# MAKING SENSE OF AED LAWS





According to **this Sudden Cardiac Arrest Foundation article** the American Heart Association estimates that there were 356,461 EMS-assisted out of hospital cardiac arrests (OHCAs) in 2017 of persons of all ages in the US. Of these, approximately 98% were adults and just over 10% survived.

# MAKING SENSE OF **AED LAWS**

This article in the New England Journal of Medicine supports the notion that immediate bystander-initiated cardiopulmonary resuscitation (CPR), along with defibrillation with an automated external defibrillator (AED) vastly improves a victim's chance of survival.

The 2018 Update of AHA's Heart Disease and Stroke Statistics shows that 20% of out-of-hospital cardiac arrests are "shockable" arrhythmias, those that respond to a shock from an AED, making AEDs in public places highly valuable.

# MAKING SENSE OF **AED LAWS**

## THE GOOD SAMARITAN LAW

A Good Samaritan is someone who compassionately renders personal assistance to the unfortunate. The Good Samaritan doctrine takes on a much more complicated and controversial meaning when applied in the law. This definition by USLegal.com states, "A good samaritan in legal terms refers to someone who renders aid in an emergency to an injured person on a voluntary basis."

(b) (C)

ZOLI

The Good Samaritan law is designed to provide protection from civil litigation to a person who attempts to rescue another person, should any unintended harm result from the rescue attempt. The principle essentially offers legal protection when someone voluntarily, without a desire for compensation, provides reasonable assistance, including CPR and the use of an AED device, to someone else who appears to be severely ill, injured, or impaired.



HISTORY OF THE GOOD SAMARITAN LAW California first enacted the Good Samaritan law in 1959 to protect physicians, stating that, "No person licensed under this chapter, who in good faith renders emergency care at the scene of the emergency, shall be liable for any civil damages as a result of any acts or omissions by such person in rendering the emergency care." The law was meant to grant immunity to doctors who gave aid in emergencies. It was later amended to include non-medical lay persons.



# HOW DOES THE LAW APPLY TO INDIVIDUALS?

Florida was the first state to enact a broad access law in April 1997 (Chapter 34 of 1997). Since 2001, all fifty states and the District of Columbia have some type of Good Samaritan law. **The details of these AED laws** differ by jurisdiction, including who is protected from liability and under what circumstances.

In some states, Good Samaritan laws protect all individuals who find themselves in emergent situations where a person requires assistance, while other states' laws only shield those who have completed basic first aid training and are certified by a national health organization. In still other states, the Good Samaritan law extends to off-duty and volunteer first responders. For more information on Good Samaritan laws in your state, visit **plustrac.com/aed-laws**.



AED laws are a source of confusion, but the use of an AED and its availability in public places such as workplaces and schools can save lives. According to **research** by Mark Sherrid, MD, of New York University Langone Medical Center and others, certain states require or recommend AED placement in settings such as schools and workplaces.

Communities with comprehensive AED programs that include CPR and AED training for rescuers have a higher survival rate than others, **nearly 40%**, for cardiac arrest victims.



### AUTOMATED EXTERNAL DEFIBRILLATORS (AEDS)

An AED is a portable, electronic medical device that is designed to allow less trained individuals to provide lifesaving assistance to victims experiencing sudden cardiac arrest (SCA). Victims experiencing SCA have a medical condition in which the heartbeat stops abruptly and unexpectedly. If not treated within minutes, the SCA becomes fatal.

AEDs were first designated for public use by the FDA in the 1990's to treat SCA. Good Samaritan laws soon followed to provide protection for someone who gives aid in an emergency to an injured person. Eventually, basic CPR training included AED training. As time passed, it became clear that having AEDs in high-risk and highly populated areas was needed.

When a victim collapses due to SCA, there is a race against the clock to complete the **5 step Chain of Survival**. This chain needs to be completed within 5 minutes for the victim to have a chance of surviving.

# AED LAWS

THE 5 LINKS IN THE AMERICAN HEART ASSOCIATION VERSION OF THE CHAIN OF SURVIVAL ARE:

- 1. Immediate recognition of cardiac arrest and activation of the emergency response system
- 2. Early CPR with an emphasis on chest compressions
- 3. Rapid defibrillation
- 4. Effective advanced life support
- 5. Integrated post-cardiac arrest care





Having an AED on the premises when someone collapses from SCA allows the AED to be retrieved quickly. Use of an AED before EMS arrival doubles the odds of survival according to **the conclusions of this study** in the Journal of the American College of Cardiology. With simple audio and visual commands, AEDs are designed to be used by anyone. A bystander can easily open the device and follow instructions that could result in saving a life.

