

The Heartbreak of Not Making Automated External Defibrillators Available For Public Use

SAMUEL D. HODGE, JR.^{*} & DARIA KOSCIELNIAK^{**}

An automated external defibrillator (AED) is one of the greatest advancements in defibrillator technology in the past several decades. Its purpose is to treat sudden cardiac arrest, the leading cause of death in this country. An AED checks the heart's rhythm and will dispatch an electric jolt when needed to reestablish the organ's normal electrical pattern. The magic of this portable device is that anyone can use it and it is relatively inexpensive to purchase. Studies have shown that access to AEDs can improve the odds of surviving a cardiac arrhythmia outside of the hospital and the American Heart Association estimates that an AED can improve a person's chances of surviving the cardiac event by 49–75%.

Not everyone shares the same enthusiasm for the widespread availability of AEDs. There is a patchwork of statutes, rules, and regulations concerning the use of AEDs, and a number of entities are fearful of liability issues. While airlines are mandated to have AEDs on commercial aircraft, and Congress encourages the placement of these life-saving devices in federal buildings, private industries have resisted most proposed laws that require the installation of an AED

^{*} Samuel D. Hodge, Jr. is a skilled litigator and professor of Legal Studies at Temple University where he teaches both law and anatomy. He has authored more than 150 articles in medical and legal journals and has written six medical/legal texts. Professor Hodge is considered one of the most popular CLE speakers in the country, enjoys an AV Preeminent rating, and has been named a top-rated lawyer in Pennsylvania.

^{**} Daria Koscielniak is a 2016 graduate of the Temple University Beasley School of Law and a former student in Professor Hodge's anatomy class.

on their premises. Health clubs, shopping centers, hotels, and country clubs are examples of businesses in this category. Various theories have been advanced to defeat any proposed law that requires mandatory installation, but the bottom line seems to be a liability concern. This article will explore the history of AEDs, the legislation on the topic, and the cases that have arisen in an attempt to impose liability against an entity for the failure to have an AED on the premise during a cardiac event.

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INTRODUCTION

Would a couple thousand dollars be a reasonable price to pay to save someone's life? This seemingly innocent question continues to be debated in response to whether health clubs, hotels, shopping centers, and other similar businesses should be required to have AEDs available on their premises in the event of a cardiac emergency.¹

¹ AED (Automated External Defibrillators), NEWNAN CPR, <http://newnancpr.org/aed/> (last visited Feb. 24, 2016).

The AED is touted as the greatest advancement in defibrillator technology in the past several decades.² The AED was introduced in 1978³ and ultimately gained approval for use by the general population.⁴ Its purpose is to treat sudden cardiac arrest (SCA), the leading cause of death in this country.⁵ SCA occurs when the heart abruptly stops beating, causing an interruption of blood flow to the brain and other body structures.⁶ An AED checks the heart's rhythms and dispatches an electric jolt, when needed, to reestablish the heart's normal electrical pattern.⁷ The magic of these portable devices is that anyone can use them.⁸

Each year more than 350,000 individuals suffer cardiac arrest outside of a hospital, and less than 10% survive the episode.⁹ No one is immune from a cardiac event,¹⁰ but they occur more frequently in the aging population, especially among those with prior heart problems.¹¹ Immediate cardiopulmonary resuscitation (CPR) and AED use can more than double a person's chances of surviving the incident.¹² Unfortunately, too few of these portable devices are available

² ROY LIDDLE ET AL., *ABC of Resuscitation: The Automated External Defibrillator*, 327 *BMJ* 1216, 1216 (2003), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC274065/pdf/bmj32701216.pdf>.

³ Chris Nelson, *A Little Defibrillator History and Its Potential Future*, AED.COM (May 29, 2013), <http://www.aed.com/blog/a-little-defibrillator-history-and-its-potential-future/>.

⁴ *Id.*

⁵ Roy Maurer, *AEDs in the Workplace: Benefit or Burden?*, SOC'Y FOR HUMAN RES. MGMT. (Mar. 29, 2013), <https://www.shrm.org/resourcesandtools/hr-topics/risk-management/pages/aeds-workplace-benefit-burden.aspx>.

⁶ *What Is an Automated External Defibrillator?*, NAT'L HEART, LUNG, AND BLOOD INST., <https://www.nhlbi.nih.gov/health/health-topics/topics/aed> (last updated Dec. 2, 2011).

⁷ *Id.*

⁸ NEWNAN CPR, *supra* note 1.

⁹ *Facts: Every Second Counts; Rural and Community Access to Emergency Devices*, AM. HEART ASS'N, https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_472102.pdf (Jan. 2015) [hereinafter *Facts: Every Second Counts*].

¹⁰ *Sudden Death in Young People: Heart Problems Often Blamed*, MAYO CLINIC (Apr. 14, 2014), <http://www.mayoclinic.org/sudden-death/art-20047571>.

¹¹ *Facts: Every Second Counts*, *supra* note 9.

¹² *Id.*

for public use. In fact, “64% of Americans have never even seen an AED.”¹³

I. THE HEART AND ITS ARRHYTHMIAS

The heart is a vital organ made up of four chambers,¹⁴ with an average size that is slightly larger than a person’s fist.¹⁵ The main task of this circulatory organ is to pump blood throughout the body, a job efficiently done about 100,000 times a day.¹⁶ The organ consists of thick muscular cells, which form the bulk of the cardiac wall.¹⁷ Contractions of these muscles are controlled by specialized fibers that emit electrical signals that are dispersed across the top to the bottom of the heart.¹⁸ These impulses tell the heart when to contract, thereby forcing blood to be pumped around the body in a systematic fashion.¹⁹ An electrocardiogram (EKG) records and measures this electrical activity.²⁰

These specialized fibers consist of the natural pacemaker or sinoatrial node (SA), which initiates the heartbeat,²¹ the atrioventric-

¹³ *Id.*

¹⁴ SAMUEL D. HODGE, JR. & JACK E. HUBBARD, CLINICAL ANATOMY FOR LAWYERS 358 (2012) (The heart has four chambers, the atria and ventricles. The top chambers act as a reservoir for the blood and the lower chambers or ventricles are the pumps. The left ventricle is the most important of these four chambers since it pumps the oxygenated blood to the aorta for distribution throughout the body.).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* at 360.

¹⁸ *Id.*; see also NAT’L HEART, LUNG, AND BLOOD INST., *What Is Atrial Fibrillation?*, <https://www.nhlbi.nih.gov/health/health-topics/topics/aed> (last updated Sept. 18, 2014).

¹⁹ HODGE, *supra* note 14, at 360–61.

²⁰ *Id.* at 361.

²¹ *Id.* at 360. The sinoatrial node is located in the right upper chamber and is the starting point for the heart’s electrical activity. *Understanding the Heart’s Electrical System and EKG Results*, NAT’L HEART, LUNG, AND BLOOD INST., <http://www.nhlbi.nih.gov/health/health-topics/topics/hb/> (last updated July 9, 2012).

ular node (AV), which acts as the bridge between the atria and ventricles,²² the Purkinje fibers,²³ which transmit the electrical signals throughout the ventricles, and the right and left AV bundles.²⁴ Without this electrical system to stimulate the myocardium, the heart would be unable to pump the oxygenated blood throughout the body.²⁵

All organs need a constant supply of oxygenated blood, and the heart is no different.²⁶ In fact, this process is so vital to the heart that it has its own vascular system known as coronary circulation.²⁷ Part of the aorta, the largest blood vessel in the body, branches off to form the left and right coronary arteries thereby supplying the heart with oxygenated enriched blood.²⁸ When a coronary artery is blocked or restricted, the volume of blood to the heart is diminished or stopped.²⁹ This outcome is termed cardiac ischemia.³⁰ Pain produced by this condition is dubbed angina.³¹ If the ischemia is so prolonged that it causes the heart tissue to die, the patient suffers a myocardial infarction or the dreaded “heart attack.”³² Most often

²² HODGE, *supra* note 14, at 360. The AV node is situated in the center of the heart and its job is to regulate the electrical signal from the sinoatrial node. It then passes the electrical signal along to the ventricles. *Atrioventricular (AV) Node*, USC CARDIOTHORACIC SURGERY, <http://www.cts.usc.edu/zglossary-avnode.html> (last visited Aug. 1, 2016).

²³ HODGE, *supra* note 14, at 360. This term refers to those heart fibers that transmit electrical impulses to the lower chambers of the heart causing the ventricles to contract, thereby propelling blood to the lungs and other body parts. *What Are Purkinje Fibers, and What is Their Function?*, REFERENCE.COM, <http://www.ask.com/science/purkinje-fibers-function-772cd3ffdad807c> (last visited Aug. 1, 2016).

²⁴ HODGE, *supra* note 14, at 362.

