
White Paper

**Understanding AED Program Legal Issues:
An Overview of Laws and Liability Risks Impacting AED Programs**



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White Paper

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Legal Notice

Information contained in this White Paper is not intended as legal advice. While reasonable efforts have been made to ensure the accuracy of information as of the date of publication, the AED legal and regulatory landscape continues to evolve. Legal and public policy questions surrounding AED programs can be complex. If you need specific advice, seek the services of an experienced and competent professional.

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SCOPE OF THIS WHITE PAPER

Automated external defibrillators (AEDs) are now found in a rapidly growing number of locations for use by non-healthcare-professionals. These small, easy to use safety devices help treat victims of sudden cardiac arrest - the leading cause of adult death in the United States.

The public health benefits of widespread AED deployment are well known. However, a complex legal and regulatory environment and the risk of negligence liability face organizations that implement AED programs. In some sectors, organizations that do not implement AED programs also face negligence liability risks.

This White Paper, *Understanding AED Program Legal Issues: An Overview of Laws and Liability Risks Impacting AED Programs*, highlights the ever shifting legal and public policy framework within which AED programs function and the importance of well designed and operated AED programs as a way to manage negligence liability risk. This White Paper is intentionally high level and is not intended to provide detailed and specific legal and public policy information. However, by reviewing the complex AED program law and policy labyrinth, executives and managers can better understand how to design, implement and operate AED programs that save lives and manage risk.

THE CHALLENGE OF SUDDEN CARDIAC ARREST

When considering how to address sudden cardiac arrest (SCA) in out-of-hospital settings, it is important to understand why a growing number of organizations embrace automated external defibrillator programs and the benefits such programs offer. The primary reason is that a significant number of people are dying of SCA in public settings and a therapy exists that can treat the condition causing many of these deaths.

Out-of-hospital sudden cardiac death strikes over 350,000 people annually in the U.S. – the equivalent of 3 jumbo jet crashes per day.¹ Most individuals who experience SCA have not been previously identified as high risk individuals² and events usually occur outside of medical settings.³ Thirteen percent of workplace fatalities reported between 1999 and 2000 resulted from sudden cardiac arrest.⁴ The overall SCA survival rate in the United States is estimated to be less than 5 percent.⁵

¹ Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden Cardiac Death in the United States, 1989 to 1998. *Circulation*. 2001;104:2158-2163, 2158.

² Gratton M, Lindholm DJ, Campbell JP. Public-access defibrillation: where do we place the AEDs? *Prehospital Emergency Care*. 1999 Oct-Dec;3(4):303-5.

³ Engdahl J, Holmberg M, Karlson BW, Luepker R, Herlitz J. The epidemiology of out-of-hospital 'sudden' cardiac arrest. *Resuscitation*. 52 (2002) 235–245.

⁴ Cardiac Arrest and Automated External Defibrillators (AEDs). OSHA Technical Information Bulletin TIB 01-12-17, December 17, 2001.

⁵ Culley LL, Rea TD, Murray JA, Welles B, Fahrenbruch CE, Olsufka M, Eisenberg MS, Copass MK. Public Access Defibrillation in Out-of-Hospital Cardiac Arrest: A Community-Based Study. *Circulation* 2004;109:1859-1863.

Most sudden cardiac death results from sudden cardiac arrest caused by a cardiac arrhythmia known as ventricular fibrillation (VF).⁶ The only effective emergency treatment for VF is defibrillation which involves the delivery of an electric pulse (shock) to the heart using a medical device known as a defibrillator. While CPR (cardiopulmonary resuscitation) is often promoted as a therapeutic treatment for cardiac arrest victims, it does not stop VF but may briefly extend the time window within which a successful defibrillator shock can be delivered.^{7,8,9}

Time is the single most critical factor impacting a sudden cardiac arrest victim's chances of surviving. Survival rates from VF can exceed 90 percent if defibrillation occurs in the first 1-2 minutes but then declines by approximately 7-10 percent per minute for every minute thereafter.^{10,11,12} After about 10 minutes, the chances of survival are near zero. While calling 9-1-1 is important, emergency medical services systems are generally not designed to respond quickly enough, often enough, to meaningfully increase a cardiac arrest victim's chances of surviving.

AEDs are small, portable, low-cost medical devices designed to quickly deliver life-saving defibrillation therapy to SCA victims. AEDs have emerged as the best strategy for treating SCA in non-medical settings prior to the arrival of professional emergency response personnel. It is now well established that AEDs are very easy to use – even by minimally trained or non-trained individuals (including naïve, untrained sixth graders).^{13,14,15}

Because of their tremendous benefits, AEDs are ever more rapidly finding their way into new locations. AEDs can now be found in settings as varied as health clubs, offices, manufacturing plants and theme parks - increasing the chances one will be nearby when SCA occurs. The closer AEDs are to SCA victims, the faster therapy can be delivered and the higher the probability lives will be saved. This is why AED programs are rapidly increasing in number and scope.

⁶ Holmberg M, Holmberg S, Herlitz J. Incidence, duration and survival of ventricular fibrillation in out-of-hospital cardiac arrest patients in Sweden. *Resuscitation*. 2000;44:7-17.

⁷ Hallstrom AP, Ornato JP, Weisfeldt M, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med*. 2004 Aug 12;351(7):637-46.

