EXHIBIT 1
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SB 95

Testimony on SB 95

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Cardiovascular disease, including heart disease and stroke, is the leading cause of death in Montana and in the United States. In 2004, there were 1,791 deaths (five deaths per day) among Montana residents from heart disease, and 516 (29%) of these deaths (ten deaths per week) from sudden cardiac arrest occurred out-of-the hospital. The median rate of survival to hospital discharge for witnessed sudden cardiac arrest is 6% in the United States. As Senator Smith indicated, some of these deaths could be prevented by quickly identifying persons experiencing sudden cardiac arrest, activating the Emergency Medical Services system by calling 911, providing CPR and using an automated external defibrillator (AED), providing advanced cardiac life support services, and transporting to the appropriate acute care setting where additional treatment can be performed.

Let me elaborate on the use on an AED. Many persons experiencing sudden cardiac arrest have an abnormal heart rhythm called ventricular fibrillation, which causes the heart to quiver so it does not pump blood effectively. Over 40% of persons experiencing sudden cardiac arrest have ventricular fibrillation. Treating ventricular fibrillation requires the delivery of a shock to the heart, which allows the victim's heart to resume a normal rhythm. This is what an AED does.

AEDs are highly accurate, user friendly computerized devices with voice and audio prompts that guide the user through the life saving steps. They are designed for lay users and first responders to reduce the time to defibrillation, which is a key to improving the likelihood of

survival for the victim. The rescuer turns on the AED and attaches adhesive electrodes to the victim. The AED records the victim's cardiac rhythm and prompts the rescuer to deliver a shock, if the victim is experiencing ventricular fibrillation. Public AED programs, that include EMS activation and CPR, have been shown to reduce the time to defibrillation for persons experiencing sudden cardiac arrest, and to improve survival rates. In Montana numerous pubic AED programs have been established. The Department has also utilized Federal grant funding to purchase and distribute AEDs to targeted public locations throughout the state, including EMS and law enforcement services, government buildings, and Community Health Centers. These sites were targeted because the likelihood of witnessed sudden cardiac events happening in these locations is high, and the frequency of high-risk persons at these locations.

To establish an AED program in Montana currently, four criteria need to be met:

a) planning and oversight of a community lay program by physician;

b) training in CPR and AED use for anticipated rescuers;

c) linkages with the local EMS system; and

d) regular AED maintenance and readiness-tests for AEDs and program staff

There are a number of potential barriers to establishing public AED programs in Montana. One is the potential liability for persons who oversee these programs, rescuers, and the facilities where these programs are located. The State of Montana has addressed this issue by providing "good Samaritan" limited immunity for these individuals and facilities. A second potential barrier relates to persons eligible to provide oversight for these programs. The current Montana law indicates that only a physician or an individual designated by a physician can oversee an AED program.

In 2005, the American Heart Association published revised national guidelines for public AED programs that changed the recommendations for program oversight. The American Heart Association now recommends that oversight for an AED program can be performed by a health care professional with training and expertise in areas such as emergency care and cardiovascular care. These professionals include not only physicians, but also mid-level practitioners, nurses, and paramedics. The American Heart Association recognized that while it is good to have physician oversight for these programs, it is not necessary to have that level of expertise. Additionally, obtaining physician oversight for these programs may not always be feasible. Removing this barrier from our State law will allow the continued establishment of these critical programs here in Montana. The changes in the statute included in SB 95 would accomplish this goal.

Thank you for considering this bill. On behalf of the Department I would like to thank Senator Smith for sponsoring this important legislation.

Community Lay Rescuer Automated External Defibrillation Programs

Key State Legislative Components and Implementation Strategies

A Summary of a Decade of Experience for Healthcare Providers, Policymakers, Legislators, Employers, and Community Leaders From the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy

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Abstract— Cardiovascular disease is a leading cause of death for adults ≥40 years of age. The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for about 250 000 out-of-hospital deaths annually in the United States. Since the early 1990s, the AHA has called for innovative approaches to reduce time to cardiopulmonary resuscitation (CPR) and defibrillation and improve survival from sudden cardiac arrest. In the mid-1990s, the AHA launched a public health initiative to promote early CPR and early use of automated external defibrillators (AEDs) by trained lay responders in community (lay rescuer) AED programs. Between 1995 and 2000, all 50 states passed laws and regulations concerning lay rescuer AED programs. In addition, the Cardiac Arrest Survival Act (CASA, Public Law 106-505) was passed and signed into federal law in 2000. The variations in state and federal legislation and regulations have complicated efforts to promote lay rescuer AED programs and in some cases have created impediments to such programs. Since 2000, most states have reexamined lay rescuer AED statutes, and many have passed legislation to remove impediments and encourage the development of lay rescuer AED programs. The purpose of this statement is to help policymakers develop new legislation or revise existing legislation to remove barriers to effective community lay rescuer AED programs. Important areas that should be considered in state legislation and regulations are highlighted, and sample legislation sections are included. Potential sources of controversy and the rationale for proposed legislative components are noted. This statement will not address legislation to support home AED programs. Such recommendations may be made after the conclusion of a large study of home AED use. (***Circulation*. 2006;113:1260-1270.**)