²⁵ *Electrical System*, HEART RHYTHM SOC’Y, <http://www.hrsonline.org/Patient-Resources/The-Normal-Heart/Electrical-System> (last visited Aug. 1, 2016).

²⁶ *Understanding Heart Attack: The Basics*, WEBMD, <http://www.webmd.com/heart-disease/understanding-heart-attack-basics> (last visited Aug. 1, 2016).

²⁷ HODGE, *supra* note 14, at 362.

²⁸ *Id.*

²⁹ *Id.* at 363.

³⁰ WEBMD, *supra* note 26.

³¹ *Id.*

³² *Id.*

this medical emergency is caused by underlying coronary artery disease.³³

In contrast to a heart attack, sudden cardiac arrest occurs when the normal electrical activity to the heart is interrupted causing the heart rate to become irregular.³⁴ By way of analogy, a myocardial infarction occurs when the plumbing fails to work because the pipes are clogged, whereas a sudden cardiac arrest involves a short in the electrical system.³⁵

SCA has little advanced notice of its onset, and the odds of making it to the hospital alive are slim.³⁶ These cardiac arrhythmias can be caused by any number of conditions, and they can result in a diminished blood flow to the brain.³⁷ Ventricular fibrillation is the most serious of these arrhythmias, causing an ineffective pumping of the lower chambers of the heart because the ventricles start to quiver and become non-functional.³⁸ SCA can cause loss of consciousness and subsequent death if CPR and defibrillation are not immediately undertaken.³⁹ It is estimated that the “window of op-

³³ *What Is a Heart Attack?*, NAT'L HEART, LUNG, AND BLOOD INST., <https://www.nhlbi.nih.gov/health/health-topics/topics/heartattack/> (last updated June 22, 2015).

³⁴ *Frequently Asked Questions: Sudden Cardiac Arrest and Automatic External Defibrillators*, DEFIBTECH, <http://www.defibtech.com/support/faq> (last visited Aug. 1, 2016).

³⁵ *Id.*

³⁶ Salynn Boyles, *Portable Defibrillators at Home*, WEBMD HEALTH NEWS (Feb. 8, 2002), <http://www.webmd.com/heart-disease/news/20020208/portable-defibrillators-at-home>.

³⁷ HODGE, *supra* note 14, at 363. The National Heart, Lung and Blood Institute defines a cardiac arrhythmia as “a problem with the rate or rhythm of the heartbeat. . . . During an arrhythmia, the heart may not be able to pump enough blood to the body. Lack of blood flow can damage the brain, heart, and other organs.” *What Is an Arrhythmia?*, NAT'L HEART, LUNG, AND BLOOD INST., <http://www.nhlbi.nih.gov/health/health-topics/topics/arr/> (last updated July 1, 2011).

³⁸ HODGE, *supra* note 14, at 363.

³⁹ *Sudden Cardiac Death (Sudden Cardiac Arrest)*, CLEVELAND CLINIC, <http://my.clevelandclinic.org/services/heart/disorders/arrhythmia/sudden-cardiac-death> (last visited Aug. 27, 2016).

portunity” is ten minutes or less; thus, the quicker the AED is employed, the better the chance is of restoring the heart’s normal rhythm.⁴⁰

II. AUTOMATED EXTERNAL DEFIBRILLATORS

AEDs are small, battery-charged units about the size of a laptop that may be used without formal training.⁴¹ Once the box is opened, a voice offers step-by-step instructions including how to attach sticky pads embedded with sensors to the victim’s chest.⁴² The pads are placed in predetermined positions; one is attached above the right nipple and the other is located below the left nipple to the side of the rib cage.⁴³ These sensors will automatically transmit vital information to the unit about the heart’s rhythm, and the AED will decide whether to send an electrical shock to the chest.⁴⁴ If a shock must be administered, the operator will be informed by a computer-generated voice so the rescuer can stand aside.⁴⁵ If necessary, a jolt will then be delivered⁴⁶ in an attempt to restore the heart’s normal rhythm.⁴⁷ The amount of electrical energy varies since there are two protocols: escalating protocol and fixed protocol.⁴⁸ This difference reflects the several “schools of thought in the medical community.”⁴⁹ Some experts believe that a steady low-energy charge is appropriate to restore the heart’s proper rhythm, while other experts

⁴⁰ Guidelines for Public Access Defibrillation in Federal Facilities, 66 Fed. Reg. 28,495, 28,496 (May 23, 2001) [hereinafter Guidelines for Public Access Defibrillation]. For every sixty seconds that elapses between the cardiac episode and use of the AED, the chances of living is decreased by 7 to 10%. *Id.*

⁴¹ *What is an Automated External Defibrillator?*, *supra* note 6.

⁴² *Id.*

⁴³ *How To Use an Automated Electronic Defibrillator*, NAT’L HEART, BLOOD AND LUNG INST., <https://www.nhlbi.nih.gov/health/health-topics/topics/aed/howto-use> (last updated Dec. 2, 2011).

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *How Does an Automated External Defibrillator Work?*, HEARTSINE (Dec. 17, 2012), <http://heartsine.com/2012/12/how-does-an-automated-external-defibrillator-work/>.

⁴⁷ *Id.*

⁴⁸ *Escalating and Non-Escalating Automated AEDs*, AED BRANDS, <https://www.aedbrands.com/resource-center/choose/escalating-and-non-escalating-aed-devices/> (last visited Aug. 28, 2016).

⁴⁹ *Id.*

believe that the AED should be able to increase its electrical jolt if the charge is unsuccessful with the initial application.⁵⁰ It must be noted, however, that the AED is not designed for a person who has flat-lined.⁵¹ That victim can only be resuscitated by CPR and cardiac drugs.⁵²

Studies have shown that access to AEDs improves the odds of surviving a cardiac arrhythmia outside of the hospital.⁵³ One set of researchers ascertained that almost 70% of those with cardiac events in public places could have been helped if AEDs had been strategically placed.⁵⁴ The American Heart Association estimates that an AED can improve a person's chances of surviving the cardiac event by 49% to 75%.⁵⁵ For instance, the Offices of Occupational Health and Safety (OSHA) reported that Chicago's O'Hare International Airport placed AEDs around their facility and found that the survival rate for a cardiac event was increased to 64%,⁵⁶ whereas the casinos in Las Vegas achieved a 53% survival rate among patrons in ventricular fibrillation.⁵⁷

These and other promising studies have caused a number of organizations to recommend making AEDs available in public locations.⁵⁸ For example, OSHA publishes articles in support of making AEDs available in the workplace.⁵⁹ The American Health & Safety Institute, American Heart Association, American Red Cross, and

⁵⁰ *Id.*

⁵¹ Ashley Fidler, *TV Myth: Shocking A Flatlined Heart Rhythm Will Revive Patient*, AED.COM (Oct. 15, 2015), <http://www.aed.com/blog/tv-myth-shocking-a-flatline-heart-rhythm-will-revive-patient/>.

⁵² *Id.*

⁵³ *AEDs in Schools, Public Places Increase Survival Rates, Studies Find*, CLUB INDUSTRY (Aug. 12, 2009), <http://clubindustry.com/studies/aeds-schools-public-places-increase-survival-rates-studies-find>.

⁵⁴ *Id.*

⁵⁵ AMERICAN HEART ASSOCIATION, *CPR, AED & Sudden Cardiac Arrest Fact Sheet*, RESCUE TRAINING INST., INC. (Apr. 2011), http://www.rescuetraininginstitute.com/CPR_Statistics.html.

⁵⁶ *Boosting Survival Rates*, OCCUPATIONAL HEALTH AND SAFETY (June 1, 2005), <https://ohsonline.com/Articles/2005/06/Boosting-Survival-Rates.aspx?Page=3>.

⁵⁷ LIDDLE ET. AL., *supra* note 2, at 1217.

⁵⁸ *See generally* Guidelines for Public Access Defibrillation Programs in Federal Facilities, 66 Fed. Reg. 28,495, 28,496 (May 23, 2001).

⁵⁹ OCCUPATIONAL HEALTH AND SAFETY, *supra* note 56.

National Safety Council have given their support for early defibrillation in both public and workplace environments.⁶⁰

Not everyone shares the same enthusiasm for the widespread availability of AEDs.⁶¹ The units have been known to malfunction during a rescue attempt⁶² and have been recalled.⁶³ There is a patchwork of statutes, rules, and regulations concerning the use of AED devices and some individuals and entities are fearful of liability issues.⁶⁴ Critics claim that there is not enough evidence to demonstrate that private use of these devices is warranted.⁶⁵ For instance, in a home setting, the closest person to the victim will either pick up the phone and call 911 or may forget where the device is located.⁶⁶

The American Red Cross has the lofty goal of providing a victim suffering from SCA with both access to an AED and an individual trained to use the unit within four minutes.⁶⁷ AEDs, however, continue to be underemployed.⁶⁸ Unlike fire extinguishers, many AEDs are not plainly visible or are locked away in remote locations inside facilities that purchased these life-saving devices.⁶⁹ The units have a shelf life between five to ten years and it is possible that they may

⁶⁰ Guidelines for Public Access Defibrillation, 66 Fed. Reg. at 28,496.

