

Saving Lives, Managing Risk™: Understanding AED Program Legal Issues

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INTRODUCTION

Automated external defibrillators (AEDs) are now being placed in a rapidly growing number of businesses and other public locations for use by non-healthcare-professions. 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 clear. However, a complex legal and regulatory landscape and the risk of negligence liability face businesses and industries that implement AED programs.

This overview, "Saving Lives, Managing Risk: Understanding AED Program Legal Issues," highlights the often changing public policy framework within which AED programs operate and the importance of well designed and documented AED programs as a way to manage negligence liability risk. This overview 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.

SUDDEN CARDIAC DEATH AND THE PUBLIC HEALTH IMPERATIVE FOR AEDS

Many organizations are embracing the notion of public access defibrillation and many policy-makers are considering mandated deployment of portable defibrillators in public settings. This is because people are dying and a therapy exists that can treat the condition causing many of these deaths.

Out-of-hospital sudden cardiac death strikes between 350,000 and 450,000 people annually in the U.S. – at least 1,000 per day.¹ Most individuals who experience SCA have not been previously identified as high risk individuals² and events usually occur in public places or at home rather than in medical settings.³ Because of this, the overall SCA survival rate in the United States is estimated to be between 5 and 7 percent.⁴

Most sudden cardiac death results from sudden cardiac arrest ("SCA") caused by a cardiac arrhythmia known as ventricular fibrillation ("VF").⁵ 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, it only extends the time window for a very few minutes within which to deliver a successful shock.^{6,7,8}

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.^{9,10,11} 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.

In response to a 1992 challenge by the American Heart Association (AHA)¹², the medical device industry developed an automated external defibrillator capable of being operated by lay users. 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.

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 industries
- Requirements relating to the deployment and use of AEDs
- Good Samaritan immunity
- Funding for AED programs (not addressed in this overview)

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-professional settings. This overview provides a high level explanation of the complex legal framework which AED program executives must be aware of, and comply with, as they design and operate AED programs. Following is a discussion of:

- Federal AED laws
- State AED laws
- Legal liability risk
- Managing AED program risk

FEDERAL AED LAWS

Federal laws provide the basic framework for the deployment of AEDs. These laws currently focus on medical device oversight, AED use mandates, and Good Samaritan immunity.

U.S. FDA Oversight of AEDs

The U.S. Food, Drug and Cosmetic Act¹⁶ 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.¹⁷ The FDA is primarily focused on device clearance, prescription requirements, and training requirements.

Device Clearance. When clearing AEDs for sale, the FDA issues what are known as 510(k) clearance letters. These letters are device specific 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 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. The FDA's 510(k) database can be searched at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Prescription requirement. Until recently all AEDs could only be sold or purchased with a prescription.¹⁸ However, FDA regulations do not detail what an AED prescription means. As a result, prescriptions are written to cover AED use by everyone from individual persons, to AED program sites, companies, buildings, and the like. 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 and where SCA events will occur. While not formally sanctioning this model, the FDA has not challenged it.

The AED prescription model is now 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.¹⁹ OTC status is being sought for other AEDs and it seems likely that many AEDs may soon be available over-the-counter. One important benefit of this change 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.²⁰ These training requirements are variously described to include training in the use of the specific AED,²¹ and "training in basic life support, advanced life support, or other physician-authorized emergency medical response."²² Beyond this, the agency permits states and localities to determine specific training requirements.²³ There are some clearance letters that do not include this training restriction.²⁴ 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.

Cardiac Arrest Survival Act - AEDs in Federal Buildings and National Good Samaritan Immunity

The Cardiac Arrest Survival Act (CASA)²⁵ 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 Health and Human Services (HHS) department to establish guidelines for placing AEDs in federal buildings
- Create a form of qualified Good Samaritan immunity for the emergency use of AEDs.

AEDs in federal buildings. HHS published the CASA required guidelines in May 2001.²⁶ These guidelines seek to “provide a general framework for initiating a design process for a public access defibrillation (PAD) program in Federal facilities.”²⁷ 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.²⁸

These guidelines are intended for use by federal AED program planners but can serve as a general reference resource for others.

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.²⁹ AED acquirers receive similar immunity if certain requirements are met. However, AED trainers and medical oversight physicians do not receive 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 presences and location of the acquired AED(s);
- properly maintain and test the AED(s); and
- provide appropriate training to expected AED users.³⁰

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.”³¹ 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).”³²

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, can only be answered by the courts.

