

RisKey A Guide to Controlling Risk



Automated External Defibrillators October 2010

Highlights

- Legislation
- Risk Identification
- Goal of an AED program
- Statutes
- Program Recommendations
- Resources

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DAS
DEPARTMENT OF
ADMINISTRATIVE
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RisKey

A Guide to Controlling Risk

AUTOMATED EXTERNAL DEFIBRILLATORS

Automated External Defibrillator (AED) is a small portable machine that shocks a human heart back into a normal rhythm. They are used sudden cardiac arrest (SCA) events.

AEDs are more common in the public places around us. This RisKey provides resources and information to help agencies identify risks and concerns and provide a framework for making an informed decision about AEDs.

Highlights of RisKey

- [Legislation](#)
- [Risk Identification](#)
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Legislation

The Oregon Legislature passed a pair of bills in 2009 (SB556) and early 2010 (SB1006) that update or amend ORS 431.680, 431.690 and ORS 30.802. These bills require the placement of AEDs in certain public assembly areas. These “public assembly areas” are defined as a single building 50,000 square feet or larger **AND** where:

- The public gathers in groups for discussion, shopping, entertainment, amusement, transportation uses; (places of education and worship are excluded) **OR**
- Business activities are conducted during business hours **AND**
- At least 50 individuals gather on a normal business day.

Locations used for education or worship are excluded.

ORS 431.690 require higher education campuses to have at least one AED in gathering areas. If campuses have more than one gathering place, at least one AED needs to be readily available.

Click below to view the statutes.

ORS 30.802 Good Samaritan Law <http://www.leg.state.or.us/ors/030.html>

ORS 431.690 AED Public Assembly Law <http://www.leg.state.or.us/ors/431.html>

The US Food and Drug Administration (USFDA) requires a prescription for AED purchase. Several vendors have clearance from the FDA to waive this requirement. Check the FDA's

database to see if an AED requires a prescription. The State Procurement Office has purchasing agreements available for AEDs. Contact your agency procurement staff for a list.

For more information, check the following links.

CFR 870.5310 Title 21 Chapter 1, FDA Medical Devices [CFR - Code of Federal Regulations Title 21](#).

Risk Identification

- AED users may try to perform life-saving strategies outside their level of training and comfort.
- Agencies may have inconsistencies in how they manage their AED program.
- Agencies may not meet statutory requirements.



The Goal of an AED Program

The goal of an effective Agency AED program is to increase the rate of survival of people who suffer a Sudden Cardiac Arrest event by using the consistent application of policy, procedure, and training. Effective AED programs deliver a shock to a victim within 3 to 5 minutes of collapse.

Program Recommendations

AED program recommendations include:

- Develop a plan that incorporates the best practices outlined in the “American Heart Association AED Implementation Guide.”
- Assign a dedicated agency program coordinator.
- Obtain medical oversight from a licensed physician.
- Notify local EMS of the location of the AED in the building.
- Notify Local EMS immediately after each use of the AED.
- Debrief each use of the AED to determine if the process worked correctly. Make changes as necessary to incorporate best practices for your location.
- Maintain a schedule for the AED and supporting supplies.
- Provide quality training for onsite responders.
- Use volunteers as responders to maintain immunities under the Good Samaritan Act, ORS 30.800.
- Follow the manufacturer guidelines for testing and maintenance of the AED.
- Ensure enough trained staff are available so at least one is present during regular business hours.
- Store the AED in an accessible location during regular business hours.
- Clearly indicate the presence and location of each AED on your site.
- Establish a policy to activate EMS and 9-1-1 as soon as the need for the use of the AED is recognized.



For more information, see the American Heart Association’s [AED Implementation Guide](#)

NOTE: An AED is used with Cardio Pulmonary Resuscitation (CPR). In 2005, the American Heart Association updated its CPR standards. AEDs programmed prior to 2006 may not comply with the updated standards. Contact the manufacturer to reprogram or replace the unit.

Resources

USDA Searchable Database Link - [UDSA 510\(k\) Premarket Database](#)

ORS 431 Public Health and Safety – AED Requirements - [ORS 431.690](#)

ORS 30.800 Good Samaritan Law and 30.802 Liability for use of an AED - [Chapter 30 — Actions and Suits in Particular Cases](#)

SB556 Text - <http://www.leg.state.or.us/09reg/measpdf/sb0500.dir/sb0556.en.pdf>

SB1006 Text - <http://www.leg.state.or.us/10ss1/measpdf/sb1000.dir/sb1006.en.pdf>

Federal Regulations governing AED Use - [CFR - Code of Federal Regulations Title 21](#)

American Heart Association AED Implementation Guide - [AED Implementation Guide](#)

Senate Bills 1000 – 1099 from 2010 Special Session - As of October 2010 the most current language (not in statute yet) - <http://www.leg.state.or.us/10ss1/measures/sb1000.html>