⁶¹ Maurer, *supra* note 5.

⁶² *Report on AED Failures: A Reminder that Maintenance is Vital*, SUDDEN CARDIAC ARREST FOUND. (Aug. 30, 2011, 12:00 AM), <http://www.sca-aware.org/sca-news/report-on-aed-failures-a-reminder-that-maintenance-is-vital>. It has been reported that more than 1,000 people have died over a fifteen-year period because of AED mechanical issues and in about 25% of these cases the problem was battery failure. *Id.*

⁶³ Maurer, *supra* note 5.

⁶⁴ Lee Bowman et al., *AEDs: If Publicly Available, Thousands of Victims Could be Saved a Year*, WPTV (Aug. 22, 2013, 5:50 PM), <http://www.wptv.com/news/local-news/investigations/aeds-if-publicly-available-thousands-of-victims-could-be-saved-a-year>.

⁶⁵ Corrine Grace, *Learn the Advantages and Disadvantages of AED*, WINNIPEG FIRST AID (Apr. 11, 2014), <http://firstaidwinnipeg.ca/learn-the-advantages-and-disadvantages-of-aed/>.

⁶⁶ *Id.*

⁶⁷ Bowman et al., *supra* note 64.

⁶⁸ *Id.*

⁶⁹ *Id.*

never be used.⁷⁰ Nevertheless, they must be continuously maintained, which includes the replacement of parts.⁷¹ Much of the battery's power is used for self-testing rather than performing the devices primary function.⁷²

A multitude of diverse organizations have issued pronouncements on AEDs in support of their purchase and use.⁷³ The American College of Emergency Physicians believes that early defibrillation with AEDs is a valid and widely accepted approach for use outside of a hospital setting.⁷⁴ Nevertheless, before programs promoting their extensive adoption can be implemented, the devices must be coordinated with emergency medical services that have been created to maximize the likelihood for survival in the ventricular fibrillation patient.⁷⁵ The American College of Occupational and Environmental Medicine is in favor of employer-created programs to use AEDs in a workplace setting.⁷⁶ The organization created guidelines to foster awareness of these life-saving devices in the workplace as long as there is medical direction and control.⁷⁷ The International Association of Chiefs of Police and the International Association of Fire Chiefs encourage their leaders to work together to promote the utilization of these life-saving devices by firefighters and police officers, especially because these public servants are usually the first to arrive on the scene of a heart attack victim.⁷⁸

⁷⁰ Maurer, *supra* note 5.

⁷¹ Bowman et al., *supra* note 64.

⁷² Mark Harris, *The Shocking Truth About Defibrillators*, IEEE SPECTRUM (Feb. 27, 2012), <http://spectrum.ieee.org/biomedical/devices/the-shocking-truth-about-defibrillators/0>.

⁷³ See, e.g., *American College of Emergency Physicians*, NAT'L CTR. FOR EARLY DEFIBRILLATION, http://www.early-defib.org/03_04.html (last visited Mar. 28, 2016); *American College of Occupational and Environmental Medicine*, NAT'L CTR. FOR EARLY DEFIBRILLATION, http://www.early-defib.org/03_04.html (last visited Mar. 28, 2016).

⁷⁴ *American College of Emergency Physicians*, *supra* note 73.

⁷⁵ *Id.*

⁷⁶ *American College of Occupational and Environmental Medicine*, *supra* note 73.

⁷⁷ *Id.*

⁷⁸ *International Association of Chiefs of Police and International Association of Fire Chiefs*, NAT'L CTR. FOR EARLY DEFIBRILLATION, http://www.early-defib.org/03_04.html (last visited Mar. 28, 2016).

In the United Kingdom, the Faculty of Sports and Exercise Medicine fully embraces AEDs, and it published a statement to generate more awareness that the prompt use of these devices can increase the survival rate for sudden cardiac arrest.⁷⁹ Furthermore, Iowa State University's position that AEDs can increase the odds of people surviving a cardiac event prompted it to establish an AED program for the school campus.⁸⁰ The program provides continuity and consistency across the University with regards to installation, maintenance, and use of AED devices in response to a cardiac emergency.⁸¹ The buildings, departments, and units that house this equipment are responsible for maintaining them.⁸²

As for private industry, the National Golf Course Owners Association acknowledges that AEDs can save a person's life; however, they support a voluntary AED program.⁸³ The Association is opposed to any state-mandated AED use laws because of concern that "significant liability issues [may] arise that are not covered by Good Samaritan laws," and that liability may arise if the equipment does not work, is missing, or does not reach the victim in a timely fashion.⁸⁴

Philip R. Kiester, Chair of the National Club Association⁸⁵ and General Manager of the Country Club of Virginia,⁸⁶ is in favor of equipping facilities with AEDs. Mr. Kiester believes that private

⁷⁹ Z. Iqbal & J. Somauroo, *Automated External Defibrillators in Public Places: Position Statement from the Faculty of Sport and Exercise Medicine UK*, 49 BRIT. J. SPORTS MED. 1363, 1364 (2015).

⁸⁰ *Automated External Defibrillator (AED)*, IOWA ST. U.: POL'Y LIBR. (Aug. 1, 2007), <http://www.policy.iastate.edu/policy/defibrillator>.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Position Statement: Automatic External Defibrillators Adopted by the NGCOA Board of Directors*, NAT'L GOLF COURSE OWNERS ASS'N (May 3, 2003), <http://www.ngcoa.org/pageview.asp?doc=1675>.

⁸⁴ *Id.*

⁸⁵ See Telephone Interview with Philip R. Kiester, Chair, National Club Association, General Manager, Country Club of Va. (Apr. 22, 2016). The National Club Association is made up of 600 private clubs. Its mission is to defend, protect, and advance the interests of private, social, and recreation clubs. It develops best practices but cannot impose rules upon its members. *Id.*

⁸⁶ *Id.* This is a private country club located in Richmond, Virginia that is spread out over 1,000 acres of land and has 7,500 members. It has three golf courses and other recreational facilities including a pool, tennis courts, and restaurants. *Id.*

clubs are in the “safety business and have a moral obligation to provide [their] members with a safe environment.”⁸⁷ “It is common knowledge,” the manager explained, “that country clubs have senior members who are susceptible to cardiac events, so it is incumbent upon the private facility to have automated external defibrillators readily available in case of an emergency.”⁸⁸ He continued, “watching a person die is a powerful experience,⁸⁹ and in a moment you realize that there is only one chance to save that person’s life. You can’t worry that you might be sued if something goes wrong.”⁹⁰ As a result, the Country Club of Virginia has twelve devices on premises that are checked monthly to make sure they are in proper operating condition, and the staff is trained in CPR and AED operation.⁹¹ Also, a club cart equipped with an AED either roams the golf course or is stationed at the first hole in case of an emergency because ambulance access to the golf course is not feasible.⁹² It is worthwhile to note that Virginia is generally not a plaintiff-friendly state, so there is a lower possibility of a lawsuit being brought as a result of improper or unsuccessful use of an AED. This tendency may contribute to the willingness to implement and use AED devices.⁹³

III. LEGISLATIVE REGULATIONS AND RECOMMENDATION

A. Regulation by the Food and Drug Administration

The manufacturing and use of AEDs has been the subject of various government pronouncements.⁹⁴ The Food and Drug Administration (FDA) is tasked with regulating businesses who manufacture, repackage, and/or import medical devices in the United

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* (Mr. Kiester admits that his views are skewed by personal experiences. Before automated external defibrillators were readily available, several country club members that he knew personally died in his presence.).

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *See, e.g., Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/> (last updated Aug. 14, 2015).

States,⁹⁵ thus AEDs fall within their control.⁹⁶ Medical devices are generally classified based upon their risk level from the lowest risk, Class I, to the highest, Class III.⁹⁷ AEDs are classified as Class III medical devices.⁹⁸ Despite this high-risk classification, manufacturers of AEDs were not initially required to submit a premarket approval application (PMA) to demonstrate a reasonable assurance of safety and effectiveness.⁹⁹ Instead, the units were allowed to enter the market following a 510(k) submission¹⁰⁰ usually reserved to lower risk devices.¹⁰¹ This policy seems to show the underlying thought that PMA regulations “may be overly restrictive and may slow the pace of improved AED technology reaching the marketplace.”¹⁰²

On January 28, 2015, however, the FDA issued a directive requiring AED manufacturers to submit PMAs.¹⁰³ The agency strengthened its review on the “safety and reliability” of the units and “their necessary accessories, including batteries, pad electrodes, adapters and hardware keys for pediatric use.”¹⁰⁴ William Maisel, M.D., M.P.H, the Acting Director of the Office of Device Evalu-

⁹⁵ *Id.*

⁹⁶ *FDA Executive Summary: Circulatory System Devices Panel; Automated External Defibrillators, 515(i) Reclassification*, U.S. FOOD & DRUG ADMIN. 2 (Jan. 25, 2010), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM240579.pdf> [hereinafter *FDA Executive Summary*].