Key Words: AHA Scientific Statements ■ fibrillation ■ defibrillation ■ resuscitation ■ sudden cardiac arrest

Cardiovascular disease is a leading cause of death for adults ≥40 years of age.[1,2] The American Heart Association (AHA) estimates that sudden cardiac arrest is responsible for ≈250 000 out-of-hospital deaths annually in the United States.[3] Since the early 1990s, the AHA has called for innovative approaches to reduce time to cardiopulmonary resuscitation (CPR) and defibrillation and improve outcome from sudden cardiac arrest.[4] In the mid-1990s, the AHA launched a public health initiative to promote early CPR and early use of automated external defibrillators (AEDs) by trained lay responders in community public access defibrillation (PAD) programs.[5–7] In 1998, in response to requests

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from its training network, the AHA circulated an internal report to assist in developing legislation that would remove barriers to these programs.[8]

Between 1995 and 2000, all 50 states passed laws and regulations governing lay rescuer AED programs. In 2000, the Cardiac Arrest Survival Act (CASA) was passed and signed into federal law (Public Law 106-505). CASA called for the development of guidelines for establishing AED programs in federal buildings. CASA provides limited immunity from civil liability for the emergency AED user and the AED acquirer if the state has not otherwise granted immunity for such persons under other statutes. Since 2000, most states have reexamined lay rescuer AED statutes, and many have passed legislation giving grants to local governments to obtain AEDs and to require AEDs or AED programs in certain venues (eg, state buildings, health clubs).

The AHA applauds state and federal policymakers and advocates across the country for enacting lifesaving legislation to promote lay rescuer AED programs. After a decade of experience, the AHA has collected information about policies, legislation, and regulations and their impact on the establishment and success of community lay rescuer AED programs.

The purpose of this policy statement is to help policymakers develop new legislation or revise existing legislation to remove barriers to effective community lay rescuer AED programs. Important areas that should be considered in state legislation and regulations are highlighted, and examples of model legislation are included. Potential sources of controversy and the rationale for proposed legislative components are noted. This statement will not address legislation to support home AED programs. Such recommendations may be made after the conclusion of a large study of home AED use.

Background

As noted above, the AHA estimates that ≈250 000 deaths are caused by coronary artery disease in the out-of-hospital setting annually in the United States.[3] This number is commonly accepted as a surrogate for the number of sudden cardiac arrests that occur in the out-of-hospital setting annually. The median published rate of survival to hospital discharge for witnessed sudden cardiac arrest in the United States is 6.4%.[9–11]

In the first minutes after collapse, many victims of witnessed sudden cardiac arrest demonstrate an abnormal heart rhythm called ventricular fibrillation (VF), which causes the heart to quiver so that it does not pump blood effectively.[12] Treatment of VF requires delivery of a shock with a defibrillator. Delivery of a shock can stop VF (defibrillation), allowing the victim's normal heart rhythm to resume. The victim needs CPR to maintain blood flow to the heart and brain until a defibrillator is available and often requires CPR in the first minutes *after* defibrillation until the heart is able to pump blood effectively.[13,14] CPR is important both before[15] and after[16] defibrillation for improving survival from VF sudden cardiac arrest. Even a brief interruption of chest compression can be detrimental.[17]

AEDs are highly accurate, user-friendly computerized devices with voice and audio prompts that guide the user through the critical steps of operation. AEDs were designed for use by lay rescuers and first responders to reduce time to defibrillation for victims of VF sudden cardiac arrest.[18] The rescuer turns the AED on and attaches it to the victim with adhesive electrodes or pads. The AED records and analyzes the victim's cardiac rhythm. If a shock is indicated, the AED charges to the appropriate energy level and prompts the rescuer to deliver a shock. If the device is fully automated and a shock is indicated, the AED can deliver a shock without further action by the rescuer. AEDs require little maintenance and are relatively inexpensive (<$2000).

As of August 8, 2005, the US Food and Drug Administration (FDA) classified AEDs as Class 3 medical devices, with most requiring a prescription. This means that AEDs require "special controls" to ensure their safety and effectiveness. One goal of the prescription requirement is to ensure that AEDs are used in organized programs with appropriate planning and oversight, appropriate training of anticipated rescuers, and appropriate monitoring of the quality of care associated with use of these devices. Although the AHA strongly supports these program elements, it could find no published evidence that the prescription requirement itself increased the likelihood of rescuer training or effective AED use. In 2004, the FDA cleared the labeling of one commercially available AED without a prescription. It is anticipated that similar labeling will be cleared for more AEDs in the near future. Such labeling may make AEDs available for home use. At this time there is insufficient evidence for the AHA Emergency Cardiovascular Care (ECC) Committee to make recommendations about home AED programs.