⁸ Berg RA, Hilwig RW, Ewy GA, Kern KB. Precountershock cardiopulmonary resuscitation improves initial response to defibrillation from prolonged ventricular fibrillation: a randomized, controlled swine study. *Crit Care Med*. 2004 Jun;32(6):1352-7.

⁹ Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad BH, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: a randomized trial. *JAMA*. 2003 Mar 19;289(11):1389-95.

¹⁰ Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* 2000 Aug 22;102(8 Suppl I):I60-61. ("Guidelines 2000")

¹¹ Valenzuela T, Roe DJ, Cretin S, et al. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. *Circulation*. 1997;96:3308–3313.

¹² Larsen MP, Eisenberg MS, Cummins RO, et al. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med*. 1993; 22:1652–1658.

¹³ Grundy JW, Comes KA, DeRook FA, et al. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation*. 2000;100:1703–1707.

¹⁴ Eames P, Larsen PD, Galletly DC. Comparison of ease of use of three automated external defibrillators by untrained lay people. *Resuscitation*. 2003 Jul;58(1):25-30.

¹⁵ Lawson L, March J. Automated external defibrillation by very young, untrained children. *Prehosp Emerg Care*. 2002 Jul-Sep;6(3):295-8.

AED programs are now widely promoted in public settings for reasons of employee, visitor and guest health and safety. Congress specifically found that AED programs ensuring widespread public access to defibrillators have dramatically improved survival rates from cardiac arrest.¹⁶ As noted above, the U.S. Occupational Safety and Health Administration (OSHA) calculated that 13 percent of workplace fatalities reported between 1999 and 2000 resulted from sudden cardiac arrest. Accordingly, OSHA has long recommended that “employers should consider use of AEDs at their worksites to reduce the time to defibrillation with the goal of improving survival.”¹⁷ A growing number of AED programs are becoming an essential component of health and safety programs.

LAWS IMPACTING AED PROGRAMS

Introduction

AED programs exist within a complex mosaic of laws, regulations and court cases impacting a variety of AED program characteristics. Laws (statutes) and regulations may come from the United State Congress, federal regulatory agencies, state legislatures, state regulatory agencies, and even local governments.

There are now a wide variety of statutes and regulations in place directly affecting AED programs. These laws address a number of subjects including:

- Regulation and oversight of the manufacture and sale of AEDs
- AED program mandates for specific venues
- Requirements relating to the deployment and use of AEDs
- Good Samaritan immunity
- Funding for AED programs (not addressed in this White Paper)

In addition, negligence lawsuits help define the types of venues that may have a legal obligation (i.e., duty) to deploy AEDs as well as those AED program characteristics essential to a “reasonable” (i.e., legally defensible) AED program design.

Taken together, laws, regulations and court cases create the set of rules guiding the purchase, deployment and use of AEDs in non-healthcare settings. This White Paper provides a high level explanation of the complex legal framework which AED program executives must be aware of as they design, implement and operate AED programs.

¹⁶ Cardiac Arrest Survival Act of 2000, P.L. 106-505, § 402 (7).

¹⁷ Cardiac Arrest and Automated External Defibrillators (AEDs). OSHA Technical Information Bulletin TIB 01-12-17, December 17, 2001.

Federal AED Laws

Federal laws are fairly limited in scope and only minimally impact how AED programs are created and how they operate. These laws currently focus on medical device oversight, an AED deployment mandate, and, to some extent, Good Samaritan immunity protection.

U.S. FDA Oversight of AEDs

The U.S. Food, Drug and Cosmetic Act¹⁸ grants to the U.S. Food and Drug Administration (FDA) the power to oversee the manufacture and sale of AEDs because they are medical devices. While intended for use by non-healthcare-professionals, AEDs are currently classified by the FDA as Class III medical devices because they contain cardiac rhythm recognition detection systems.¹⁹ The FDA is primarily focused on device clearance, prescription requirements, and training requirements.

Device Clearance. When granting permission to manufacturers allowing the sale of AEDs, the FDA issues what are known as 510(k) clearance letters. These letters are device specific (e.g., each make and model receives a separate 510(k) clearance) and detail each AED's "indications for use" as well as any conditions imposed by the agency relating to the sale and use of each device. All clearance letters say that AEDs are intended for use on sudden cardiac arrest patients who are unconscious, pulseless, and not breathing. Most 510(k) clearances for currently marketed devices require that AEDs be sold via a prescription, and may include requirements relating to training, medical oversight, and the patient's condition. In general, a purchaser can consider any AED that has received a 510(k) clearance letter to be safe and appropriate for public use.

Prescription requirement. Until recently all AEDs could only be sold or purchased with a prescription.²⁰ However, FDA regulations do not detail what an AED prescription means. As a result, prescriptions are written to authorize the sale of AEDs to everyone from individual persons, to AED program sites, companies, buildings, and the like. Unlike any other therapeutic context, there is no physician-patient relationship giving rise to an AED prescription. This can be explained by the fact that AEDs do not fit a traditional prescription model. In general, AED prescriptions cannot be patient specific since it is nearly impossible to predict who will become a sudden cardiac arrest victim, where SCA events will occur or who will use the device to deliver treatment. While not formally sanctioning the existing broad prescription model, the FDA has not challenged it. More importantly from a risk management perspective, the agency has not explained how it intends the prescription model to work in the AED context.