⁹⁷ *Id.* at 3.

⁹⁸ *Id.* at 4.

⁹⁹ *Id.* at 2.

¹⁰⁰ *Id.* A 510(k) form is a premarket submission made to this governmental agency to show that the device is as safe and effective as a device that is not subject premarket approval. *510(k) Premarket Notification*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> (last visited Aug. 9, 2016).

¹⁰¹ *FDA Executive Summary*, *supra* note 96, at 2.

¹⁰² *Id.* at 13.

¹⁰³ Ryan Marotta, *FDA Tightens AED Regulations*, PHARMACY TIMES (Jan. 28, 2015), <http://www.pharmacytimes.com/product-news/fda-tightens-aed-regulations>.

¹⁰⁴ *FDA Takes Steps to Improve Reliability of Automated External Defibrillators*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm431907.htm> (last updated Feb. 4, 2015) [hereinafter *FDA Takes Steps*].

ation in the FDA's Center for Devices and Radiological Health, recognizes that AEDs are life-saving devices; but he believes this more regulated system will allow the FDA to better monitor how they are designed and manufactured, thereby allowing the agency to correct "long-standing problems and ultimately improving the reliability of these devices."¹⁰⁵ These corrections are crucial because since 2005, manufacturers have issued 111 recalls affecting more than two million AEDs and the FDA received 72,000 medical device reports associated with the failure of these units over a nine-year period.¹⁰⁶ Because the FDA recognizes the importance of AEDs, they will remain available for sale while manufacturers work to meet the new PMA requirements.¹⁰⁷ The agency will continue to receive information about an AED manufacturer's quality systems information with the hope of decreasing failures and the need for recalls.¹⁰⁸

B. Legislative Action and Implementation of Programs by the Federal Government

The federal government recognizes the importance of these life-saving devices and has mandated their availability in certain situations.¹⁰⁹ In 1996, the Food and Drug Administration approved the use of AEDs on commercial aircrafts,¹¹⁰ and in 1998, the Aviation Medical Assistance Act (AMAA) was enacted.¹¹¹ The AMAA specifies that:

[T]his equipment cannot be required on helicopters or aircraft with payload capacity of 7,500 pounds or less (about 30 seats or less). With respect to aircraft

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *See id.*

¹⁰⁹ Richard Lazar, *Understanding Legal Issues*, NAT'L CENT. FOR EARLY DEFIBRILLATION, http://www.early-defib.org/03_06_02.html (last visited Aug. 9, 2016).

¹¹⁰ BUD SHUSTER, AVIATION MEDICAL ASSISTANCE ACT OF 1998, H.R. Rep. No. 105-456, at 3 (1998).

¹¹¹ *Id.* at 1.

of more than 7,500 pounds, the Committee has chosen to leave it to the detailed analysis by the FAA as to where to draw the line.¹¹²

The Federal Aviation Administration's (FAA) administrative rules mandate that every commercial aircraft be equipped with specified life-saving equipment, including AEDs, and that flight crew members are trained in their use.¹¹³ The total estimated cost of this program over a ten-year period amounts to \$16 million and demonstrates the government's belief that AEDs are necessary, life-saving devices.¹¹⁴

Congress felt it was important to practice what it preached, so in 2000, the Federal Cardiac Arrest Survival Act (CASA) was enacted.¹¹⁵ The law's general purpose is to encourage the placement and use of AEDs in federal buildings.¹¹⁶ Importantly, CASA also grants civil immunity to any person who uses or acquires an AED so long as any resulting harm was not due to the failure of an acquirer to: (1) notify emergency response personnel of the device's placement, (2) properly maintain and test the device, or (3) provide appropriate AED training to an employee, unless the AED user was not an employee or expected user of the unit.¹¹⁷ "This [f]ederal immunity provision supersedes the law of a State to the extent that the State has no statute or regulations providing for such immunity."¹¹⁸ "[W]here a [s]tate law provides immunity only to the user but not to the acquirer, the [f]ederal law would apply so as to extend protection

¹¹² *Id.* at 5.

¹¹³ Lazar, *supra* note 109; see FED. AVIATION ADMIN., AC NO. 121-33B, ADVISORY CIRCULAR: EMERGENCY MEDICAL EQUIPMENT 5 (2006), http://www.faa.gov/documentLibrary/media/Advisory_Circular/AC121-33B.pdf.

¹¹⁴ Press Release, Fed. Aviation Admin., FAA Requires Airlines to Carry Heart Device (April 12, 2001), http://www.faa.gov/news/press_releases/news_story.cfm?contentKey=1262.

¹¹⁵ See 42 U.S.C. §§ 201-238 (2006).

¹¹⁶ Austin S. Kilaru et al., *Use of Automated External Defibrillators in US Federal Buildings: Implementation of the Federal Occupational Health Public Access Defibrillation Program*, 56 J. OCCUPATIONAL & ENVTL. MED. 86, 86 (2014).

¹¹⁷ 42 U.S.C. § 238q(a) (2006).

¹¹⁸ Harini Raj, *Cardiac Arrest Survival Act of 2000 Signed into Law – Legislative Intent and Implications*, FROST & SULLIVAN (Dec. 6, 2000), <https://www.frost.com/sublib/display-market-insight.do?id=LKOU-4T5LKJ>.

to the acquirer as well.”¹¹⁹ As a result, CASA offers protection to both the users and acquirers of AEDs throughout the United States.¹²⁰

This immunity is not without limitation and there are four statutory exceptions.¹²¹ These exceptions are:

(1) [I]f the harm was 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; (2) the person is a licensed or certified health professional acting within the scope of the license or certification of the professional and within the scope of the employment or agency of the professional; (3) the person is a hospital, clinic, or other entity whose purpose is providing health care directly to patients, and the harm was caused by an employee or agent who used the device while acting within the scope of the employment or agency; (4) the person is an acquirer of the device who leased the device to a health care entity (or who otherwise provided the device to such an entity for compensation without selling the device to the entity), and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent.¹²²

A study was then conducted to analyze the survival rate after a cardiac incident with the use of AED devices in federal buildings.¹²³ Using a Federal Occupational Health (FOH) database, researchers examined reported events in which an AED was used in medical emergencies between 1999 and 2012.¹²⁴ The study found that 39% of those who experienced ventricular fibrillation or ventricular

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ 42 U.S.C. § 238q(b) (2006).

¹²² *Id.*

¹²³ Kilaru, *supra* note 116, at 86.

¹²⁴ *Id.*

tachycardia in a federal building survived to hospital discharge.¹²⁵ Researchers concluded that public access defibrillation, along with protocols to install, maintain, and deploy AEDs and train first responders, would increase the survival after cardiac arrest in the workplace.¹²⁶

The FOH does much more in addition to conducting research on AED devices.¹²⁷ In 2001, it issued *Guidelines for Public Access Defibrillation Programs in Federal Facilities* through a collaboration between HHS and the General Services Administration (GSA) in response to a presidential memorandum concerning establishing guidelines for the placement of AEDs in federal buildings.¹²⁸ The guidelines provide a framework for addressing key elements for public access defibrillation (PAD) programs in federal facilities in order for facility-specific plans and programs to be developed in an informed manner.¹²⁹ The wealth of information tackles issues such as what types of AEDs should be selected.¹³⁰ The guidelines provide that only commercially available AEDs cleared for marketing by the FDA should be considered by the PAD program.¹³¹ Additionally, medical oversight is necessary in that AEDs “are to be used under the advice and consent of a physician only by individuals with the proper training and certification.”¹³² A physician is not required to be present to manage the PAD program on a day-to-day basis but should ensure that the quality of the program is maintained.¹³³ In addition, legal counsel should review any PAD program to ensure

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *About FOH*, FED. OCCUPATIONAL HEALTH, <http://www.foh.hhs.gov/about.html> (last visited Aug. 9, 2016). (“FOH is a non-appropriated agency within the Program Support Center (PSC) (<http://www.psc.gov/>) of the U.S. Department of Health and Human Services (HHS) (<http://www.hs.gov/>). FOH works in partnership with federal organizations nationally and internationally to design and deliver comprehensive occupational health solutions exclusively to federal employees.”).

¹²⁸ *Guidelines for Public Access Defibrillation*, 66 Fed. Reg. at 28,495.

¹²⁹ *Id.* at 28,496.