Successful lay rescuer AED programs should increase the survival rate of victims of witnessed VF sudden cardiac arrest. Two factors have a significant impact on adult survival from VF sudden cardiac arrest: the time from collapse to defibrillation and the time from collapse to CPR. If no CPR is provided, for every minute of delay between collapse and defibrillation, the victim's chance of survival from VF sudden cardiac arrest falls by 7% to 10%.[19,20] If bystander CPR begins immediately after collapse, the fall in survival is more gradual, decreasing ≈3% to 4% for every minute between collapse and defibrillation.[19,20] Survival-to–hospital discharge rates of 49% to 74% have been reported in airports,[21] commercial airlines,[22,23] casinos,[24] and community police AED programs[16,25–28] when a victim of witnessed VF sudden cardiac arrest receives immediate bystander CPR and shock delivery within 3 to 5 minutes of collapse. Bystander CPR can double[19,20] or triple[29] survival rates at many intervals to defibrillation. AED programs that fail to shorten time to defibrillation and time to bystander CPR have not documented any improvement in survival rates.[30]

In 2000, to determine the effectiveness of community lay rescuer AED programs on survival from out-of-hospital sudden cardiac arrest in a large prospective study, the AHA joined the National Heart, Lung, and Blood Institute (NHBLI) and others to fund a randomized controlled trial of community lay rescuer AED programs. In this study, the Public Access Defibrillation (PAD) trial,[31] nearly 20 000 rescuers were trained in 993 facilities in 24 urban and suburban regions in North America. The trial reported the

outcome of attempted resuscitation in 239 episodes of out-of-hospital sudden cardiac arrest. In this study, all lay rescuers in all study units were trained to recognize emergencies, phone 9-1-1, and provide CPR. Lay rescuers in half of the study sites were also trained and equipped to use AEDs. Fifteen victims of VF sudden cardiac arrest treated in lay rescuer CPR programs without AEDs survived to hospital discharge. During the same period, 30 victims of VF sudden cardiac arrest who were treated in programs that also included early defibrillation with AEDs survived to hospital discharge.[31] The differences between the programs were statistically significant and supported the authors' conclusion that promotion of organized lay rescuer AED programs could save thousands of lives in the United States every year.

Grassroots support for community lay rescuer AED programs has been strong, but placement of AEDs and their use by lay rescuers have raised concerns about legal liability for rescuers, owners of the premises on which AEDs are placed, buyers of AEDs, physician prescribers (if appropriate) of AEDs, public defibrillation program directors, and persons responsible for rescuer training. These nonrescuer program participants are referred to as "facilitators" in this statement.

Questions also have been raised about the amount of training and support required to establish the programs. In the PAD trial, even when extensive initial training was provided to anticipated rescuers, bystander CPR was performed for only ≈65% of the victims of sudden cardiac arrest, and AEDs delivered shocks to only 34% of victims at sites where rescuers were trained and equipped to use AEDs.[31] These results show that even in a well-designed lay rescuer AED program, training in CPR as well as AED use is needed.

Successful community lay rescuer programs require attention to planning as well as training. For example, AEDs must be placed in conspicuous locations, and rescuers must rehearse early recognition of an emergency, early call to the emergency medical services (EMS) system, early CPR, and early defibrillation. The program must be linked with the EMS system and must have a plan for retraining and ongoing quality improvement.

Legislative Efforts to Support Community Lay Rescuer AED Programs

As noted above, all states have legislation or regulations to facilitate lay rescuer AED programs, but these laws and regulations and their components vary widely from state to state. A complete list of existing state legislation and regulations is available at the AHA Web site (www.americanheart.org/statepolicy).

The passage of CASA in 2000 played an important role in triggering the acceptance of AEDs as lifesaving devices and setting the standards for immunity protection for AED use. As noted above, CASA provides limited immunity for rescuers and, under some conditions, for those who acquire AEDs. CASA "supersedes the law of the state" if the state "has no statute or regulations to provide persons in such class with immunity from civil liability for. . .[the use]. . .of automated external defibrillator devices in emergency situations." At the time CASA was enacted, it filled the gap in liability protection for AED acquirers in ≈12 states.

Essential Elements of Community AED Programs

The AHA has identified 4 essential elements of AED programs.[32,33] These elements have been ratified by experts of the AHA ECC Committee as important for increasing survival from witnessed prehospital VF sudden cardiac arrest. These program elements are briefly described below, and they are further explained in the subsequent discussion of key legislation elements.

