be retrievable within a short response time window, one AED can only cover approximately 275,000

square feet. Moreover, public access AEDs are only used in approximately 2 percent of all SCA incidents (AED utilization rate). These factors highlight how improved SCA survival rates can only be achieved by:

- Increasing the number of AEDs deployed in public settings
- Improving utilization rates for existing and new AEDs by requiring 911 agencies to receive AED location information and make that information immediately available to those calling to report SCA emergencies
- Combining both strategies described above

Model 911 AED Law

The model 911 AED law (Model 911 AED Law) provided below is founded on the following principles:

- 911 agencies serve a vital public safety function and act as the central point of contact for those seeking to help SCA victims
- Integrating 911 agencies into community-based AED response systems represents a cost-effective strategy that has the potential to at least double the utilization rates of all public access AEDs thereby saving more lives

Model 911 AED Law

(Life-Saving AED Location Emergency Communications Act)

[Note: These provisions are intended to be added to state emergency communications statutes. They are not intended to be included in AED Good Samaritan immunity laws.]

An act to require AED acquirers to report AED location information to 911 dispatch agencies, to integrate 911 dispatch agencies into community-based AED response systems, and to provide for immunity.

Section 1. Every person or entity that acquires an automated external defibrillator (AED) shall report, at a minimum, the following information to the local 911 dispatch agency:

- (a) The presence and precise location of each AED;
- (b) Any change of AED location; and
- (c) The removal of any AED .

Section 2. The report specified in section 1 shall be made within 30 days of acquiring, moving or removing an AED.

Section 3. Each 911 dispatch agency that dispatches calls for emergency medical assistance shall, within 180 days of the effective date of this act, develop and implement a system to receive, record and update AED location information reported by AED acquirers and to make AED location information immediately available to 911 callers reporting potential sudden cardiac arrest emergencies.

Section 4. Persons and entities specified in this Act are immune from civil liability for damages arising out of the reporting, receiving, recording or updating of AED location information absent gross negligence or willful or wanton misconduct.

AED DEPLOYMENT MANDATES – AN OVERVIEW

This AED deployment mandate overview is provided as general information for policymakers. The issue of mandates can be politically challenging and often involves many competing perspectives. The following discussion offers a framework for policymakers considering this type of public policy initiative.

Generally, individuals and organizations buy AEDs for the following three reasons:

- Voluntary choice: Individual choice often driven by an organizational champion based on growing awareness, a life saved or a potentially preventable death
- Coerced voluntary choice: Fear that the failure to have an AED may create the risk of a negligence lawsuit based on a violation of a perceived standard of care (court imposed standard of care)
- Statutory mandate: A mandatory duty to deploy AEDs imposed by legislative policymakers (legislatively imposed standard of care)

Only legislative mandates directly control the number and location of AEDs placed in public settings. Otherwise, AED acquisition and placement is left to voluntary organizational or individual choice. Mandates have the potential to more rapidly increase the number of AEDs in a community while voluntary deployment results in a much slower, ad hoc AED adoption rate.

Legislative AED mandates can take two forms. They can be targeted at specific locations or industries (targeted mandates) or they can apply more broadly based on general site parameters or characteristics (general mandates). To date, legislative AED deployment mandates have been of the targeted variety focusing on such locations as airlines (the only federal AED mandate), schools, health clubs, large occupancy buildings, government buildings, law enforcement vehicles, and places of public assembly. Broad-spectrum general mandates (e.g., those that might require AEDs at all locations with 100 or more persons on site per day) have not yet been embraced.

Policymakers considering mandated AED deployment should recognize that targeted mandates such as those focused on health clubs or schools will necessarily result in a very limited overall public health benefit. This is because targeted mandates result in only a small, incremental increase in the number of AEDs deployed within a community, cover only a very limited response area, and impact a very small percent of a community's population. In contrast, general mandates have the potential to significantly increase a community's sudden cardiac arrest survival rates by more rapidly adding a large number of AEDs over a wide area and thus covering a much larger population base.

Though the specific time, place, and victims of sudden cardiac arrest are impossible to forecast with any precision, the generalized risk of SCA at any particular location is based on the number of people per day visiting the location, age demographics and, to some extent, activities engaged in. When viewed from the context of SCA risk, AED mandates enacted to date run a wide gamut. The two most publicized types of AED mandates relate to health clubs and schools. Health clubs tend to fall on the higher end of the risk continuum based on research suggesting those engaged in vigorous physical exercise face a statistically higher chance of experiencing SCA. In contrast, schools tend to fall on the lower end of the risk continuum based on population and age demographics. Yet, due to their political appeal, both of these location types face a growing number of targeted AED mandates. To date, the vast majority of the population base remains unprotected.

It is true that general AED mandates would require that public and private entities incur significant costs associated with the purchase of large numbers of AEDs and related program expenses. However, when viewed in comparison with other areas of public safety such as fire protection, these costs appear quite reasonable in relation to the benefits obtained.

Approximately 6,000 people per year in the U.S. die in fires. Over the last few decades, public and private entities have been required to spend about \$37 billion dollars on fire suppression systems to address this risk. In contrast, SCA strikes 350,000 per year in the U.S. representing a public health threat orders of magnitude greater than fires (6,000 SCA victims die approximately every 6 days). Sudden cardiac arrest is the leading cause of adult death in the U.S. The condition is treatable with rapid defibrillation. The cost of equipping buildings with AEDs is far less than the cost of fire suppression systems and will result in the saving of thousands more lives. From a public health and public policy perspective, a general AED mandate would appear to be reasonable. In sum, the subject of general AED mandates is worthy of serious public policy consideration.

ABOUT THE AUTHOR

Attorney Richard A. Lazar is widely recognized as the leading expert in AED program design and operations, risk management, law and public policy. He serves as President and CEO of Atrus, Inc., a technology-based services company that developed a system that provides real-time AED location information to 911 agencies and an automated notification system to alert bystanders to rapidly retrieve nearby AEDs (www.AtrusInc.com). He also served as CEO of AED Risk Insights, a provider of AED program design, risk management, public policy advocacy, and information services. Earlier in his career, Richard practiced emergency medical services law, designed EMS systems, and was an emergency medical technician. He holds a B. S. in Public Administration from the University of Oregon, a J. D. from Lewis & Clark Law School, and remains an active member of the Oregon State Bar.