¹³⁰ *Id.* at 28,498.

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

that it adheres with all applicable federal, state, and local authorities.¹³⁴ The guidelines also address practical issues of implementation such as placement and access to AEDs, the equipment necessary to be placed with AEDs, and maintenance of the device after usage, which includes incident reports and restocking of supplies.¹³⁵ Furthermore, the guidelines recommend an ongoing training program for lay responders/rescuers (LRR).¹³⁶

To further encourage the use of AEDs beyond federal facilities, Congress created the Rural and Community Access to Emergency Devices Program,¹³⁷ to reduce the high cost of AED implementation.¹³⁸ “This competitively awarded community grant program allows rural communities to buy AEDs, train lay rescuers and first responders in their use, and place them in public areas where sudden cardiac arrest is likely to occur.”¹³⁹ “The program has been successful, but underfunded.”¹⁴⁰ In 2015, an appropriation of only \$3.364 million was approved.¹⁴¹ No funding, however, was requested for 2016 by the Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services, because the organization felt that access to emergency medical devices and training in this fiscal year may be addressed through other funding sources, such as the Rural Outreach and Rural Network Development programs.¹⁴²

¹³⁴ *Id.*

¹³⁵ *Id.* at 28,500.

¹³⁶ *Id.* at 28,499.

¹³⁷ Public Health Improvement Act, Pub. L. No. 106-505, § 411-13, 114 Stat. 2314, 2340-43 (2000); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 312-13, 116 Stat. 594, 634-37 (2002).

¹³⁸ *See Facts: Every Second Counts, supra* note 9.

¹³⁹ *Id.*

¹⁴⁰ *Id.* It appears that only \$450,000 was made available in 2016 to fund up to three grantees for a project period of three years. *Rural Access to Emergency Devices Grant Program*, FIRE GRANTS HELP, <http://www.firegrantshelp.com/search-grants/760451-rural-access-to-emergency-devices-grant-program/> (last visited Aug. 10, 2016).

¹⁴¹ *Facts: Every Second Counts, supra* note 9.

¹⁴² HEALTH RES. & SERVS. ADMIN., DEP'T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2016: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 13 (2016), <http://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

C. *State Regulations Regarding the Implementation and Use of Automated External Defibrillators*

There is a blatant lack of uniformity in state statutes, rules, and regulations concerning the use of AED devices¹⁴³ that causes both individuals and entities to be apprehensive about potential liability issues.¹⁴⁴ The majority of states have adopted legislation regarding the implementation and use of AEDs.¹⁴⁵ According to the National Conference of State Legislatures (NCSL),

most of the statutes enacted from 1997 to 2001 include one or more provisions to: (1) Establish legislative intent that an ‘automatic external defibrillator may be used by any person for the purpose of saving the life of another person in cardiac arrest.’ (2) Encourage or require training in the use of AED devices by potential users. (3) Require AED devices to be maintained and tested to manufacturer’s standards. (4) Create a registry of the location of all such defibrillators, or notification of a local emergency medical authority. (5) Allow a ‘Good Samaritan’ exemption from liability for any individual who renders emergency treatment with a defibrillator. (6) Authorize a state agency to establish more detailed requirements for training and registration.¹⁴⁶

D. *Duty Owed to a Person Suffering Sudden Cardiac Arrest*

The duty owed to an individual suffering SCA varies greatly depending upon the context and jurisdiction.¹⁴⁷ Generally, “[a] bystander or passerby has no legal obligation to provide affirmative medical aid to an ill or injured person, even if the bystander has the ability to help.”¹⁴⁸ This reflects the general “no duty to rescue” rule

¹⁴³ Maurer, *supra* note 5.

¹⁴⁴ *Id.*

¹⁴⁵ *AED State Laws*, AED BRANDS, <https://www.aedbrands.com/resource-center/choose/aed-state-laws/> (last visited Mar. 25, 2016).

¹⁴⁶ *Id.*

¹⁴⁷ CRAIG ALAN HARTPENGE, EARLY ACCESS TO AUTOMATED EXTERNAL DEFIBRILLATORS 79 (Lulu.com 2010).

¹⁴⁸ *Id.*

in the United States, which is followed by most jurisdictions.¹⁴⁹ Emergency medical service (EMS) providers, however, such as paramedics and emergency medical technicians (EMTs), do have a legal duty to respond to and treat victims of medical emergencies while on duty in the course and scope of their employment.¹⁵⁰ Specific responsibilities imposed on these responders vary from state to state and are influenced by court cases, statutes, and regulations.¹⁵¹

For instance, in *Schronk v. City of Burleson*,¹⁵² the family of a decedent brought a wrongful death action against a city in Texas and the manufacturer of an AED after EMTs employed by the city failed to revive the decedent.¹⁵³ The EMTs attempted to resuscitate the victim with an AED, but were unsuccessful because the battery was too weak to administer a defibrillating shock.¹⁵⁴ The petitioners claimed the city was negligent based on its failure to properly maintain the AED.¹⁵⁵ In response, the city claimed that it did not waive its immunity.¹⁵⁶

The court first examined Section 101.021(2) of the Texas Civil Practice and Remedies Code, which “waives a governmental unit’s immunity from suit and liability for personal injury or death proximately caused by a condition or use of tangible personal property if a private person would be liable under the same circumstances.”¹⁵⁷ The court found that there was no dispute that the firefighter used the AED in an effort to resuscitate the victim, or that the AED failed to work because the battery was not sufficiently charged.¹⁵⁸ The dispositive issue was whether the decedent could have survived if a properly functioning AED was utilized.¹⁵⁹ Ultimately, the court concluded that there was a disputed material of fact regarding whether

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Schronk v. City of Burleson*, 387 S.W.3d 692 (Tex. App. 2009).

¹⁵³ *Id.* at 697.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 698.

¹⁵⁷ *Id.* at 709.

¹⁵⁸ *Id.* at 711.

¹⁵⁹ *Id.*

the use of the AED was a proximate cause of death.¹⁶⁰

Next, the court examined whether the city waived its immunity:¹⁶¹

According to section 101.055(2) of the Tort Claims Act, there is no waiver of immunity under the Act for the conduct of an emergency responder ‘if the action is in compliance with the laws and ordinances applicable to emergency action, or in the absence of such a law or ordinance, if the action is not taken with conscious indifference or reckless disregard for the safety of others.’¹⁶²

The petitioners offered evidence that the emergency service department failed to maintain the AED in accordance with the manufacturer’s guidelines in violation of Section 779.003, which states: “A person or entity that owns or leases an automated external defibrillator shall maintain and test the automated external defibrillator according to the manufacturer’s guidelines.”¹⁶³ The court again found that there was a disputed material fact.¹⁶⁴ This time, the issue was whether an action of a city employee that involved responding

¹⁶⁰ *Id.* at 712. This determination was made after examining testimony from an expert doctor who took into account the decedent’s heart condition “before she suffered the cardiac arrest, examined studies regarding cardiac patients who received CPR ‘in combination with electrical,’ and concluded that, in reasonable medical probability, there is a better than 51% chance that Helen would have been successfully defibrillated and would have survived her cardiac arrest if the AED had functioned properly.” *Id.* The court also examined prior case law. *Id.* (Bustillos v. Rowley, 225 S.W.3d 122, 129–31 (Tex. App. 2005) (expert report that it was ‘more likely than not’ that patient would have survived adequately addressed causation regarding failure to monitor cardiac patient); Marvelli v. Alston, 100 S.W.3d 460, 481 (Tex. App. 2003) (expert’s testimony that plaintiff’s vision would have ‘in reasonable medical probability’ been saved held legally sufficient to establish cause-in-fact); Bottoms v. Smith, 923 S.W.2d 247, 251–52 (Tex. App. 14th 1996) (expert’s testimony that, if appropriate tests had been done, polyp would have been identified and patient would have better than 70% survival rate held sufficient to create fact issue on proximate cause regarding patient’s death”).

¹⁶¹ *Schronk*, 387 S.W.3d at 712–713.

¹⁶² *Id.*

¹⁶³ *Id.* at 713.

¹⁶⁴ *Id.*

to a 911 call violated a statute applicable to the action.¹⁶⁵ The Texas court chose to remand the case for further proceedings.¹⁶⁶

In addition to EMS providers, there are other groups that may be compelled by law to render a reasonable level of medical aid and to quickly summon outside emergency medical assistance.¹⁶⁷ One example is common carriers, such as airlines, cab companies, passenger railroads, and cruise ship operators.¹⁶⁸ A common carrier is under a duty to its passengers to take reasonable action to protect them against unreasonable risk of physical harm and to administer first aid after the common carrier knows, or has reason to know, that passengers are ill or injured.¹⁶⁹ The common carrier must continue to care for the person until the injured individual can be cared for by others.¹⁷⁰ Innkeepers, such as hotel and motel operators, comprise another group that has a similar duty to its guests and visitors.¹⁷¹

Lastly, virtually all other commercial business establishments fall under the category of premise owners.¹⁷² These premise owners are possessors of land who hold the property open to the public, and, as a result, have a similar duty to those who enter.¹⁷³ The general duty of care has been made more specific as applied in the context of AED devices.¹⁷⁴ The following section will explore case law involving AEDs and some of the state statutory requirements that these various groups must adhere to in greater detail.