1. **Planned and practiced response.** The AHA recommends planning and oversight of community lay rescuer AED programs by a person with experience and expertise in resuscitation programs. Such a person is typically a health-care professional with experience in occupational health, emergency, or cardiovascular care. The program director decides on the number and location of AEDs placed. AEDs should be placed where there is a high likelihood of sudden cardiac arrest. In the PAD trial, such locations had the equivalent of ≥250 adults >50 years of age present for 16 hours per day or a history of an average of ≥1 witnessed sudden cardiac arrest every 2 years.[31] The local EMS agency may provide useful information on placement of AEDs (see below). When possible, AEDs should be placed where they can be reached within a short (1 to 1½ min) brisk walk from all areas in the program site. The program director helps to decide whether AEDs should be placed in a highly visible location to facilitate their use by bystanders who are not part of the organized response plan. The program director also oversees the training and retraining of anticipated rescuers, confirms that devices are properly maintained, develops a mechanism to report AED use, establishes a link to the local EMS service, evaluates AED use, and supports a process of quality improvement.
2. **Training of anticipated rescuers in CPR and use of the AED.** This element does not require training of every *potential* rescuer but does require the training of *anticipated* rescuers. Thus, rescuers who are likely to be present should be trained, but the site should not be expected to train every person who could possibly be present. The goal is to ensure that a trained rescuer is present at all times (eg, during business hours). In training, high priority should be placed on recognizing the emergency; phoning 9-1-1; providing CPR and early defibrillation; and using an AED in a safe, appropriate, and effective manner. CPR training should stress that rescuers must deliver effective chest compressions with minimal interruption.[33] Training should include practice in response to a simulated arrest at regular intervals so that responders are familiar with their roles in the resuscitation effort.
3. **Link to the local EMS system.** At a minimum, the program director should inform the local EMS dispatcher that an AED program has been established and give the type and location of AED(s) on site. The AED program must develop a reporting procedure with the EMS system to share patient information. The EMS system also may be able to give information about public locations where sudden cardiac arrest has occurred or provide personnel or other resources to help establish the program and the process of ongoing quality improvement (see below). Each community must decide on the best course of action for its members.
4. **A process of continuous quality improvement, including a plan for on-site AED maintenance and readiness-**

for-use checks. Quality improvement protocols should be used to evaluate the program response to any cardiac arrest. The *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care* recommended that programs establish a goal of ≤90 seconds from arrival of the AED at the victim's side to delivery of the first shock.[32] Program directors and participants must identify and eliminate factors that cause delay in CPR or delivery of the first shock with the AED. In airports[21] and casinos,[24] high rates of survival to hospital discharge after witnessed VF arrest have been documented when immediate CPR was provided and defibrillation occurred within 3 to 5 minutes of the victim's collapse. In the casino study, the rate of survival from witnessed VF sudden cardiac arrest was 74% when the first shock was delivered within 3 minutes but fell to 49% when the first shock was delivered between 3 and 5 minutes after collapse.[24] In the airport study,[21] the rate of survival from witnessed VF sudden cardiac arrest was 74%; all victims received bystander CPR, and a shock was delivered within 5 minutes of collapse. In that study, AEDs were located within a brisk 1-minute walk from any location.

Additional information on AED program implementation is available at http://www.americanheart.org/presenter.jhtml?identifier=3027304.

Recommended State AED Legislation

In general, advocates for AED legislation will need to adapt legislation for each state, but all AED legislation should be broad enough to be "permissive" or "facilitating." The AHA has a policy Web site (www.americanheart.org/statepolicy) to assist policymakers in developing legislation tailored to their state's needs.

The legislation typically begins with a preamble to document the need for the legislation and its potential benefits. Specific sections within the legislation should recommend important program components without "micromanaging" implementation. The AHA recommends addressing these 4 key components in AED legislation:

1. Good Samaritan limited immunity (without qualification) for rescuers and program facilitators
2. CPR and AED training for anticipated rescuers
3. Link with the EMS system
4. Support of the following program elements to increase the likelihood of successful resuscitation of victims of sudden cardiac arrest:
   a. Planned and practiced response
   b. Plan for training of anticipated rescuers in CPR and use of an AED
   c. Plan for link with EMS system
   d. Plan for ongoing process of quality improvement, including evaluation of each episode of sudden cardiac arrest, on-site maintenance, and readiness-for-use checks

State AED Legislation Preamble

Simple yet powerful statistics support this type of AED legislation. First, the legislation should note the approximate number of state deaths from sudden cardiac arrest. The number of state deaths can be found in state reports, or advocates can use the population of the state to estimate this number (see Table 1). The estimated incidence of sudden cardiac arrest reported in the United States is 0.55 per 1000 (55 per 100 000).[1,2,31,34,35]

TABLE 1. Preamble for State Legislation Supporting Community Lay Rescuer Automated External Defibrillation Programs

- Whereas out-of-hospital sudden cardiac arrest results in the death of approximately 55 persons/100 000 population per year and approximately 20% of these arrests are caused by sudden ventricular fibrillation that occurs in the presence of witnesses (so-called "witnessed ventricular fibrillation sudden cardiac arrest"), and
- Whereas, in the population of (state), approximately (state population* divided by 1818) citizens will die of cardiac arrest every year, and
- Whereas lay rescuer programs that provide early recognition, early cardiopulmonary resuscitation, and early defibrillation within the first minutes of a cardiac arrest can increase survival of victims of witnessed ventricular fibrillation sudden cardiac arrest by 7 times or more and so should save an estimated (the state population* divided by 27 750) or more additional victims of sudden cardiac arrest every year in this state, and
- Whereas automated external defibrillators are extremely accurate computerized devices that can be operated by laypersons with minimal training, and
- Now, therefore, be it enacted by the ____ of the State of _____, etc.

Note: This increase in survival rate is derived from the estimated frequency of sudden cardiac arrest in the population (55/100 000 population per year) and predicted improvement in survival of witnessed VF sudden cardiac arrest with activation of a community lay rescuer AED program. An estimated 20% of all episodes of sudden cardiac arrest are witnessed VF arrests (most in public places). The estimated increase in survival is conservatively calculated as an increase from ≈6% survival of victims of witnessed VF sudden cardiac arrest with delayed CPR and defibrillation to survival of ≥40% of victims of witnessed VF sudden cardiac arrest with prompt recognition, early CPR, and early defibrillation. Therefore, of the 11 people who die of witnessed VF sudden cardiac arrest per year per 100 000 population, ≥40% (4.4 per 100 000 per year) would be expected to survive with establishment of community lay rescuer AED programs.