Because of recent technological advances, the AED is now an important medical tool. Trained non-medical personnel can use AEDs to treat a person in cardiac arrest. The AED device guides the user through the application and use process by audible or visual prompts without requiring any prior medical training.

The American Heart Association notes that at least 20,000 lives could be saved annually by quick use of AEDs. Ultimately, with broad use of AEDs among trained responders, up to 50,000 deaths due to sudden cardiac arrest could be prevented.

To promote the purchase and use of publicly accessible AEDs, the US government passed the **Cardiac Arrest Survival Act** (CASA) in 2000. This legislation provided immunity from civil liability for the emergency AED user in federal buildings, if the state had not granted immunity already. This further extended Good Samaritan protections, which are intended to dispel any fear that you or your employees might face legal or criminal consequences for trying to help a person in need.



### THAT IS THE KEY QUESTION. ISN'T IT?

Generally, the state AED laws distinguish between the requirements for the individual, the user; and the entity that purchased the unit, the buyer or owner.

The term, "Good Samaritan", refers to the individual user, not the buyer. So, as an agent of the buyer, your concern has to be with regard to how your facility is protected from, or exposed to, civil litigation when the AED is used.

### How do these Laws apply to My facility?



There are a number of considerations to take into account when looking to assure that your facility is properly protected. The key considerations include the following:

HOW DO THESE LAWS APPLY TO MY FACILITY?

<b>\</b> +∕	ACQUISITION
<b>(Ĵ)</b>	NOTIFICATION
C(+)	MEDICAL DIRECTION
$\bigcirc$	LOCATION
۲ ۲	TRAINING
X	MAINTENANCE
	POST-USE FOLLOW-UP



ACQUISITION OF AN AED DEVICE

**Д** 

### NOTIFICATION AND DOCUMENTATION REQUIREMENTS

AEDs are classified as Class III medical devices in the United States by the Food and Drug Administration (FDA). This means that these devices require thorough and rigorous testing for safety; it also means that, as a Class III medical device, an AED requires a prescription (or medical authorization) at time of purchase.

The American Heart Association strongly encourages that when AEDs are placed in the community or a business or facility, that they be part of a defibrillation program in which:

- Persons that acquire an AED notify the local EMS office.
- A licensed physician or medical authority provides medical oversight to ensure quality control.
- Persons responsible for using the AED are trained in CPR and how to use an AED.

# **Д**)

### NOTIFICATION AND DOCUMENTATION REQUIREMENTS

To ensure your AED device is truly public and verified, you can use a free notification registry, such as the **National AED Registry**.

Laws differ by state and agency, but documentation and notification requirements exist in most jurisdictions. In California, for example, the following apply:

- Notify the local emergency medical service agency of the existence, location, and type of AED.
- Maintain records of the maintenance and testing of the AED as required by law.

Additionally, building owners in California must follow specific requirements to obtain immunity through the Good Samaritan law:

- Annually notify building tenants of the location of the AED unit(s) and provide information to tenants about how to voluntarily take CPR and AED training.
- Annually offer a demonstration to at least one person associated with the building on how to properly use an AED in an emergency.
- Post instructions on how to use the AED next to the AED in 14-point font.

# E

### MEDICAL DIRECTION REQUIREMENTS

# 

In the United States, in addition to the federal requirements for medical authorization to acquire an AED, some, but not all, states require some sort of ongoing medical direction of the AED program. Individual areas and counties may impose additional requirements for purchasing or owning an AED. Medical direction involves the creation of protocols and response plans—what to do and where to go if a sudden cardiac arrest occurs. Some states require that the prescribing physician be licensed in the state where the AED is to be used. Other states allow for medical oversight by way of a national AED program management provider.

Although not generally specified by state law, there are a few things to consider when determining how many AED units are right for you and where you should place them. The primary objective for any public access defibrillation program is to achieve a **3-minute response time** from collapse of the victim to the arrival of the AED unit. When placing your device(s), use the 3-minute response time from collapse to arrival of the device as a guide to determine where to place the unit(s) and how many you need.