E. The Statutory Requirements, Relevant Case Law, and the Implications on Public Entities

1. AIRLINES

Among common carriers, the airline industry was the first to face litigation regarding AED devices. In *Somes v. United Airlines*,

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ HARTPENCE, *supra* note 147, at 79.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.* at 80.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

Inc.,¹⁷⁵ Steven Somes suffered SCA while on board a flight.¹⁷⁶ His wife brought suit on the basis of the failure to equip the aircraft with “certain medical equipment, including an automatic external defibrillator,” because her husband would have allegedly survived the in-flight emergency had the plane contained such equipment.¹⁷⁷ The airline moved to dismiss the case on the basis of various theories of preemption.¹⁷⁸ The court, however, did not buy the defendant’s argument and the case ultimately settled.¹⁷⁹

Talit v. Nw. Airlines, Inc. involves a similar fact pattern.¹⁸⁰ The plaintiff filed suit after her husband died from SCA due to a lack of an AED device onboard the flight.¹⁸¹ The issue was whether the airline had a duty to carry a defibrillator on the flight in question.¹⁸² Both parties agreed that at the time of the incident, there were no regulations requiring that a defibrillator be carried aboard, and the airline admitted that it did not equip its aircraft with defibrillators.¹⁸³ “The plaintiff’s counsel asked for an opportunity to locate an expert witness to testify as to the industry standard at the time of the flight regarding the placement of defibrillators on aircraft.”¹⁸⁴ The parties agreed that if the plaintiff failed to produce an expert, then the case would be withdrawn.¹⁸⁵

These cases paved the way for the AMAA and FAA to implement the current mandates that every commercial aircraft be equipped with specified life-saving equipment, including AEDs, and that flight crew members be trained in their use.¹⁸⁶ However, other than mandating that the AED be on board the airline, factors related to the use of the device are up to the air carriers and its agents.¹⁸⁷ Access to the equipment is typically provided to trained

¹⁷⁵ *Somes v. United Airlines, Inc.*, 33 F. Supp. 2d 78 (D. Mass. 1999).

¹⁷⁶ *Id.* at 80.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Somes v. United States*, W-G-LAW.COM, <http://www.w-g-law.com/practice/somes.html>, (last visited Aug. 8, 2016).

¹⁸⁰ *Talit v. Nw. Airlines, Inc.*, 752 A.2d 1131 (Conn. App. Ct. 2000).

¹⁸¹ *Id.* at 1132.

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *See* FED. AVIATION ADMIN., *supra* note 113, at 9–10.

¹⁸⁷ *Id.* at 1.

crew members or to other persons qualified and trained in the use of emergency medical equipment.¹⁸⁸ Airlines can choose whether to allow fellow passengers to assist another and have access to the devices.¹⁸⁹ The FAA does not define who can use the devices because that would limit access to those on a flight who might be able to assist in a cardiac emergency.¹⁹⁰ In a similar vein, the FAA has also left the decision of whether to offer treatment or take other action, such as safely diverting the aircraft, up to the airline carrier and its agents.¹⁹¹

2. HEALTH CLUBS

Examining state statutory regulations pertaining to health clubs reveals that Arkansas, California, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, and the District of Columbia all have laws that require health clubs to have at least one AED on their premises.¹⁹² Michigan defines a health club as:

[A]n establishment that provides, as its primary purpose, services or facilities that are purported to assist patrons in physical exercise, in weight control, or in figure development, including, but not limited to, a fitness center, studio, salon, or club.¹⁹³ A health club does not include a hotel or motel that provides physical fitness equipment or activities, an organization solely offering training or facilities for an individual sport, or a weight reduction center.¹⁹⁴

Interestingly, most states do not include hotel fitness facilities in their definition of a health club.¹⁹⁵

¹⁸⁸ *Id.* at 5.

¹⁸⁹ *Id.*

¹⁹⁰ *See id.*

¹⁹¹ *Id.*

¹⁹² AED BRANDS, *supra* note 145.

¹⁹³ Act of Feb. 16, 2006, No. 23, § 333.26311, Mich. Pub. Acts 40 (2006) (regulating certain health clubs with respect to potential medical emergencies).

¹⁹⁴ *Id.*

¹⁹⁵ AED Brands, *supra* note 145 (For example, California and Michigan do not include hotel fitness facilities in their definitions of health clubs.); *see also*

State requirements imposed on health clubs vary based upon the definition of a “health club” or other similar terminology and the stringency of the mandates imposed.¹⁹⁶ For example, Arkansas requires “health spas”¹⁹⁷ to not only have an AED device, but also mandates that “[a]t all time[s] during staffed business hours, the spa shall ensure that at least one (1) employee who has completed a knowledge and skills course in operating an automated external defibrillator and in cardiopulmonary resuscitation is assigned to be on duty.”¹⁹⁸ This law also requires that an AED sign showing the location of the AED be in plain view, and a sign with AED and CPR instructions be posted, as well.¹⁹⁹

Despite the existence of statutory requirements that health clubs have AEDs on their premises,²⁰⁰ case law does not necessarily support the intent of the statutes.²⁰¹ Perhaps this is an instance of the courts playing catch up because many of the statutory requirements were not adopted until the early to mid 2000s.²⁰² For instance, *Atcovitz v. Gulph Mills Tennis Club, Inc.* involved a claim against a tennis club for failing to have an AED on-site to treat the victim of sudden cardiac arrest.²⁰³ In 1996, “Jerry Actovitz suffered a stroke, secondary to a heart attack, while playing tennis at the Gulph Mills Tennis Club.”²⁰⁴ An ambulance was called and arrived ten minutes

Requiring Automatic External Defibrillator Devices in Health Clubs, ch. 420, 2006 Mass. Acts 1324.

¹⁹⁶ See generally AED Brands, *supra* note 145.

¹⁹⁷ ARK. CODE ANN. § 20-13-1306 (2016) (Arkansas falls on the more stringent side of the spectrum. The state defines “health spa” as “any person, firm, corporation, organization, club or association engaged in the sale of: (1) Memberships in a program of physical exercise that includes the use of one (1) or more of sauna, whirlpool, weightlifting room, massage, steam room, or exercising machine or device; or (2) [t]he right or privilege to use exercise equipment or facilities, such as a sauna, whirlpool, weightlifting room, massage, steam room, or exercising machine or device . . .”).

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ See, e.g., *id.*

²⁰¹ See generally *Atcovitz v. Gulph Mills Tennis Club, Inc.*, 812 A.2d 1218 (Pa. 2002).

²⁰² *State Laws on Cardiac Arrest and Defibrillators*, NCSL.ORG (Jan. 31, 2012), <http://www.ncsl.org/research/health/laws-on-cardiac-arrest-and-defibrillators-aeds.aspx>.

²⁰³ *Id.* at 1220.

²⁰⁴ *Id.*

later, at which time emergency personnel administered AED shocks.²⁰⁵ “Actovitz ‘sustained severe and permanent injuries, including anoxic encephalopathy with multiple permanent central nervous system disorders.’”²⁰⁶ Actovitz and his wife brought suit alleging that “had Gulph Mills possessed an AED device and used it on Atcovitz promptly, his injuries would have been significantly less and, therefore, Gulph Mills is liable to him for damages.”²⁰⁷ On appeal, the Supreme Court of Pennsylvania sought out to determine whether a tennis club owes a duty to its members to have an AED available on its premises.²⁰⁸ The court examined the Pennsylvania Emergency Services Act and the AED Good Samaritan Act, and found that neither imposed a duty upon Gulph Mills to acquire, maintain, and use an AED.²⁰⁹ The court also stated that the appellees did not “cite any other case, statute, or regulation that would have imposed such a duty on Gulph Mills at the time of Atcovitz’s injuries in January 1996.”²¹⁰

Unfortunately, the plaintiff’s injuries occurred prior to Pennsylvania’s adoption of a statutory requirement that health clubs have AED devices in 2012.²¹¹ Although the court found that Gulph Mills did not owe a duty to plaintiffs to have an AED on premises, the court did not consider the current Pennsylvania AED requirement.²¹² In a dissenting opinion, one justice opined that whether a tennis club owes a duty to its members to acquire and maintain an AED was not at issue before the court.²¹³ Instead, the question was whether the EMS Act and Department of Health regulations promulgated pursuant to that Act specifically prohibited the club from using an AED.²¹⁴ The justice also stated he would “affirm the

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 1224.

