Public Access/Layperson Defibrillator (AED) Program Implementation Guidelines

I. Purpose:

This is a guidance document to assist businesses and organizations to implement Public Access/layperson Automated External Defibrillator (PAD) programs within the County. Using automated external defibrillators (AED) for out-of-hospital cardiac arrests has been proven to increase survival rates. The Santa Cruz County EMS Agency supports the use of public access AEDs within the County, and these guidelines are intended to facilitate the proliferation of AED programs.

II. Authority:

A. California Statutes Pertaining to Automated External Defibrillators effective January 1, 2006.

B. California Code of Regulations Title 22, Division 9, Chapter 1.8 Sections 100031 through 100043, as revised January 8, 2009.

C. All health clubs and health studios in California are required to have an automated external defibrillator (AED) program in place as required in the California Health and Safety Code, Section 104113.

III. Requirements of Business/Organization:

A. Become familiar and comply with California AED regulations and statutes, referenced above.

B. Notify the County of each AED unit being acquired in the County, compliance with the implementation checklist and anytime an AED is used. Submit the information by mail to:

   - Santa Cruz County EMS Agency
   - P. O. Box 962
   - Santa Cruz, CA 95060

C. Every time an AED is used, complete the Notification of AED Use form, and submit via Fax to Santa Cruz County EMS Agency (831) 454-4488, within 24 hours of use.

IV. Implementation Checklist

NOTE: Note that while California statutory law does not require that you have an AED medical director, current California regulations do contain such a requirement. This is because the State EMS Authority has not yet revised the regulations to match the statute. In a memo (see last page of this document), the State EMS Director explains that statutes take precedence over regulations and, therefore, a physician is no longer required to authorize each individual to use an AED.
Listed below are key elements taken from the California AED regulations and statutes. These elements are placed in this checklist format to assist in implementing public access/layperson AED programs within the County.

- Notify the County EMS Agency of the existence, location, and type of every AED within the county. The business or organization responsible for the device must, at the time the device is acquired and placed, notify EMS.

- Expected AED users/rescuers must complete a training course in cardiopulmonary resuscitation (CPR) and in use of the AED device. The training curriculum must comply with regulations adopted by the California Emergency Medical Services Authority, the standards of the American Heart Association, or the American Red Cross. The training shall include a written and skills examination.

- The business/organization must develop an internal emergency response system plan for the site of the AED. The AED program must comply with State regulations and requirements for training, notification, and maintenance. The internal emergency response system plan will include the procedures to be followed in the event of an emergency that may involve the use of an AED. The plan must also include provisions for immediate notification of 911 and immediate notification of AED-trained on-site personnel, upon discovery of the emergency.

- The business/organization in possession of the AED must comply with all regulations governing the training, use, and placement of the device.

- The AED must be maintained and regularly tested according to the manufacturer’s operation and maintenance guidelines, the American Red Cross, and American Heart Association. Maintenance and testing must also comply with any applicable rules and regulations set forth by the US Food and Drug Administration and any other applicable authority.

- The AED must be checked for readiness at least once every 30 days and after each use. Records of these periodic checks shall be maintained by the business/organization in possession of the device.

- A mechanism shall exist to ensure that any person rendering emergency care or using the AED activate the emergency medical services system (911) immediately. Further, the business/organization in possession of the AED is responsible for reporting any use of the AED to Santa Cruz County EMS.

- A mechanism shall exist that assures the continued competency of the expected AED users/rescuers employed by the business/organization in possession of the AED. Such mechanism shall include periodic training and skills proficiency demonstrations sufficient to maintain competency.

- For every AED unit acquired up to five units, no less than one employee per AED unit shall complete a training course in CPR and AED. After the first five AED units are acquired, for each additional five AED units acquired, one additional employee shall be trained beginning with the first additional AED unit acquired. The business/organization in possession of the AED shall have trained employees available to respond to a cardiac emergency during normal operating hours.

- A mechanism shall exist to ensure that any person rendering emergency care or using the AED activate the emergency medical services system (911) immediately. Further, the business/organization in possession of the AED is responsible for reporting any use of the AED to Santa Cruz County EMS. (see next page)
Notification of AED Use

To be completed by on-site contact and faxed within 24 hours of AED use to:

831-454-4488 ATTENTION: EMS

Name of AED Service Provider:__________________________________________________________

Date of Occurrence: ___________________ Time of Occurrence:__________________________

Place of Occurrence: (Address and specific location):

__________________________________________________________________________________

Patient's Name:__________________________________________________________

Patient's Age: ___________ Patient's Gender:_______________

Did anyone witness collapse/arrest? _____________________________

Time AED Service Provider or User was notified: _________________

Approximate down time prior to arrival of AED Provider or User: _________________

Was CPR used prior to AED on victim? ________________

Time of first shock (if given): _________________ Total number of shocks: ________________

Did victim regain a pulse at scene? ________________

Lay Responder Name(s):

__________________________________________________________________________________

__________________________________________________________________________________

Name and phone number of person completing form:____________________________________

Additional comments/information: __________________________________________________________

__________________________________________________________________________________

__________________________________________________________________________________

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__________________________________________________________________________________
DATE: May 9, 2003
TO: All Interested Parties
FROM: Richard E. Watson
       Interim Director

SUBJECT: Automated External Defibrillator Regulatory Information

The EMS Authority has received inquiries regarding the inconsistencies between the Layperson AED Regulation (effective February 2003) and the recently enacted language of Assembly Bill (AB) 2041 (Vargas), Chapter 718, Statutes of 2002. The following is a brief explanation of the differences.

AB 2041 was initially introduced as a spot bill after the EMS Authority was well into the revision of the Layperson AED Regulations. AB 2041 was amended and eventually signed by the Governor as the Layperson AED Regulation revision was nearing the deadline for completion. Because there were significant improvements to the proposed Layperson AED Regulations, which have not been revised since their inception in 1991, the decision was made to complete the Layperson AED Regulations as proposed. This decision was made because if the EMS Authority made the changes reflected in AB 2041 the rulemaking process may have been jeopardized resulting in the EMS Authority having to start the rulemaking process over.

The major inconsistencies between the current Statutory Law and the Regulatory Law are:

1. The current Statute no longer requires a physician to authorize each individual to use the AED. The newly revised Layperson AED Regulations do require a physician's authorization to use the AED based on the previous statutory language, and
2. The current Statute establishes minimum numbers of trained personnel in relation to the number of AEDs acquired, whereas the newly revised AED regulations require all AED users to be trained in the use of the AED.

In cases where there are inconsistencies between statutory law and regulatory law, the statute takes precedence over regulation.

The EMS Authority is aware of the inconsistencies between these two bodies of law and intends to revise the Layperson AED Regulations when staff workloads permit. If you have questions, please contact Michael Conley at the EMS Authority (916) 322-4336.