This means three minutes from "drop to shock". When determining placement, an important factor is to identify the locations at which the rate of cardiac emergencies may be higher. Keep in mind the following:

#### THE VOLUME OF EMPLOYEES AND VISITORS:

Areas such as cafeterias or a call center with many cubicles would warrant AED placement due to the high population density.

### **HIGH-RISK ACTIVITIES:**

Another important area that warrants placement of an AED in close proximity would be a location that has those involved in high-risk activity. Think of places where heart rates are up due to physical activity, such as corporate fitness centers, swimming pools, or other recreational areas. Companies with increased physical labor, like warehouses, loading docks, or assembly lines should consider this an area at risk for higher numbers of cardiac emergencies.

#### IDENTIFY WHERE TO PLACE YOUR AEDS

- Get a floor plan, a stopwatch, and a clipboard to identify the locations with the fastest access to the most people.
- Identify areas where an AED could be mounted on a wall in a high-traffic area where it would be visible to many people.
- Calculate the time it takes to get the AED to the victim and consider delays such as elevators, stairs, restricted access areas, and crowded areas.
- Take your stopwatch to the proposed AED location and start timing (do not run during this exercise, quickly walk). Walk north for 1.5 minutes and mark the area you are standing in on the floor. Return to the proposed AED location and repeat the exercise south, east, and west.
- Draw a circle through the marked locations (which indicate the radius of 1.5 minutes from the proposed AED location). You can see what is covered and what is left out. If the highly populated coverage areas have circles that are touching, you have thoroughly protected as may employees and visitors as possible.

Remember that once the AED reaches the victim, it should take less than 90 seconds to prepare the AED and deliver the shock. The "drop-to-shock" time is critical for successful defibrillation.



# TRAINING

AEDs have been designed so that persons with no medical background or training can provide the life-saving defibrillating shock when appropriate. However, some states, notably New York, New Jersey and Rhode Island, require the AED user to have completed a designated AED training course to be immune from civil litigation. New York even goes so far as to prohibit anyone from using an AED who has not been so trained.

Even without a state law requiring training, your facility should ensure that your employees are properly trained. Proper training needs to include both basic cardiopulmonary resuscitation (CPR) and AED use.

CPR TRAINING: The American Heart Association says that early CPR is an important part of providing lifesaving aid to people suffering sudden cardiac arrest. After the AED is attached and delivers a shock, the typical AED will prompt the operator to continue CPR while the device continues to analyze the victim.

AED TRAINING: Furthermore, the AED operator must know how to recognize the signs of a sudden cardiac arrest, when to activate the AED system, and how to do CPR. For this reason, it is important for those who operate the AED to receive formal training on the AED model they will be using so they are familiar with the device and can operate it successfully in an emergency situation. This training also will teach the operator how to avoid hazardous situations.

# MAINTENANCE

AEDs can be lifesavers, but they are not fail-safe. According the **Sudden Cardiac Arrest Foundation**, portable defibrillators needs regular maintenance to prevent failures. Like any machine, AEDs need to be maintained. Batteries run down and need to be replaced. Electrode pads that attach to a patient's chest also deteriorate and have to be replaced every year or so. Maintenance should not be spotty.

States vary with regard to the on-going maintenance that is required to provide immunity from civil suit to the owner. However, practically all require that the AEDs be maintained and tested on a routine basis in accordance with the manufacturers recommendations. Failure to do so may void the immunity provided by some states.

### **ROUTINE MAINTENANCE**

According to the American Heart Association (AHA), it is important to visual inspection on a weekly or monthly basis to ensure AEDs are in working order. The AHA recommends a program coordinator or another designated be selected and this person can do the inspections. This coordinator should develop a written checklist to assess the readiness of the AEDs and supplies. A checklist supplements regularly scheduled, more detailed inspections.

One important thing to check regularly is the AED's light. An AED performs self-tests on its internal circuitry to ensure readiness. These self-checks are done weekly and monthly, and sometimes daily. A status indicator or readiness display will show an alert when a problem is found. This is why it is important for you to conduct regular inspections.



### FULL INSPECTIONS

These more detailed inspections are the ones recommended by the manufacturer. Also, talk with your manufacturer regularly to get the latest information about software updates or upgrades.