Key Components in Legislation to Facilitate Successful Community Lay Rescuer AED Programs

Good Samaritan Limited Immunity for Rescuers and Program Facilitators

Key: Good Samaritan Limited Immunity for Rescuers

A major impediment to lay rescuer use of AEDs is the failure to provide Good Samaritan limited immunity to lay rescuers who use AEDs in emergencies. Good Samaritan legislation is intended to protect rescuers from civil liability as long as the rescuer provides reasonable and prudent care in good faith. The AHA recommends that state legislation extend Good Samaritan limited immunity to any AED user, without conditions such as a requirement for training. Good Samaritan limited immunity should extend to anyone who acts in good faith, without specific compensation, as a reasonable and prudent person with the same level of training would respond. Although training of anticipated rescuers is recommended, Good Samaritan limited immunity should cover serendipitous or unexpected users who act in good faith.

Many states have removed an important impediment to the establishment of community lay rescuer AED programs by

TABLE 2. Sample Wording of Legislation to Address Good Samaritan Limited Immunity for AED Users

Wording That May Create an Impediment (Not Recommended)*	Wording That May Facilitate Legislation (Recommended)†
"Any person who has attended and successfully completed a course in cardiopulmonary resuscitation that has been approved by the State Board of Health, who in good faith and without compensation, renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator . . . shall not be liable."	"Any person who in good faith and without compensation renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator . . . shall not be liable."

*From House Bill 2097, General Assembly of Virginia, 1999 (amended in 2003). The 1999 legislation was amended because it required training as a condition for Good Samaritan limited immunity. This created an expectation for serendipitous rescuers that is more stringent than for any other Good Samaritan acts.

†From House Bill 1860, General Assembly of Virginia, 2003.

extending Good Samaritan limited immunity to lay rescuers who use the AED as part of gratuitous service in an emergency. CASA also provides limited immunity for lay rescuers in federal buildings. Some states, however, have added conditions to the limited immunity provision for lay rescuers, even when rescuers operate as Good Samaritans. Such conditions can create impediments to establishment of community AED programs (see Table 2).

As noted above, Good Samaritan laws typically require that emergency care be rendered gratuitously, or they differentiate Good Samaritan care from that delivered by healthcare professionals in the context of employment. Responders such as police officers and firefighters who are required to provide CPR and use AEDs in the course of their duties still can be considered Good Samaritans if they are not specifically paid for the attempted resuscitation itself. For example, the Good Samaritan statute may state, "For purposes of this section, the term 'compensation' shall not be construed to include the salaries of police, fire, or other public officials or personnel who render such emergency service." These potential rescuers are typically paid the same salary whether or not they are called on to render aid on a given day: They receive no specific compensation for the emergency response or rescue, so their response is considered gratuitous.

Corporations may attempt to maintain Good Samaritan status for their employees who are AED rescuers by requesting that employees volunteer for resuscitation training and rescue "duty" and be trained and equipped to provide CPR and use an AED. Whether this approach is helpful for a specific entity must be assessed on the basis of local laws and after consultation with competent counsel and risk-management professionals.

Some corporations have added insurance riders to existing policies to cover AED use by their personnel. The Las Vegas gaming casinos, for example, took this approach to their AED program, in which security officers were trained in AED use.[24] The purchase of insurance riders for lay rescuers is not the norm, however.

In recent years, some insurance carriers have advised policyholders that placement of AEDs on a property is covered under a general liability plan. In fact, some insurance companies offer resources to encourage the development of community lay rescuer AED programs. For example, some insurers offer grants for the purchase of AEDs.[36]

In some states, opposition to broadening of the Good Samaritan legislation raises the concern that actions beyond ordinary and simple negligence (ie, *gross negligence, willful or wanton behavior, flagrant indifference to safety, intent to harm*, and other standards set out by specific states) will be protected by such amendments to the Good Samaritan legislation. However, Good Samaritan *limited* immunity means that immunity is limited to simple negligence.

The definition of misuse of the AED that constitutes an action beyond simple negligence will need to be determined by the courts. Risk of negligent use of an AED is reduced by recommended program components, such as approved training of designated or likely (anticipated) rescuers in CPR and use of the AED, course supervision, and skills review—a classic risk-management approach. A standard, broad-based Internet search and a search by legal search services for reported cases[37] and news stories about allegations of or awards for negligent use of AEDs did not reveal any such claims at the time this statement went to press. Although these search techniques have inherent limitations, we are unaware at this time of any claims alleging negligent use of AEDs. This information is not intended to provide legal advice or endorsements of any specific services. A lawyer should be consulted about the application of this information to particular situations.

Recommended: Good Samaritan Limited Immunity for AED Program Facilitators

Another impediment to development and implementation of AED programs has been the lack of limited immunity from legal action for several groups involved in AED programs. These groups include premises owners, AED acquirers, program directors, and trainers; these are referred to collectively as program facilitators.