The Aviation Medical Assistance Act of 1998³³ – Requiring Airlines to Deploy AEDs

Following a study required by this Act, the FAA adopted new rules requiring that most commercial aircraft carry AEDs as of April 12, 2004.³⁴ Additional rules require that flight attendants receive initial and recurring training in CPR and the use of an AED.³⁵ This landmark Act led to the first mandate of any kind 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 discussed above, the U.S. Congress legislatively required airlines to place AEDs on commercial aircraft. States and localities are now adopting similar mandates for other industries.

Examples of current legislative AED deployment mandates include:

- Public schools: New York³⁶ and Nevada (high schools)³⁷
- Health and fitness clubs: Illinois³⁸, New York³⁹, Louisiana⁴⁰, and Rhode Island⁴¹ (also being considered in Michigan, New Jersey and Pennsylvania)
- State and other public buildings: Arizona⁴², California⁴³, Nevada⁴⁴, New Jersey⁴⁵, New York⁴⁶
- Sporting arenas: Nevada⁴⁷
- Large occupancy buildings: Las Vegas, Nevada⁴⁸

In light of current trends and the known public health benefits of AED programs, it is likely additional mandates will soon emerge. Office buildings, hotels and other large public venues are probable 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 often covered include but are certainly not limited to:

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

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.

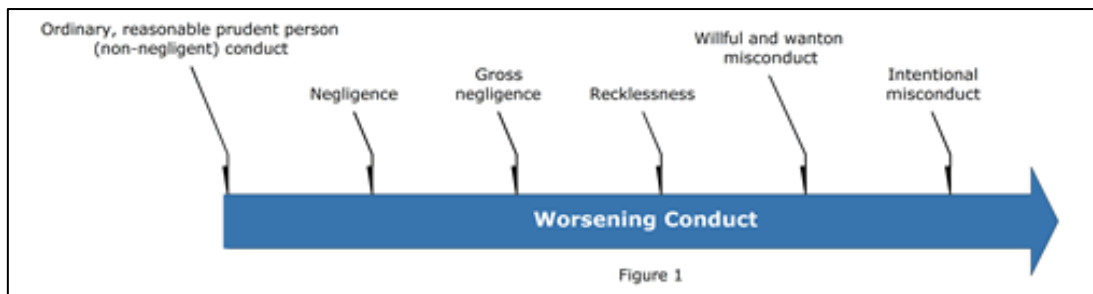
AED Good Samaritan Immunity

The concept of immunity means an exemption from an otherwise existing 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 granting some form of AED Good Samaritan immunity to various AED program constituents. Conditions imposed by these laws vary widely and follow no consistent pattern or public policy rationale. It is important to remember that, for 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 conditions imposed by selected state AED Good Samaritan laws:

Degree of unreasonableness permitted. The degree of misconduct found in the world of negligence law can be characterized and defined along the continuum shown in Figure 1 (different states use different words but along the same lines):



By definition, Good Samaritan laws make it more difficult to sue AED programs by protecting certain levels of misconduct from liability. This level of protection varies widely from state to state. For example, California immunizes all but “acts of gross negligence or willful or wanton misconduct.”⁴⁹ 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”⁵⁰ Thus, in these states and others like them, both reasonable (non-negligent) and negligent (unreasonable) conduct are protected from liability.

In contrast, states like Virginia⁵¹ and Kansas⁵² 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.

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 Arizona⁵³ expressly limit immunity to only trained AED operators. In contrast, states like Georgia⁵⁴ and Indiana⁵⁵ 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,⁵⁶ providers of CPR and AED training,⁵⁷ AED acquirers,⁵⁸ and AED medical oversight physicians and program managers⁵⁹ (assuming all other conditions are met). In contrast, Pennsylvania offers immunity only to AED users and acquirers.⁶⁰

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 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 probably 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 AHA, "a potential disincentive to lay users of AEDs . . . is the threat of a personal injury claim."⁶¹ While this apprehension is understandable, any actual liability risk associated with AED programs appears to be quite small. Still, 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