The AED prescription model may now be in a period of transition. On September 16, 2004, the FDA cleared the first AED for sale over-the-counter (OTC) rather than by prescription.²¹

¹⁸ 21 U.S.C. § 301 et. seq.

¹⁹ 21 CFR § 870.5310, 21 CFR § 870.1025.

²⁰ 21 CFR § 801.109.

²¹ FDA 510(k) Number K040904 (09-16-04).

OTC status is being sought for other AEDs and it seems likely that other models may ultimately be available over-the-counter. The pace of this transition is much slower than many anticipated. One important benefit of this broader change, when it occurs, is that consumers are likely to begin perceiving AEDs as consumer safety products like smoke detectors, fire extinguishers, and security systems rather than complicated medical devices.

Training. Most current 510(k) clearance letters indicate that particular AEDs are intended to be used only by trained individuals.²² These training requirements are variously described to include training in the use of the specific AED,²³ and “training in basic life support, advanced life support, or other physician-authorized emergency medical response.”²⁴ Beyond this, the agency permits states and localities to determine specific training requirements.²⁵ There are some clearance letters that do not include a training restriction.²⁶

Training language found in 510(k) clearance letters comes from each manufacturer’s original submission to the FDA. It is not, by itself, an indication that some devices are easier to use than others.²⁷ It is also not clear how training language found in 510(k) clearance letters will be considered by courts that might be asked to contrast such requirements with those found in state laws or those required as a reasonable component of program design and operations.

Recalls. When device safety issues arise, the FDA initiates AED recalls. Recalls can occur for a variety of reasons generally relating to the safe operation of AEDs. One study suggested that approximately 22 percent of AEDs distributed between January 1996 and December 2005 were recalled²⁸ and virtually every AED manufacturer has recalled devices. The number of times AEDs may have failed due to a product design or manufacturing defect is not known but is thought to be relatively small.

Cardiac Arrest Survival Act - AEDs in Federal Buildings and Immunity

The Cardiac Arrest Survival Act (CASA)²⁹ was enacted in November 2000. Provisions of this federal law:

- Encourage but do not require the deployment of AEDs in federal buildings, and require the Department of Health and Human Services (DHHS) to establish guidelines for placing AEDs in federal buildings; and

²² E.g., FDA 510(k) Number K033474 (5-21-04).

²³ E.g., FDA 510(k) Number K040637 (8-6-04).

²⁴ E.g., FDA 510(k) Number K014157 (1-17-02).

²⁵ Automatic External Defibrillators (AEDs) and Public Access Defibrillation (PAD) Programs, www.fda.gov/cdrh/consumer/AED_PAD.html (October 26, 2000).

²⁶ E.g., FDA 510(k) Number K011144 (12-03-01); FDA 510(k) Number K013896 (6-19-02).

²⁷ Note: Given the ease-of-use characteristics of most AEDs, it is not clear how 510(k) clearance letter training indications might be raised in and impact AED related lawsuits.

²⁸ Shah JS, Maisel WH. Recalls and Safety Alerts Affecting Automated External Defibrillators. *JAMA*. 2006;296:655-660.

²⁹ 42 U.S.C. §§ 238p. and 238q.

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- Create a form of qualified Good Samaritan immunity for the emergency use of AEDs.

AEDs in federal buildings. DHHS published the CASA required guidelines in May 2001.³⁰ These guidelines seek to “provide a general framework for initiating a design process for a public access defibrillation (PAD) program in Federal facilities.”³¹ As directed by Congress, key features of the guidelines include:

- Implementing appropriate training courses in the use of AEDs, including the role of CPR;
- Proper maintenance and testing of AEDs;
- Ensuring coordination with licensed professionals in the oversight of AED training;
- Ensuring coordination with local emergency medical systems regarding the placement and incidents of use of AEDs.³²

These guidelines are intended for use by federal AED program planners but may also be viewed as serving as a general reference resource for others. The following provisions, however, make clear DHHS’s intent that its published guidelines not be relied upon as a comprehensive AED program design framework:

“The design of a PAD program in any Federal facility will be unique, and depend on many factors, including the population demographics of the facility/Federal area, and size and location of the facility/Federal area. The design process and key elements of a PAD program cited in these guidelines are intended to provide a foundation upon which individually tailored programs are developed and implemented.

This document is not intended to be a comprehensive summary of all aspects of automated external defibrillator (AED) use or PAD programs. Rather, it is aimed at providing sufficient information to understand the basic key elements of a program and to launch an effective planning and implementation process.”

* * *

“Given the wide variation in Federal work facilities, there will be significant variation in the complexities associated with program design.”³³

³⁰ Guidelines for Public Access Defibrillation Programs in Federal Facilities, www.foh.dhhs.gov/public/whatwedo/AED/HHSAED.asp

³¹ Federal PAD Program Guidelines, section 1.0.

³² 42 U.S.C. § 238p.(b).

³³ DHHS Guidelines, §§ 1.0 and 5.0.

CASA immunity. The second provision of CASA provides AED operators with conditional Good Samaritan legal liability immunity for any harm resulting from the use or attempted use of an AED.³⁴ AED acquirers receive similar immunity if certain requirements are met. However, AED trainers and medical oversight physicians are not offered immunity under this law.