Limited Immunity for Premises Owners and AED Acquirers. Major insurance carriers now routinely provide liability insurance without additional charge for sites or buildings where AEDs are placed. Some insurers offer discounts in liability insurance premiums when AED programs are established, and some insurance carriers have developed educational materials to support the establishment of community lay rescuer AED programs. Although premises owners may fear liability resulting from the use of an AED, such liability is likely to be very limited. We are aware of no lawsuits filed against lay rescuers or premises owners related to the attempted use of an AED in a Good Samaritan effort to save the life of a victim of prehospital cardiac arrest. The only lawsuits identified[37] cited failure to have AEDs on the premises. As

TABLE 3. Sample Wording of Legislation to Address Good Samaritan Limited Immunity for AED Owners/Acquirers

Example of Recommended Wording for Facilitating Legislation
Section 1. Article 1B of Chapter 90 of the General Statutes is amended by adding a new section to read: § 90–21.15. Emergency treatment using automated external defibrillator; immunity. (a) It is the intent of the General Assembly that, when used in accordance with this section, an automated external defibrillator may be used during an emergency for the purpose of attempting to save the life of another person who is in or who appears to be in cardiac arrest. . .(d) . . . the person responsible for the site where the automated external defibrillator is located when the person has provided for a program of training. . .shall be immune from civil liability arising from the use of an automated external defibrillator.

Modified from Senate Bill 1269, North Carolina General Assembly, 2000.

noted above, CASA provides limited immunity for the AED acquirer if not already provided or specified under state legislation. The AED acquirer can be a tenant or property manager of a building owned by another entity. In such cases, although the manager may have limited immunity, the building owner may not. CASA limited immunity may not apply if harm to the victim arises from one of the following:

- Failure to establish a link with the local EMS system
- Failure to properly maintain the AED
- Failure to train expected responders in the use of the AED

Ideally, state legislation will extend Good Samaritan limited immunity to premises owners (see Table 3) and the AED owner/acquirer, even in the event of the failures listed above.

Limited Immunity for Physician Prescribers and Facilitators. In recent years, the price of malpractice coverage for AED program prescription and oversight has fallen. If this trend continues, it is anticipated that there will be no additional cost of medical malpractice insurance for physicians who prescribe AEDs. In addition, if the FDA clears more AEDs for use without a prescription, the prescription requirement may gradually be eliminated. As noted above, the AED program is most likely to improve survival from witnessed VF sudden cardiac arrest if the program includes a planned and practiced response, appropriate training and equipment, a link with the local EMS system, and a process of ongoing quality improvement. Whether or not a prescription is required, it is helpful if a healthcare provider or resuscitation expert oversees the planning and implementation of the program, including training, monitoring of quality improvement, device maintenance, and link to the EMS system. If limited immunity is provided to physician facilitators (eg, prescribers where applicable) or program directors, the wording may follow that in Table 4.

TABLE 4. Sample Wording of Legislation to Address Limited Immunity for Physician Facilitators and Program Directors

Example of Recommended Wording to Address Limited Immunity for Physician Facilitators and Program Directors
"Immunity from civil liability will be provided to: (3) Any physician or other medical professional who authorizes, directs, or supervises the installation or provision of automated external defibrillator equipment in or on any premises or conveyance other than a medical facility."

Modified from Senate Bill 51, Georgia House of Representatives, 2001; GA Code 51–1-29.3.

TABLE 5. Sample Wording of Legislation to Address Limited Immunity for Trainers of Anticipated AED Rescuers

Example of Recommended Wording to Address Limited Immunity for Trainers
"No person or entity which teaches or provides a training program for cardiopulmonary resuscitation that includes training in the use of automated external defibrillators shall be held liable for any civil damages as a result of such training or use if such person or entity has provided such training in a manner consistent with the usual and customary standards for the providing of such training."

Modified from Senate Bill 132, Kansas State Legislature, 2003; K.S.A. 65–6149a.

Limited Immunity for Trainers. Trainers of anticipated AED program rescuers have not been granted limited immunity in most states, and they are not mentioned in CASA. When state legislation provides Good Samaritan limited immunity for trainers, the immunity typically specifies that the trainer must deliver training in accordance with the guidelines and policies of an approved or national training organization and the trainer must be authorized to deliver that course or curriculum (see Table 5).

Key: CPR and AED Training for Anticipated Lay Rescuers

Although limited immunity for lay rescuers should not be contingent on training, the AHA strongly recommends that AED programs ensure the training of anticipated rescuers in CPR and use of AEDs. This training should include early recognition of signs of cardiac arrest; indications for phoning 9-1-1; and training in rescue breathing, chest compressions, and safe and efficient use of an AED. These rescuer actions are time critical and require not only initial training but frequent retraining to maintain effective responses. Many community lay rescuer AED programs have documented the link between prompt rescuer actions (recognition of the emergency, early CPR, and shock delivery within 3 to 5 minutes) and survival from VF sudden cardiac arrest.[16,21,24,26,28,30,38]

Although AEDs are user friendly and the steps in their operation are often intuitively obvious, the effectiveness of an AED for cardiac arrest requires more than simple operation. The rescuer must know when to use an AED (ie, recognize cardiac arrest), how to operate it, how to troubleshoot it (eg, a hairy or sweaty chest may prevent good contact between the skin and electrode pads), and how to combine AED use with CPR.