In California, for example, AEDs must be maintained and regularly tested according to the maintenance guidelines set forth by the manufacturer, the American Heart Association, and the American Red Cross. This includes any applicable laws and regulations set forth by the governmental authority under the federal FDA and any other state or federal laws.

## RECALL/CORRECTIVE ACTIONS NOTIFICATION AND RESPONSE

The fact that recalls happen all to often is addressed in this 2013 SHRM **article** by Roy Maurer, AEDs in the Workplace: Benefit or Burden? It states that, "The defibrillator industry has recalled hundreds of thousands of devices ...".

Recalls continue to happen as evidenced by this **manufacturer's** Class 1 recall required by the FDA.

While it is the responsibility of the manufacturer to initiate the recall, and give direction to the device owners as to how to comply with the recall, it is the responsibility of the owner to comply with it. This is crucial because, as stated in the **Cardiac Arrest Survival Act of 2015**,

# POST-USE REQUIREMENTS

After using the AED, there are some steps you need to take. First, you will need to tell EMS responders some specifics about what happened when they arrive. Such as,

- whether or not you witnessed the arrest,
- how long the victim was down,
- and how many shocks you delivered

On arrival, EMS personnel will attach their own defibrillator to the patient and assume CPR responsibilities. They may or may not remove your electrode pads. Ultimately, the pads you attached must be disposed of and someone must clean up any leftover packaging or waste.

### GETTING THE AED BACK INTO SERVICE

After emergency personnel have left with the patient, you must get the AED ready to be used again. Each time your AED is attached to a person, you must replace the electrode pads. Depending on the make and model of your AED, you may or may not need to replace the battery or charge pack.

When replacing items on your AED, it is important to note the "use by" or "install by" date on the replacements to ensure they have not expired. In some cases, the unit may also need to be cleaned or disinfected. Follow all instructions provided by your specific AED manufacturer for replacing, recycling, and disposing of batteries and electrode pads. AEDs collect event information during a SCA. This is digitally recorded and transferred to a computer for later review. The recording may need to be retrieved, depending on your organizations AED policy. Someone on your response team may need to provide the AED data to your medical director or contact your AED program management service. Consult your organization's AED policy for specific details.



### WRITTEN DOCUMENTATION

Someone from your emergency response team must document the cardiac arrest event in writing. Generally, this requires completion of a post-event form called a medical incident or accident report form.

Complete this in writing as soon as possible after the incident. The form calls for details of the incident such as:

- time of the event
- name of person completing report
- date, time location of the incident
- whether or not the cardiac arrest was witnessed
- who started CPR and when
- when the AED arrive
- who operated the AED
- name of responding EMS agency



All fifty states and the District of Columbia have laws to guarantee immunity from civil suit to the Good Samaritan user of an AED as well as to the facility owner of the AED device. However, there is no cohesive uniform law that has been adopted by every state, consequently the statutes of the various states differ quite drastically.

### AED PROGRAM MANAGEMENT SERVICE

The answer to the problem is to partner with an AED management service, such as the **PlusTrac<sup>TM</sup>** AED Management Program. PlusTrac<sup>TM</sup> is designed to make sure that you keep compliant with state laws for acquisition, notification, training and use and for manufacturer recommendations for maintenance and testing. PlusTrac<sup>™</sup> lets you know when refresher training is needed, reminds you when you need to report AED use and automatically notifies you when there's an AED recall and when you need to perform AED maintenance or take corrective actions.

Should your program's compliance ever be questioned, **PlusTrac**<sup>™</sup> can demonstrate that your program management system complies with all Good Samaritan requirements. Monitoring legal issues and ensuring ongoing regulatory compliance can be burdensome.

#### YOU NEED TO KNOW THE FOLLOWING:

- How many trained rescuers are required onsite?
- Should your AED be stored in an alarmed cabinet next to a telephone?
- How many signs do you need?

Unless you are a dedicated full-time AED program manager, you probably lack the time and resources to set up and maintain an AED program that is fully compliant with all of the **Good Samaritan** regulations that apply to your facilities in their various locations.

## FOR FURTHER INFORMATION ON HOW TO MAKE SENSE OF THE AED LAWS THAT APPLY TO YOUR FACILITY,

# CONTACT US TODAY.