While any person who uses or attempts to use an AED qualifies for immunity under CASA, AED acquirers are subject to additional requirements. Specifically, AED acquirers must:

- properly notify local EMS agencies of the presence and location of the acquired AED(s);
- properly maintain and test the AED(s); and
- provide appropriate training to expected AED users.³⁵

CASA immunity is specifically unavailable if any harm is caused by “willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the victim who was harmed.”³⁶ This is a typical immunity approach that permits liability only for significant misconduct but protects conduct that constitutes a mistake or ordinary negligence.

How federal CASA immunity and state level AED immunity applies in specific situations remains a complex and unanswered question (see state Good Samaritan law section below). This is because CASA specifically provides:

“With respect to a class of persons for which [CASA] provides immunity from civil liability, [CASA] supersedes the law of a State only to the extent that the State has no statute or regulations that provide persons in such class with immunity for civil liability arising from the use by such persons of automated external defibrillator devices in emergency situations (within the meaning of the State law or regulation involved).”³⁷

Because all states now have some form of AED Good Samaritan immunity statute, this could mean that CASA immunity is no longer applicable in any state. However, the scope and conditions of state immunity statutes vary widely. Therefore, an important question is whether CASA immunity might be available if it provides more expansive immunity than found under a particular state’s law. For example, unlike CASA, some states limit immunity coverage to only trained users. Would CASA immunity be available to an untrained bystander who seeks to help an SCA victim? This question, and others like it, must ultimately be answered by the courts.

³⁴ 42 U.S.C. § 238q.(a).

³⁵ 42 U.S.C. §§ 238q.(a)(1) – (3).

³⁶ 42 U.S.C. § 238q.(b)(1).

³⁷ 42 U.S.C. § 238q.(c)(1)(B).

The Aviation Medical Assistance Act of 1998³⁸ – Requiring Airlines to Deploy AEDs

Following a study required by the Aviation Medical Assistance Act of 1998 (Act), the FAA adopted new rules requiring that most commercial aircraft carry AEDs as of April 12, 2004.³⁹ Additional rules require that flight attendants receive initial and recurring training in CPR and the use of an AED.⁴⁰ This landmark Act led to the first mandate of any kind, and the only existing federal mandate, requiring deployment of AEDs in a specific setting.

State AED Laws

State AED laws currently are focused on AED program mandates, AED program requirements, and Good Samaritan immunity.

AED Program Mandates

As a general rule, no organization is legally required to deploy AEDs. As with many general rules, however, there are a number of exceptions to this one.

A legal duty to have AEDs can arise in two contexts. First, a community expectation (i.e., a “standard of care”) can emerge under general negligence principles suggesting that a particular type of venue must have AEDs. For a variety of reasons, the two venues currently at greatest risk of being exposed to an AED standard of care are health clubs (in states without AED mandates) and schools. Whether a standard of care exists is determined on a case-by-case basis in court. The standard of care issue is discussed in greater detail later in this White Paper.

The second way a legal duty to have AEDs can arise is by legislative dictate. As a matter of public health policy, federal and state (sometimes even local) legislatures can mandate the deployment of AEDs in specific locations.

As discussed above, the Federal Aviation Administration, following the direction of the U.S. Congress, passed rules requiring airlines to place AEDs on commercial aircraft. This remains the only federal AED mandate. A variety of AED mandates have also emerged at the state and local level.

Examples of current legislative AED deployment mandates include the following. Note, this is not an exhaustive list of mandates.

- Public schools: Arkansas,⁴¹ Florida,⁴² New York⁴³, Nevada (high schools)⁴⁴, and Texas⁴⁵

³⁸ 49 U.S.C. § 44701, Pub. L. 105-170 (1998).

³⁹ 14 CFR §121.803(b)(4).

⁴⁰ 14 CFR §121.805(b)(5).

⁴¹ Arkansas Code Annotated § 6-10-121.

⁴² Florida Statutes Annotated § 1006.165.

⁴³ New York Education Law § 917.

⁴⁴ Nevada Revised Statutes § 450B.600 1.(a).

⁴⁵ Texas Education Code § 38.017.

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- Health and fitness clubs: California⁴⁶, Illinois⁴⁷, Massachusetts⁴⁸, New York⁴⁹, Louisiana⁵⁰, Oregon⁵¹, and Rhode Island⁵²
 - State and other public buildings: Arizona⁵³, California⁵⁴, Nevada⁵⁵, New Jersey⁵⁶, and New York⁵⁷
 - Sporting arenas: Nevada⁵⁸
 - Large occupancy buildings: New York⁵⁹ and Las Vegas, Nevada⁶⁰

In light of current trends and the known public health benefits of AED programs, it is likely additional mandates will continue to emerge. Office buildings, hotels and other large public venues are probable and appropriate targets for new state and local AED deployment mandates.

AED Program Requirements

States now impose numerous and often burdensome requirements on AED programs. Program elements as well as conditions, restrictions and limitations addressed by state laws vary widely. Generally, topics found in state laws include but are certainly not limited to:

- Good Samaritan immunity
- Medical oversight
- Permissible AED users
- Agency AED deployment notification
- Written policies, procedures and protocols
- Quality assurance program participation
- AED and CPR training
- Equipment inspection and maintenance
- Post event reporting

⁴⁶ California Health & Safety Code § 104113.