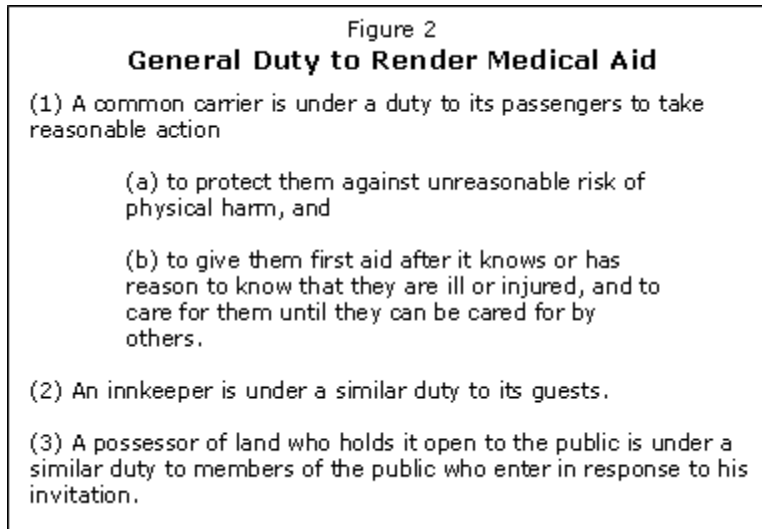
"Duty" in negligence law is defined as "an obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another."⁶² If a legal duty is found to exist, it is possible for liability to be imposed. In the absence of a legal duty, no liability can be 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 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."⁶³

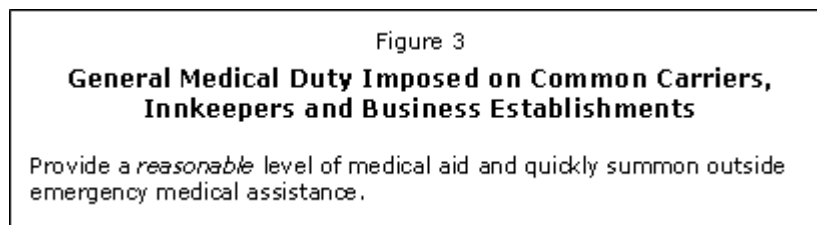
Courts recognize, however, that EMS providers such as paramedics and EMTs generally have a legal duty to respond to and treat victims of medical emergencies. Specific responsibilities imposed on these responders vary from state to state and are influenced by court cases, statutes and regulations.

The following section, 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 (Figure 2).⁶⁴ 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.



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 (Figure 3). 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.



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 SCA, 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 SCA 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 will likely emerge against 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.*⁶⁵ 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.

*Busch Entertainment Group.*⁶⁶ 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:

- *Chai v. Sports Fitness Clubs of America.*⁶⁷ – jury found for defense, but case settled for \$2.25 million.
- *Somes v. United Airlines, Inc.*⁶⁸ – settled before trial on undisclosed terms.
- *Kleinknecht v. Gettysburg College*⁶⁹ - case sent back to the lower court for trial, result unknown.
- *Ferguson v. Trans World Airlines*⁷⁰ - case set for jury trial, result unknown.



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

*Madison v Ernest N. Morial Convention Center.*⁷¹ 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.



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

*Mandel v. Canyon Ranch, Inc.*⁷² 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.



No Liability for Failing to Have an AED

*Atcovitz v. Gulph Mills Tennis Club, Inc.*⁷³ 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*⁷⁴ - 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.*⁷⁵ – 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, it is likely the next wave of suits will target 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 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 risk 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 quite 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.
- **Program certification**: Becoming “certified” by a trusted third party can help minimize and share liability risk.
- **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 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.

EDLPC Legal Notice

Information in “Saving Lives, Managing Risk: Understanding AED Program Legal Issues” is not intended as legal advice. While every effort is made to ensure the accuracy of information, 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 a competent professional.

About EDLPC

The Early Defibrillation Law & Policy Center (EDLPC) was founded in 2003 to help save lives by increasing the availability and use of automated external defibrillators in public settings. EDLPC designs and certifies effective life saving Cardiac Arrest Survival Systems™ (CASS™) that increase the chances of survival, ensure compliance with existing laws and regulations, and reduce the risk of negligence lawsuits. EDLPC helps its clients create new programs and assesses existing programs. Additional information about EDLPC is available at www.edlpc.com.

EDLPC's founder is Richard A. Lazar, a nationally recognized expert on AED laws, regulations and program operations. Richard authored *Saving Lives, Managing Risk: Understanding AED Program Legal Issues* to help AED program executives and planners better understand the legal framework within which AED programs operate. Richard can be contacted at rlazar@edlpc.com.

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

¹⁶ 21 U.S.C. § 301 et. seq.

¹⁷ 21 CFR § 870.5310, 21 CFR § 870.1025.

¹⁸ 21 CFR § 801.109.

¹⁹ FDA 510(k) Number K040904 (09-16-04).

²⁰ E.g., FDA 510(k) Number K033474 (5-21-04).

²¹ E.g., FDA 510(k) Number K040637 (8-6-04).

²² E.g., FDA 510(k) Number K014157 (1-17-02).