²¹⁰ *Id.*

²¹¹ PA. STAT. ANN. TIT. 73 § 2174.

²¹² *See generally Atcovitz*, 812 A.2d 1218 (Pa. 2002).

²¹³ *Atcovitz*, 812 A.2d at 1225 (Nigro, J., dissenting).

²¹⁴ *Id.*

Superior Court's order and remand the case to the trial court to consider in the first instance whether there is any basis on which to conclude that [the club] owed a duty to [the plaintiffs]."²¹⁵

As more states began to implement statutory requirements mandating that health clubs have at least one AED on the premises, a question remained as to whether there is also a duty for employees to use the AED or whether health clubs could choose to forgo administering the AED device to their members as long as the unit is present.²¹⁶ New York addressed this question in two cases.²¹⁷ In *Digiulio v. Gran, Inc.*,²¹⁸ Albert Digiulio suffered a cardiac event while running on a treadmill at the defendant's health club.²¹⁹ The club called 911 and began performing CPR.²²⁰ In fulfillment of the New York statute, the club purchased an AED, which it stored in a glass cabinet on a nearby wall.²²¹ The cabinet had a visible key lock mechanism, but it was unlocked at the time.²²² The club's assistant manager panicked in the moment and assumed the cabinet was locked, searching for the key until EMS personnel arrived.²²³ EMS used their own AED device and administered shocks.²²⁴ Unfortunately, Mr. Digiulio suffered anoxic brain damage and was hospitalized until his death.²²⁵

The ensuing lawsuit alleged that Mr. Digiulio should have been treated with the club's AED device before the EMS personnel arrived, which may have prevented the brain damage from occurring.²²⁶ The plaintiff "acknowledged that the club 'literally' complied with the statute by having the AED and a certified employee on premises, but argued that the statute imposed a duty to make the

²¹⁵ *Id.*

²¹⁶ *See, e.g.*, *Digiulio v. Gran, Inc.*, 903 N.Y.S.2d 359, 360 (N.Y. App. Div. 2010), *aff'd*, 952 N.E.2d 1064 (N.Y. 2011).

²¹⁷ *See generally id.*; *Migliano v. Bally Total Fitness of Greater N.Y., Inc.*, 985 N.E.2d 128 (N.Y. 2013).

²¹⁸ *Digiulio v. Gran, Inc.*, 903 N.Y.S.2d 359, 360 (N.Y. App. Div. 2010), *aff'd*, 952 N.E.2d 1064 (N.Y. 2011).

²¹⁹ *Id.* at 360.

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.* at 360–61.

AED available and to use it when necessary.”²²⁷ The court found that the statute’s limitation of liability on health clubs and their agents when “voluntarily” using AEDs did not impose a duty to use the device.²²⁸ The court determined that although the statute intends to make AEDs available and “encourage[s] their use in medical emergencies, it did not intend to impose liability on clubs for usage failures.”²²⁹

The following year, the Appellate Division of the Supreme Court of New York expanded on this earlier holding in *Miglino v. Bally Total Fitness of Greater New York, Inc.*²³⁰ The Court held that the statute concerning AED device implementation in health clubs imposed an inherent duty to make use of the statutorily required AED; thus, the plaintiff’s allegations were sufficient to state a claim for negligence.²³¹ In this case, Gregory Miglino, Sr. collapsed near the racquetball courts at the health club.²³² The club’s personal trainer directed the receptionist to call 911 while another employee retrieved the club’s AED device.²³³ The personal trainer, who was certified to operate an AED and administer CPR, responded to Miglino and took his pulse, but did not administer CPR or use the AED device.²³⁴ When he left to check the status of the 911 personnel, two club members, a doctor, and a medical student stepped in and administered CPR.²³⁵ When the EMS arrived and used the AED device, Miglino could not be revived.²³⁶

The plaintiff’s lawsuit alleged that the health club failed to meet the requirements of New York law by providing an employee who was properly certified to operate an AED or perform CPR and that the health club’s employees negligently failed to use an available AED, or failed to use it within sufficient time to save Miglino’s

²²⁷ *Id.* at 361.

²²⁸ *Id.* at 362.

²²⁹ *Id.*

²³⁰ *Miglino v. Bally Total Fitness of Greater New York, Inc.*, 937 N.Y.S.2d 63 (N.Y. App. Div. 2011), *aff’d on procedural grounds*, 985 N.E.2d 128, 131 (N.Y. 2013).

²³¹ *Id.* at 70.

²³² *Id.* at 65.

²³³ *Id.* at 65, 71.

²³⁴ *Id.*

²³⁵ *Id.* at 65.

²³⁶ *Id.* at 65-66.

life.²³⁷ The health club claimed immunity under the Good Samaritan Law, but the plaintiff countered that the law did not apply because the employee did not actually render emergency treatment to Miglino.²³⁸ The Court examined the statute and noted that the employee began to render aid by directing the 911 emergency call to be made, sought medical assistance within the club, and took Miglino's pulse.²³⁹ Based on these facts, the Court held that the plaintiff's claims stated a sufficient cause of action and affirmed the lower court's decision.²⁴⁰

Two years later, however, the Court of Appeals of New York held that the statute concerning AED device implementation in health clubs did not create a duty for a health club to use an AED; but affirmed that the plaintiff's allegations were sufficient to state a claim for negligence.²⁴¹ In that case, Chief Judge Lippman dissented in part, noting that, based on the majority's interpretation of the New York statute, health clubs are required both to purchase automated external defibrillators and train employees on how to use them, but not to actually use the devices—an interpretation that is “contrary to accomplishing the goal of the legislation.”²⁴²

In states without AED device statutory requirements, courts have been unwilling to impose a duty upon health clubs.²⁴³ Although statistics are not available on how often cardiac arrests occur in health clubs, the number of states requiring that AED devices be on the premises continues to increase.²⁴⁴ The reluctance of health clubs to purchase and use AED devices due to fear of litigation is a misapprehension.²⁴⁵ Legislative precedent does not impose greater liability and with the statistical evidence that AEDs save lives, health

²³⁷ *Id.* at 66.

²³⁸ *Id.* at 66, 70–71.

²³⁹ *Id.* at 71.

²⁴⁰ *Id.* at 70–72.

²⁴¹ *Miglino v. Bally Total Fitness of Greater N.Y., Inc.*, 985 N.E.2d 128, 132 (N.Y. 2013).

²⁴² *Id.* at 135 (Lippman, C.J., dissenting in part).

²⁴³ *See e.g.* *L.A. Fitness Int'l, LLC v. Mayer*, 980 So. 2d 550, 561–62 (Fla. Dist. Ct. App. 2008) (holding that there is no duty for the health club to have an AED device on the premises and that summoning professional medical assistance for members experiencing emergencies is a satisfactory action).

²⁴⁴ AED BRANDS, *supra* note 145.

²⁴⁵ *See, e.g.*, Lazar, *supra* note 109 (“Legal liability risks associated with early defibrillation programs are quite remote.”).

clubs may find themselves facing fewer lawsuits if they used AEDs rather than forgoing the devices.

3. HOTELS

Despite the very nature of hotels, they are not bound by any federal legal requirements to install and maintain AED devices.²⁴⁶ According to Expedia, Inc., only 7,000 of 53,000, or 13% of hotels, have “medical assistance available,” which can include AED devices.²⁴⁷ Hotels have resisted the installation of these life-saving devices because of the perceived fear of potential litigation and liability.²⁴⁸ The general view is that the hotel may incur liability for not having enough AED units on the premises, failing to place the AEDs in the appropriate places, or failing to maintain the AEDs.²⁴⁹ Another concern is how to properly train hotel employees.²⁵⁰ Hotels are also worried that the Good Samaritan provisions are not adequate and do not want to expend funds defending lawsuits over AED possession and deployment.²⁵¹ Case law, however, upholds the immunity provided to hotels by the Good Samaritan provisions as evidenced by the Third Circuit Court of Appeals’s decision in *Abramson v. Ritz Carlton Hotel Co., LLC*.²⁵²

Martin Abramson went into cardiac arrest between 8:00 and 9:00 p.m. while having dinner at the Ritz-Carlton Hotel & Spa in Rose Hall, Jamaica.²⁵³ His wife and other guests began CPR while calling out for help.²⁵⁴ At 9:07 p.m., an ambulance was called and shortly thereafter a Loss Prevention Officer of the hotel produced an

²⁴⁶ See generally Scott McCartney, *Why Hotels Resist Having Defibrillators*, WALL ST. J.: THE MIDDLE SEAT (Feb. 24, 2009, 11:59 PM), <http://www.wsj.com/articles/SB123543325221454001> (explaining that there are some state requirements to have AED devices, e.g., New York mandates that any building that has a meeting room, banquet facility or ballroom with capacity of 1,000 individuals or more must have an AED device).