⁴⁷ Illinois Public Act 93-0910 (enacted August 12, 2004).

⁴⁸ Massachusetts General Laws 93 § 78A.

⁴⁹ New York General Business Law § 627-a (effective January 16, 2005).

⁵⁰ Louisiana Act No. 885 (2004 Regular Session) (effective January 1, 2005).

⁵¹ Oregon Revised Statutes § 431.680.

⁵² Rhode Island General Laws Chapter 5-50, Public Law No. 440 (effective January 1, 2005).

⁵³ Arizona Revised Statutes § 34-401 (effective June 30, 2003).

⁵⁴ California Government Code § 8455 (effective January 21, 2004).

⁵⁵ Nevada Revised Statutes § 450B.600 1.(e) and (f) (effective July 1, 2004).

⁵⁶ New Jersey Statutes Annotated § 2A:62A-29 (effective January 8, 2002).

⁵⁷ New York Public Buildings Law § 140 (effective April 1, 2005).

⁵⁸ Nevada Revised Statutes § 450B.600 1.(d) (effective July 1, 2004).

⁵⁹ New York Public Health Law § 225.

⁶⁰ Las Vegas Uniform Fire Code § 20.1.4.12 (effective January 1, 2005).

State AED program requirements are sometimes found in stand-alone statutes and regulations. However, most such requirements are embedded within AED Good Samaritan laws. Consider the examples contained in the following section.

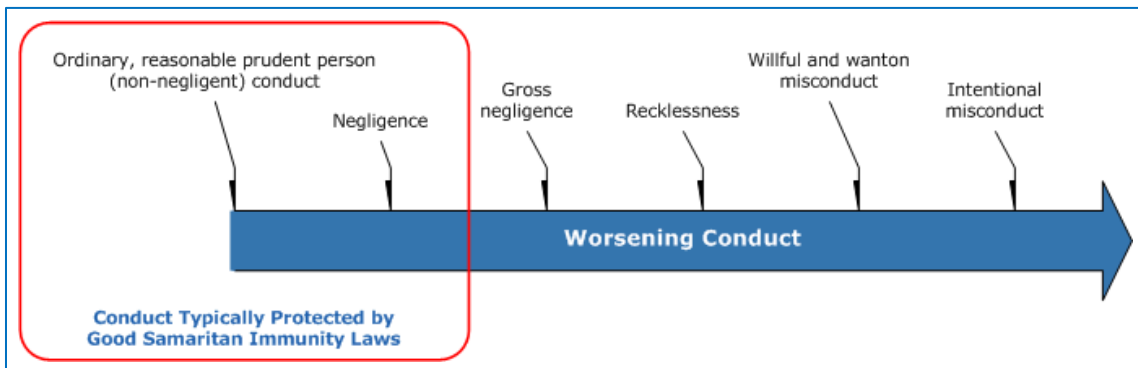
AED Good Samaritan Immunity

The concept of immunity means an exemption from an otherwise existing legal duty. This type of legal exemption is created by statute and is granted to a person or class of persons who meet stated conditions.

Laws have now been enacted in every state describing some form of AED Good Samaritan immunity ostensibly offered to various AED program constituents. The scope of coverage and conditions imposed by these laws vary widely and follow no consistent pattern or public policy rationale. It is important to remember that, for any available immunity to apply, all conditions of a Good Samaritan immunity statute must be followed.

Following are just a few examples of the wide range of coverage and condition issues addressed in selected state AED Good Samaritan laws.

Degree of unreasonableness permitted. The degree of misconduct found in the world of negligence law can be characterized along a continuum ranging from non-negligent conduct to intentional misconduct. This continuum is shown in the following chart (different states sometimes use different words but the concept is the same):



By definition, Good Samaritan laws make it more difficult to sue those involved with AED programs by protecting certain levels of misconduct from liability. The level of protection varies widely from state to state. Meaningful immunity laws typically protect non-negligent conduct and misconduct amounting only to negligence. California, for example, immunizes all but “acts of gross negligence or willful or wanton misconduct.”⁶¹ Florida immunizes all but “willful or criminal misconduct, gross negligence, reckless disregard or misconduct, or a conscious, flagrant indifference to the rights or safety of the victim who was harmed.”⁶² A

⁶¹ California Civil Code § 1714.21 (f); California Health & Safety Code § 1797.196 (e).

⁶² Florida Statutes Annotated § 768.1325 (4)(a).

very few states appear to offer immunity for conduct that is worse than negligence. Examples include Alaska⁶³ and Georgia.⁶⁴

In contrast, states like Virginia⁶⁵ and Kansas⁶⁶ offer “placebo” immunity that applies only to those who act “as an ordinary, reasonably prudent person would have acted under the same or similar circumstances.” Thus, only reasonable – or non-negligent – conduct is protected. Levels of misconduct including negligence and beyond are not protected. Alarming, as of this writing, approximately 25 percent of states appear to offer no immunity protection to anyone though existing laws create the perception that protection is available.

Permissible scope of AED users. AED immunity laws may also limit those authorized to use an AED by protecting only certain user classes. For example, states like Arizona⁶⁷ expressly limit immunity to only trained AED operators. In contrast, states like Georgia⁶⁸ and Indiana⁶⁹ recommend training or require only that expected AED users be trained. They do not limit immunity to only trained users.