CPR remains a critical component of a successful AED program for several reasons. First, the rescuer must recognize sudden cardiac arrest (ie, the victim is unresponsive and not breathing). Because immediate bystander CPR improves survival from VF sudden cardiac arrest,[15,19,20,29,39] the rescuer also should be able to perform CPR until the AED is available and after a shock ends VF. In a prospective analysis of VF waveform during resuscitation of victims of VF cardiac

arrest, predicted survival from VF was increased when the interval between interruption of chest compressions and delivery of the shock was kept to ≤15 seconds.[17] The efficient integration of CPR with AED use requires training and frequent practice. In addition, improvements in AED rhythm recognition and function are needed to minimize the time required for the AED to analyze the victim's rhythm, recommend shock delivery, charge, and deliver a shock. Such improvements will reduce interruptions in chest compressions. Additional improvements may also include the ability of AEDs to perform analysis with CPR in progress.

Recent studies have also shown that both prehospital[40] and in-hospital[41] healthcare providers deliver compressions of insufficient depth and interrupt compressions too often during CPR. Such reports support the need for stringent CPR training and frequent practice to ensure that rescuers can deliver compressions of correct depth and can minimize interruptions of chest compressions during CPR.

It is important to note that few victims with VF cardiac arrest demonstrate an organized rhythm at 60 seconds after elimination of VF by shock.[13,42] Many demonstrate pulseless electrical activity in the first minutes after successful defibrillation.[14,42] The victim of VF cardiac arrest requires CPR until the heart is able to pump blood effectively.

For all of these reasons, anticipated rescuers should be trained in a course that integrates CPR and use of the AED. It is important to include the recommendation for training and frequent retraining of anticipated rescuers in community lay rescuer AED legislation.

Key: Link With EMS System

The director of a community lay rescuer AED program should inform the EMS system that an AED is on site. State EMS lead agencies request this notification, and it should be listed as an expectation: The owner "shall" notify rather than "is requested to" or "is encouraged to" in state AED legislation.

Notification of the EMS system is helpful for several reasons. The EMS agency can serve as the interface between the AED program and the public service answering agency. If the dispatcher knows the type and location of an AED at the site of the emergency, the dispatcher can direct the rescuer to get the AED and can coach the rescuer in both CPR and AED use. If the EMS agency wants to be more involved, the agency may help train expected AED users and may play an important role in the continuous quality improvement process of the program. Finally, EMS notification is important because EMS providers will need to obtain data from any AED used to treat cardiac arrest.

Some states have legislated the establishment of an AED "registry," requiring that AED programs be registered with the local EMS agency. The purpose of such registries is to ensure that EMS dispatchers know where AEDs are placed so that they can direct a 9-1-1 caller to get and use an AED that is on site. Some states, such as Utah (Senate Bill 95/2003) and New Hampshire (Senate Bill 386/2002), have established statewide registries for the collection and distribution of information on the location of commercially owned devices. If state EMS agencies support the term "registration," it can be used. A formal registration system may be too costly and burdensome for small volunteer EMS programs, though, so for this reason, the term "notification" is recommended.

Recommended: Support of "Best Practice" Program Elements

The program director should evaluate any episode of sudden cardiac arrest at the program site and evaluate the performance of rescuers and the use of the AED. This is done to reduce time to CPR and time to delivery of a shock, helping the program achieve the goal of improving the rate of survival from sudden cardiac arrest. The continuous quality improvement process should include EMS personnel if possible.

The AED should be stored and maintained according to the manufacturer's recommendations and the recommendations provided in nationally accepted courses in CPR and use of AEDs.[43,44] Newer AEDs conduct internal battery and circuitry checks continuously and visually indicate when service or a battery change is needed. This "design for dormancy" means that minimal maintenance is necessary, such as a "readiness-for-use" visual check for "service needed" or other status indicator, confirmation of the physical integrity of the device, and a check of the contents of the carrier case. A checklist from the AED manufacturer can be copied and posted near the AED and initialed and dated to confirm that the device is checked at appropriate intervals.

The AHA recommends that the AED be stored in a carrying case near a telephone so that the device can be retrieved when 9-1-1 is phoned.[43,44] Placing the AED near a telephone shortens the time to EMS call and AED retrieval and simplifies teaching and EMS instructions. Consistent use of these common-sense recommendations will facilitate training and dispatcher instructions.

Related AHA Public Policy Initiatives

On any given day, up to 20% of the combined US adult and child population can be found in school. Although sudden cardiac arrest is much less common in children than in adults, it can occur in children and adolescents. Parents of children who have died suddenly have started a strong grassroots effort to create AED programs in schools. In response to questions about such programs and the increasing potential for medical emergencies in schools, the AHA issued a scientific statement that recommends that schools develop a medical emergency response plan[45] to deal with a variety of life-threatening conditions, including sudden cardiac arrest. The complete statement is available on the AHA Web site (http://circ.ahajournals.org/cgi/content/full/109/2/278).