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² See generally *Abramson v. Ritz Carlton Hotel Co., LLC*, 480 F. App’x. 158 (3d Cir. 2012).

²⁵³ *Id.* at 159.

²⁵⁴ *Id.*

oxygen tank and AED.²⁵⁵ After CPR and oxygen failed to help Mr. Abramson, “AED shocks were administered.”²⁵⁶ However, the plaintiff claimed that the device only produced a “quiver” of a jolt because the unit was not charged, and the court assumed that the equipment malfunctioned for the purposes of the appeal.²⁵⁷ The victim was then taken to a hospital where he later died.²⁵⁸ A medical expert opined that “if emergency personnel or functioning medical equipment had arrived at the [h]otel sooner, Mr. Abramson may have had at least a 50% chance of long-term survival.”²⁵⁹ The victim’s wife brought suit alleging the hotel breached the duty of care owed to her husband.²⁶⁰

The Court of Appeals affirmed the District Court’s determination that a hotel’s duty to a guest in a medical emergency is limited to summoning help and providing basic first aid until professionals arrive.²⁶¹ Based on the evidence that an ambulance was called when requested and that Mr. Abramson received CPR from trained medical professionals while awaiting the ambulance, the court found that the hotel did not breach its duty.²⁶² Moreover, “to the extent that the hotel incurred a heightened duty by providing an oxygen tank and AED, the Good Samaritan Act shields [it] from any liability for negligence.”²⁶³

The court examined whether the hotel, as an innkeeper, had a duty to affirmatively assist an ill person such as Mr. Abramson who was suffering from SCA.²⁶⁴ Relying on the Restatement (Second) of Torts § 314A and the accompanying commentary,²⁶⁵ the court concluded that “an innkeeper must only summon medical care when the

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ *Id.* at 159–60.

²⁵⁸ *Id.* at 160.

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.* at 161.

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.* (citing Restatement (Second) of Torts § 314A, “which provides that an innkeeper owes a duty to its guests to ‘take reasonable action . . . 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.’” The commentary further provides “[t]he defendant . . . will seldom be required to do more than give such first aid

need becomes apparent and take reasonable first aid measures until medical care arrives.”²⁶⁶ The court elaborated further, stating that the duty “clearly ‘does not extend to providing all medical care that . . . [an] innkeeper could reasonably foresee might be needed.’”²⁶⁷ Essentially, the Court of Appeals concluded that there was no duty for the Hotel to have an AED device.²⁶⁸

There is a scarcity of reported cases against hotels. Most claims seem to result in settlement, so there is little judicial guidance on the duty of a hotel to obtain and employ AEDs. Cases such as *Abramson* illustrate that courts are unwilling to impose a higher burden on hotels than what is statutorily mandated.²⁶⁹ Since hotels continue to believe the misinterpretation that installation of AED devices will cause additional liability, there is an incentive to forgo AEDs altogether rather than determining the proper methods of use and maintenance procedures.²⁷⁰

Despite this perverse incentive, several hotels that have installed AEDs quickly saw the benefits of these life-saving devices.²⁷¹ As part of a public-access defibrillation program in San Diego County,²⁷² the Sheraton San Diego Hotel and Marina obtained AEDs and six of seven people who suffered SCA over a five-year period were saved with the devices.²⁷³ A study done by the program found that “74% of cardiac-arrest victims who received AED treatment survived, while only 4% survived waiting for paramedics without AED use. . . .”²⁷⁴ In light of these statistics, it is surprising that

as he reasonably can, and take reasonable steps to turn the sick man over to a physician, or to those who will look after him and see that medical assistance is obtained.”).

²⁶⁶ *Id.*

²⁶⁷ *Id.* (quoting *Lundy v. Adamar of N.J., Inc.*, 34 F.3d 1173, 1179 (3d Cir. 1994)).

²⁶⁸ *See id.* at 162.

²⁶⁹ *See generally id.* at 160–62, n.2; *see also* *De La Flor v. Ritz-Carlton Hotel Co.*, 930 F. Supp. 2d 1325, 1330–31 (S.D. Fla. 2013) (holding that the hotel did not have a duty to keep AED in hotel’s fitness facility or to provide AED devices to assist guest when he suffered cardiopulmonary arrest).

²⁷⁰ *See* McCartney, *supra* note 246.

²⁷¹ *Id.*

²⁷² *Id.* (finding that the San Diego Program installed about 4,000 automated external defibrillators that have saved 57 lives).

²⁷³ *Id.*

²⁷⁴ *Id.*

some hotels continue to be unwilling to implement the usage of AEDs.

Information on whether or not a hotel is equipped with AEDs is not commonly found online.²⁷⁵ However, the Sheraton San Diego Hotel and Marina uses its AED implementation to its advantage and announces online its designation as a facility that incorporates the American Heart Association's Automatic AED program and abides by the program's guidelines to protect guests, attendees, and employees from SCA.²⁷⁶ An interesting question is whether the Sheraton San Diego Hotel and Marina has gained additional business due to its AED implementation. Perhaps as more hotels implement AED programs, there will be a business incentive to remain competitive and more companies will be inclined to voluntarily implement their own AED process.

4. SHOPPING CENTERS AND RETAIL STORES

It is unlikely that the type of strenuous activity occurring in health clubs takes place inside of shopping centers. However, due to the large number of individuals who suffer from SCA each year, and the high amount of patrons visiting a shopping center, it is reasonably foreseeable that a patron might suffer from such an attack in a store—or so the plaintiff alleged in *Verdugo v. Target Corp.*²⁷⁷ Mary Ann Verdugo was shopping at a Target store when she suffered SCA.²⁷⁸ The store did not have an AED, and by the time EMS arrived, responders were unable to revive Verdugo.²⁷⁹ The court found that “[i]n light of the extent of the burden that would be imposed by a requirement to acquire and make an AED available[,] and in the absence of any showing of heightened foreseeability of sudden cardiac arrest or of an increased risk of death,” Target owed no duty to purchase and make the devices accessible under California law.²⁸⁰

Oregon is currently the only state with existing requirements related to the implementation of AED devices in shopping centers and

²⁷⁵ *Id.*

²⁷⁶ *CardioReady*, SHERATON SAN DIEGO HOTEL & MARINA, http://www.starwoodhotels.com/sheraton/property/meetings/fas_detail.html?propertyID=127&fasXRefId=1001026553&language=en_US (last visited Aug. 31, 2016).

²⁷⁷ 327 P.3d 774, 775–76 (Cal. 2014).

²⁷⁸ *Id.* at 776.

²⁷⁹ *Id.*

²⁸⁰ *Id.* at 792.

includes these facilities with other areas designated as “places of public assembly.”²⁸¹ Oregon defines a place of public assembly as one with 50,000 square feet or more of indoor space “where the public congregates for purposes such as deliberation, shopping, entertainment, amusement or awaiting transportation,” or where “at least 50 individuals congregate on a normal business day.”²⁸² In addition to shopping malls and large retail stores, this definition can also include office buildings and transportation terminals.²⁸³

IV. CONCLUSION

The benefit of AED devices is clear. More than 350,000 SCA incidents occur each year, and an AED device can make the difference between life and death for the victim.²⁸⁴ The federal government recognizes the importance of these life-saving devices and has mandated their availability in the airline industry.²⁸⁵ Other businesses must follow the statutory and common law requirements of their jurisdiction.²⁸⁶ Currently, fifteen states require health clubs to acquire AEDs and make them available.²⁸⁷ Courts seem unwilling to impose any additional liability in these and other businesses such as hotels and shopping centers.²⁸⁸ In some cases, the courts’ rulings seem to defeat the purpose and intent of the jurisdictions respective statutes.²⁸⁹ Proponents argue that as awareness of the advantages of AEDs continues to grow, businesses should be more inclined to willingly implement the devices.²⁹⁰ Courts do not want to burden businesses with additional liability,²⁹¹ but businesses can still be protected through Good Samaritan immunity laws, insurance, and indemnification contracts with AED manufacturers.²⁹²

²⁸¹ See OR. REV. STAT. § 431A.455 (2015).

²⁸² *Id.*

²⁸³ *See id.*

²⁸⁴ See MAYO CLINIC, *supra* note 10.

²⁸⁵ See Lazar, *supra* note 109.

²⁸⁶ See AED Brands, *supra* note 145.

²⁸⁷ *See id.*

²⁸⁸ See, e.g., *Abramson v. Ritz Carlton Hotel Co., LLC*, 480 F. App’x 158 (3d Cir. 2012).

²⁸⁹ See, e.g., *id.*

²⁹⁰ Lazar, *supra* note 109.

²⁹¹ See, e.g., *Abramson*, 480 F. App’x at 161.

²⁹² Lazar, *supra* note 109.