Persons who receive immunity. AED programs are comprised of AED acquirers, program managers, medical oversight physicians, trainers, and AED users. All states do not offer immunity to all constituents. For example, California broadly offers immunity to AED users,⁷⁰ providers of CPR and AED training,⁷¹ AED acquirers,⁷² and AED medical oversight physicians and program managers⁷³ (assuming all other conditions are met). In contrast, Pennsylvania offers immunity only to AED users and acquirers.⁷⁴

Other conditions associated with immunity. AED Good Samaritan laws vary widely and often include a long list of conditions that must be met in order for immunity to be available. From a risk management perspective, these laws must be carefully read and understood and AED programs properly designed to ensure compliance.

Public policy considerations. It is important to recognize that AED program requirements do not necessarily further public policy and public health goals associated with widespread AED deployment. For example, many states limit immunity to only trained AED users even though studies clearly show untrained users can quickly and effectively use AEDs. Thus, this requirement needlessly reduces the number of potential rescuers available to help SCA

⁶³ Alaska Statutes § 09.65.087(a).

⁶⁴ Code of Georgia § 51-1-29.3(a).

⁶⁵ Annotated Code of Virginia § 8.01-225 A.7.

⁶⁶ Kansas Statutes Annotated § 65-6149a.

⁶⁷ Arizona Revised Statutes § 36-2263.

⁶⁸ Georgia Code Annotated § 31-11-53.1.

⁶⁹ Indiana Code IC § 34-30-12-1

⁷⁰ California Civil Code § 1714.21 (b).

⁷¹ California Civil Code § 1714.21 (c).

⁷² California Civil Code § 1714.21 (d).

⁷³ California Civil Code § 1714.21 (e).

⁷⁴ 42 Pennsylvania Consolidated Statutes Annotated § 8331.2

victims. Moreover, adding complicated and burdensome AED program requirements with no proven public health benefits likely reduces the number of organizations willing to implement AED programs. AED laws will hopefully change over time to better match the public health goals of public access defibrillation.

State AED Laws Summary

State AED laws vary widely. AED program executives and managers are urged to review applicable laws carefully when designing and implementing an AED program. This is particularly true for organizations operating in multiple states. Given the complexity of these statutes, most organizations would benefit from review by experts in this area and are urged to seek outside assistance.

NEGLIGENCE LIABILITY RISK

Introduction

Organizations considering the deployment and use of AEDs often fear negligence liability suits. As noted long ago by the American Heart Association, "a potential disincentive to lay users of AEDs . . . is the threat of a personal injury claim."⁷⁵ While this apprehension is understandable, any actual liability risk associated with AED programs appears to be quite small assuming risks are managed appropriately. Clearly, perceptions, fears and future legal direction must be addressed if widespread AED availability is to become reality.

The following sections provide an overview of negligence liability issues as they relate to AED programs. From this, organizations considering the purchase of AEDs will better understand the generally low legal liability risk associated with AED programs and how best to create AED programs that save lives and manage risk.

Negligence – an Overview

For a sudden cardiac arrest victim (or a relative) to successfully sue an AED purchaser, user, or other program constituent for negligence, four essential legal elements must be proven. These include:

- duty
- breach of duty
- causation of injury, and
- legally recognized damages

A negligence claim cannot succeed if any one of these elements is missing. Because an AED related claim is most likely to focus on the elements of duty and causation, these elements are discussed further. The breach of duty issue is directly related to duty and requires that the person suing prove that the person being sued acted unreasonably under the circumstances. Damages in AED cases are generally related to death or serious personal injury, e.g., brain damage.

Legal Duty

“Duty” in negligence law is defined as "an obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another."⁷⁶ If a legal duty is found to exist, it is possible for liability to be imposed. In the absence of a legal duty, no liability can be imposed.

In general, a bystander has no legal obligation to provide affirmative medical aid to an ill or injured person, even if the bystander has the ability to help. "[T]he law has persistently

⁷⁵Weisfeldt ML et al. American Heart Association Report on the Public Access Defibrillation Conference December 8-10, 1994. Automatic External Defibrillation Task Force. *Circulation*.1995;92:2740-2747.

⁷⁶W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 53, at 356 (5th ed. 1984) (“Prosser”).

refused to impose on a stranger the moral obligation of common humanity to go to the aid of another human being who is in danger, even if the other is in danger of losing his life."⁷⁷

Courts recognize, however, that EMS providers such as paramedics and EMTs generally have a legal duty to respond to and treat victims of medical emergencies. Specific responsibilities imposed on these responders vary from state to state and are influenced by court cases, statutes and regulations.

The following sections, from the leading statement of general negligence law, outlines the other types of relationships which may give rise to a duty to render emergency medical assistance.⁷⁸ This statement of law is adopted by many courts and will become more important as the concept of AED programs and public access defibrillation continue to evolve.

General Duty to Render Medical Aid

(1) A common carrier is under a duty to its passengers to take reasonable action

(a) to protect them against unreasonable risk of physical harm, and

(b) to give them first aid after it knows or has reason to know that they are ill or injured, and to care for them until they can be cared for by others.

(2) An innkeeper is under a similar duty to its guests.

(3) A possessor of land who holds it open to the public is under a similar duty to members of the public who enter in response to his invitation.