The AHA recommends that school medical emergency response plans have the following components: an effective and efficient system of campus-wide communication, a coordinated and practiced response plan, risk reduction, training and equipment for first aid and CPR, and a lay rescuer AED program in schools with an established need.[45] After considering several factors, some schools may decide that a need exists for a lay rescuer AED program. For example, schools with a large number of adult employees, volunteers, and visitors or schools with large, sprawling campuses that are not quickly accessible to EMS systems may wish to establish a lay rescuer AED program.

TABLE 6. Key Program Components to Recommend in State AED Legislation

1. Limited immunity for rescuers (key) and facilitators (recommended):

- *Good Samaritan limited immunity for rescuers that is not dependent on training.* The statute should confer *limited immunity to lay rescuers who use AEDs.* This limited immunity should not be conditional on nor require training for the good faith effort to be covered.
- Good Samaritan limited immunity for program facilitators, including premises owners, AED acquirers, trainers, and physician prescribers (where applicable).

2. Recommendation for training of anticipated/expected rescuers. Training should integrate both CPR and AED skills. Note that this does not affect serendipitous AED users/bystanders who happen upon the scene.

The statute *should require training of* ***expected*** *rescuers in an approved course that integrates both CPR and AED skills.* To maintain utmost flexibility with the training requirement, the statute should not prescribe a specific number of hours needed for a rescuer to be considered "trained."

3. Link with EMS systems: The statute should require that the local EMS system be notified about AEDs placed within its response area. Some EMS systems may wish to require registration, but not all EMS systems have the resources to establish a registry.

4. Support of elements that contribute to effective lay rescuer AED programs:

The statute should require a planned and practiced response. Typically this requires

- A planned and practiced response (can specify delegation of authority to a healthcare provider program director).
- Training of anticipated rescuers in CPR and AED use with a practice goal of immediate CPR and delivery of the first shock to victims of VF sudden cardiac arrest within 3 minutes of the victim's collapse.
- A link with the EMS system (see above).
- A process of ongoing quality improvement. The program director should evaluate each episode of sudden cardiac arrest and decide what steps are needed to improve response and minimize time to CPR and time to delivery of the first shock with an AED. The program director should implement a plan for on-site maintenance and readiness-for-use checks of the AED.

In 2002, the state of New York enacted a law requiring school districts, county vocational education and extension boards, and charter schools to provide and maintain at least 1 AED on site and in each instructional school facility. In addition, Assembly Bills 8779 and 10577 required that at least 1 staff member trained in CPR and the use of an AED be present at all school-sponsored activities.

In 2002, the AHA published an update to a 1998 statement recommending the development of AED programs in health clubs with >2500 members.[46] The statement encouraged the development of AED programs in facilities of sufficient size that an episode of sudden cardiac arrest might be predicted to occur there within a several-year period. The statement is available on the AHA Web site (http://circ.ahajournals.org/cgi/content/full/105/9/1147).

Some states have filed legislation requiring or encouraging the establishment of lay rescuer AED programs in health clubs. Illinois enacted a law (HB 4232) that requires physical fitness facilities to have at least 1 AED, a trained AED user, and a written plan for managing medical emergencies. New York State enacted a law (2004: S 6803/A.5084) requiring all health clubs, fitness centers, health spas, health studios, gyms, weight control studios, and martial arts/self-defense schools with a membership ≥500 to have at least 1 AED and at least 1 person (employee or volunteer) on the premises during the hours of operation who is trained in CPR and use of an AED. Other states, such as Michigan (2003: SB 50), New Jersey (2003: S. 1106/A. 453), and Rhode Island (2004: SB 2948) have acted on similar legislation in the past few years.

The PAD trial documented the lifesaving effect of well-organized lay rescuer AED programs in public places,[31] but at least two thirds of all out-of-hospital episodes of sudden cardiac arrest occur in homes.[47,48] A study is underway to determine the effectiveness of home AED programs. The results of this study may support further legislative efforts. At this time there is insufficient data for the AHA ECC Committee to make recommendations about home AED programs.

Summary

This statement describes the key program components to include in state legislation and regulations addressing community lay rescuer AED programs. The goal of the legislation should be to reduce deaths from sudden cardiac arrest by encouraging the development of programs that will increase the likelihood of immediate bystander CPR and defibrillation being provided within 3 to 5 minutes of the victim's collapse. Table 6 lists the key components recommended for community lay rescuer AED programs.

Additional Resources

The AHA has prepared additional support materials and guidelines for AED initiatives. The following materials may be helpful:

- Model AED legislation, AED Policy Toolkit: www.americanheart.org/statepolicy
- State-by-state policy analysis (review of state actions): www.ncsl.org/programs/health/aed.htm
- AED programs Q & A: http://www.americanheart.org/presenter.jhtml?identifier =3011859#training
- AED program implementation resources: http://www.americanheart.org/presenter.jhtml?identifier =3027304
- Medical Emergency Response Plan for Schools statement: http://circ.ahajournals.org/cgi/content/full/109/2/278

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