²³ Automatic External Defibrillators (AEDs) and Public Access Defibrillation (PAD) Programs, www.fda.gov/cdrh/consumer/AED_PAD.html (October 26, 2000).

²⁴ E.g., FDA 510(k) Number K011144 (12-03-01); FDA 510(k) Number K013896 (6-19-02).

²⁵ 42 U.S.C. §§ 238p. and 238q.

²⁶ Guidelines for Public Access Defibrillation Programs in Federal Facilities, www.foh.dhhs.gov/public/whatwedo/AED/HHSAED.asp

²⁷ Federal PAD Program Guidelines, section 1.0.

²⁸ 42 U.S.C. § 238p.(b).

²⁹ 42 U.S.C. § 238q.(a).

³⁰ 42 U.S.C. §§ 238q.(a)(1) – (3).

³¹ 42 U.S.C. § 238q.(b)(1).

³² 42 U.S.C. § 238q.(c)(1)(B).

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

³⁴ 14 CFR §121.803(b)(4).

³⁵ 14 CFR §121.805(b)(5).

³⁶ New York Education Law § 917 (effective September 1, 2002).

³⁷ Nevada Revised Statutes § 450B.600 1.(a). (effective July 1, 2004).

³⁸ Illinois Public Act 93-0910 (enacted August 12, 2004).

³⁹ New York General Business Law § 627-a (effective January 16, 2005).

⁴⁰ Louisiana Act No. 885 (2004 Regular Session) (effective January 1, 2005).

⁴¹ Rhode Island General Laws Chapter 5-50, Public Law No. 440 (effective January 1, 2005).

⁴² Arizona Revised Statutes § 34-401 (effective June 30, 2003).

⁴³ California Government Code § 8455 (effective January 21, 2004).

- ⁴⁴ Nevada Revised Statutes § 450B.600 1.(e) and (f) (effective July 1, 2004).
- ⁴⁵ New Jersey Statutes Annotated § 2A:62A-29 (effective January 8, 2002).
- ⁴⁶ New York Public Buildings Law § 140 (effective April 1, 2005).
- ⁴⁷ Nevada Revised Statutes § 450B.600 1.(d) (effective July 1, 2004).
- ⁴⁸ Las Vegas Uniform Fire Code § 20.1.4.12 (effective January 1, 2005).
- ⁴⁹ California Civil Code § 1714.21 (f); California Health & Safety Code § 1797.196 (e).
- ⁵⁰ Florida Statutes Annotated § 768.1325 (4)(a).
- ⁵¹ Annotated Code of Virginia § 8.01-225 A.7.
- ⁵² Kansas Statutes Annotated § 65-6149a.
- ⁵³ Arizona Revised Statutes § 36-2263.
- ⁵⁴ Georgia Code Annotated § 31-11-53.1.
- ⁵⁵ Indiana Code IC § 34-30-12-1
- ⁵⁶ California Civil Code § 1714.21 (b).
- ⁵⁷ California Civil Code § 1714.21 (c).
- ⁵⁸ California Civil Code § 1714.21 (d).
- ⁵⁹ California Civil Code § 1714.21 (e).
- ⁶⁰ 42 Pennsylvania Consolidated Statutes Annotated § 8331.2
- ⁶¹ Weisfeldt 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.
- ⁶² W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 53, at 356 (5th ed. 1984) (“Prosser”).
- ⁶³ Prosser.
- ⁶⁴ Restatement (Second) of Torts § 314A.
- ⁶⁵ 256 F.Supp.2d 28 (D. Mass. 2002).
- ⁶⁶ Hillsborough County, FL, Circuit Court (1995). See www.clubssafety.com/lawnotes/april1999.htm.
- ⁶⁷ Broward County, FL, Circuit Court, Case No. 98-16053 CA [05] (1999).
- ⁶⁸ 33 F. Supp.2d 78 (D. Mass. 1999). Note, airlines are now required by federal law to carry AEDs.
- ⁶⁹ 989 F.2d 1360 (3d Cir. 1993).
- ⁷⁰ 135 F.Supp.2d 1304 (N.D. Georgia 2000)
- ⁷¹ 834 So.2d 578 (La. App. 2002).
- ⁷² Pima County, Arizona, Superior Court, Case No. 312777. See www.clubssafety.com/lawnotes/jan1999.htm.
- ⁷³ 812 A.2d 1218 (Pa. 2002).
- ⁷⁴ 814 N.E.2d 610, 286 Ill. Dec. 622 (2004).
- ⁷⁵ 249 A.D.2d 873, 672 N.Y.S.2d 451 (1998).