* * *

**General Medical Duty Imposed on Common Carriers,
Innkeepers and Business Establishments**

Provide a *reasonable* level of medical aid and quickly summon outside emergency medical assistance (emphasis added).

Thus, in contrast to the general rule imposing no such duty on bystanders, certain groups may be compelled by law to render a reasonable level of medical aid and to quickly summon outside emergency medical assistance. These groups include common carriers (such as airlines, cab companies, passenger railroads and cruise ship operators), innkeepers (such as hotel and motel operators) and virtually all other commercial business establishments.

⁷⁷ Prosser.

⁷⁸ Restatement (Second) of Torts § 314A.

Appellate courts, trial court judges and juries define what is "reasonable," thus establishing the scope of a legal obligation or duty. The degree of reasonableness required under the facts and circumstances of a particular case evolves as society evolves. Action or inaction viewed as reasonable today may be viewed as unreasonable tomorrow.

Causation

A successful negligence lawsuit also requires proof that alleged misconduct caused legally recognized damages such as death or injury. Possible causation theories likely to arise in AED related cases include allegations that a death directly resulted from: 1) The failure to purchase and make available an AED; 2) the failure to use or timely use an available AED; or 3) the improper use of an available AED.

In all cases involving sudden cardiac death, the element of medical causation will be hotly contested. The plaintiff will cite extensive medical research showing that sudden cardiac arrest can be effectively treated with rapid defibrillation. The defense will counter by pointing out the life-threatening nature of sudden cardiac arrest and the fact that 95 percent of sudden cardiac arrest victims do not survive.

AED Related Court Cases

To date, relatively few lawsuits have arisen directly involving AEDs or AED programs. Most suits have been filed against organizations that did not have AEDs. However, a growing number of cases are emerging against organizations with AED programs for not properly responding to SCA emergencies. Following are highlights of selected AED related cases.

Liability or Potential Liability for Failing to Have an AED

*Stone v. Frontier Airlines, Inc.*⁷⁹ A widow brought a wrongful death suit against an airline claiming the lack of an AED and other medical equipment caused her 28 year old husband's death. The court held that a jury should decide whether the airline had a duty to carry AEDs. Importantly, the court considered the widow's contention that the airline was on notice as to the wide use and effectiveness of AEDs for in-flight cardiac arrests and therefore had a duty to carry AEDs. Factors giving rise to this notice included:

- General awareness that hundreds of sudden cardiac arrest deaths occur each year on commercial aircraft;
- knowledge of AED deployment and use by other carriers;
- awareness in the airline industry derived from general media coverage of AEDs and their benefits; and
- knowledge that emergency medical kits carried by the airline at the time of the event (2000) were useless to treat sudden cardiac arrest.

Factors similar to these are likely to be raised in lawsuits claiming other venues, e.g., health clubs, office buildings, hotels, etc., have a duty to deploy AEDs. The case settled.

⁷⁹ 256 F.Supp.2d 28 (D. Mass. 2002).

Busch Entertainment Group.⁸⁰ Wrongful death suit against Busch Gardens (Tampa, Florida) by mother of a 13 year old girl who died after a roller coaster ride. The suit claimed that the death resulted from the park's failure to have an AED and to provide proper emergency medical care. A jury returned a verdict of \$500,000 (reduced to \$350,000 based on a finding the mother was partially at fault).

Other cases in this category:

- *Ksypka v. Malden YMCA*.⁸¹ – trial court decided a jury should consider whether a health club had a duty to have AEDs in 2002, case believed still pending.
- *Chai v. Sports Fitness Clubs of America*.⁸² – jury found for defense, but case settled for \$2.25 million.
- *Somes v. United Airlines, Inc.*⁸³ – settled before trial on undisclosed terms.
- *Kleinknecht v. Gettysburg College*.⁸⁴ - case sent back to the lower court for trial, result unknown.
- *Ferguson v. Trans World Airlines*.⁸⁵ - case set for jury trial, result unknown.

Liability or Potential Liability for Failing to Properly Respond to SCA Emergency with Available AED

Thompson v. Rochester Community Schools.⁸⁶ Family filed a wrongful death action against several school employees after student collapsed at school and no one timely called 911, performed CPR or used the school's AED on student before paramedics arrived. A lower court ruled in favor of the employees and dismissed the case on the basis of immunity which requires proof of gross negligence. The appellate court reversed this decision ruling that a jury should decide whether the employees' actions constituted gross negligence. The case remains pending.

Madison v. Ernest N. Morial Convention Center.⁸⁷ Family brought a wrongful death suit against a convention center claiming an SCA victim's death was caused by the convention center's nurse failing to bring or timely call for an available AED. A jury found for the plaintiff and awarded \$800,000 in damages.

⁸⁰ Hillsborough County, FL, Circuit Court (1995). See www.clubssafety.com/lawnotes/april1999.htm.

⁸¹ 22 Mass.L.Rptr. 122, 2007 WL 738463 (Mass.Super.).

⁸² Broward County, FL, Circuit Court, Case No. 98-16053 CA [05] (1999).

⁸³ 33 F. Supp.2d 78 (D. Mass. 1999). Note, airlines are now required by federal law to carry AEDs.

⁸⁴ 989 F.2d 1360 (3d Cir. 1993).

⁸⁵ 135 F.Supp.2d 1304 (N.D. Georgia 2000)

⁸⁶ 2006 WL 3040137 (Mich.App.).

⁸⁷ 834 So.2d 578 (La. App. 2002).

No Liability for Failing to Properly Respond to SCA Emergency with Available AED

*Mandel v. Canyon Ranch, Inc.*⁸⁸ Wrongful death lawsuit against a health resort claiming resort employees failed to retrieve and use an available AED to treat a guest who suffered SCA. After a three-week trial, the jury returned a verdict in favor of the health resort.

*Rotolo v. San Jose Sports and Entertainment, LLC.*⁸⁹ Wrongful death lawsuit brought by the parents of a teenager who died as a result of sudden cardiac arrest while participating in an ice hockey game against the operators of the ice hockey facility. The family alleged that defendants had a duty to notify users of the facility of the existence and location of an AED at the facility and that the timely use of the AED would have greatly increased the teenager's chances of survival. The appellate court ruled that no duty to notify existed and dismissed the case. The basis of the ruling was the absence of a notification requirement in California's AED immunity laws. Hopefully, this case will be overturned on appeal and a jury, rather than a judge, will be permitted to determine whether it is reasonable to require that AED owners let people know AEDs are on site and where they are.

No Liability for Failing to Have an AED

*Atcovitz v. Gulph Mills Tennis Club, Inc.*⁹⁰ A guest brought a personal injury claim against a tennis club alleging the lack of an AED caused more severe injuries than would have been experienced if prompt defibrillation had occurred. The court dismissed the claim finding that, under Pennsylvania law as it existed in 1996 (the date on which the injury occurred), no duty required the club to acquire, maintain and use an AED.

Other cases in this category:

- *Salte v. YMCA of Metropolitan Chicago Foundation*⁹¹ - no duty requiring an Illinois health club to have an AED (note, Illinois recently enacted a statutory mandate requiring AEDs in health clubs).
- *Rutnik v. Colonie Center Court Club, Inc.*⁹² – no duty requiring a New York health club to have an AED (note, New York recently enacted a statutory mandate requiring AEDs in health clubs).

What the Cases Teach Us

Relatively few lawsuits have been brought involving AEDs and AED programs. Thus far, the majority have been initiated against organizations that failed to buy and deploy AEDs. Given the growing proliferation of AEDs in public settings, the now emerging wave of suits are targeting AED programs that fail to promptly and properly respond to sudden cardiac arrest emergencies. In all of these cases, the issue of duty will be hotly contested – both in the context of whether an organization is legally required to deploy AEDs and, for existing AED

⁸⁸ Pima County, Arizona, Superior Court, Case No. 312777. See www.clubsafety.com/lawnotes/jan1999.htm.

⁸⁹ 2007 WL 1503003 (Cal.App. 6 Dist.).

⁹⁰ 812 A.2d 1218 (Pa. 2002).

⁹¹ 814 N.E.2d 610, 286 Ill. Dec. 622 (2004).

⁹² 249 A.D.2d 873, 672 N.Y.S.2d 451 (1998).

programs, what program and operational characteristics constitute a “reasonable” AED program design.

Based on the legal history of other safety devices, it is probable that over time a duty to have AEDs will be established for certain types of locations. In addition, standards defining what constitutes a reasonable AED program implementation will also become clearer.

MANAGING AED PROGRAM NEGLIGENCE LIABILITY RISK

Strategies available to manage AED program negligence liability risks depend on whether or not an organization chooses to deploy AEDs.

For organizations electing not to deploy AEDs, risk management relies on the expectation that a court will find an absence of legal duty. Given the growing awareness of AEDs and their benefits, and AED deployment trends in venues such as health clubs, office buildings, hotels, schools and the like, it is likely more courts will find that a legal duty does indeed exist in these venues and will impose liability on organizations that fail to deploy AEDs. Ultimately, this risk management strategy relies exclusively on factors outside the control of the organization.

In contrast, a variety of risk management strategies are available to organizations that elect to implement AED programs. These strategies are controlled by the organization and include:

- Program design: The best way to manage liability risk is to carefully design, implement, and operate the AED program in a “reasonable” manner.
- Manufacturers’ indemnification: Some AED manufacturers offer liability indemnification to purchasers of their products. The types and scope of coverage vary – so read the fine print carefully.
- Good Samaritan immunity: Good Samaritan immunity laws may offer various levels of liability protection if they apply and if **all** conditions associated with the immunity are precisely followed.
- Liability insurance: Liability insurance offers a contractual way to share liability risk with an insurance company. Be sure to carefully understand the scope of coverage, any conditions that apply, and the dollar limits of coverage.

Quantifying the precise liability risk associated with AED programs is not possible. However, legal trends – in terms of court cases, legislative activity and other safety related categories – strongly suggest that organizations that carefully design and implement AED programs lower their liability risks in comparison to similar organizations that choose not to do so.

LEGAL NOTICE

Information in *Understanding AED Program Legal Issues: An Overview of Laws and Liability Risks Impacting AED Programs* is not intended as legal advice. While reasonable efforts have been made to ensure the accuracy of information as of the date of publication, the AED legal and regulatory landscape is evolving rapidly. Legal and public policy questions surrounding AED programs can be complex. If you need specific advice, seek the services of an experienced and competent professional.

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