SB

160

HOUSE COMMITTEE REPORT

(7)

Date Referred to Committee: May 5, 2003

FURTHER REFERRALS:

Date of Committee Action: May 17, 2003

The JUDICIARY Committee considered:

CSSB 160(HES)

CS FOR SENATE BILL NO. 160(HES)

CIVIL LIABILITY FOR DEFIBRILLATOR USE

"An Act relating to civil liability for use or attempted use of an automated external defibrillator; and providing for an effective date."

Recommends it be replaced with [ ] HCS *or* [ ] CS *for* ________________ (________)

*For Senate Bills with new title: [ ] Technical Title [ ] New Title: HCR*______ [ ] Same Title [ ] New Title

[ ] attach amendments
[ ] add new referral to __________Committee
[ ] Letter of Intent__________Committee

List of Abbrev for Depts.:
ADM
CED
COR
CRT
EED
DEC
DFG
GOV
HSS
LEG
LAW
LWF
MVA
DNR
DPS
REV
DOT
UA

***NEW* FISCAL NOTES**
*Assigned by Chief Clerk's Office

List by Dept(s):	*FN#	Fiscal	Indet.	Zero

***PREVIOUS* FISCAL NOTES**

List by Dept(s):	FN#	Fiscal	Indet.	Zero
LAW	1			✓

Signing with recommendations	Printed Last Name	DP	DNP	NR	AM
[signature]	Samuels	✓			
[signature]	Holm	✓			
[signature]	Gara	✓			
[signature]	Ogg	✓			
[signature]	Gruenberg	–			
Tom Anderson	ANDERSON	X			
Chair: [signature]	McGuire	✓			
Chair:					

Alaska State Legislature

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Gambell
Golovin
Hooper Bay
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Kiana
Kivalina
Kobuk
Kotlik
Kotzebue
Koyuk
Mountain Village
Noatak
Nome
Noorvik
Nuiqsut
Nunam Iqua
Pilot Station
Pitka's Point
Point Hope
Point Lay
Savoonga
Scammon Bay
Selawik
Shaktoolik
Shishmaref
Shungnak
St. Mary's
St. Michael
Stebbins
Teller
Unalakleet
Wainwright
Wales
White Mountain

May 5, 2003

MEMORANDUM

To: Representative Lesil McGuire
House Judiciary Committee

From: Senator Donald Olson

Re: Schedule hearing for SB 160, Civil Liability for Defibrillator Use

I respectively request a House Judiciary Committee hearing of SB 160 at your earliest convenience. I have attached my sponsor statement, sectional analysis and support documentation. Please contact me if you need additional information.

Thank you for your attention to this request.

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SPONSOR STATEMENT
SB 160, Civil Liability for Defibrillator Use

I introduced Senate Bill 160 to save Alaskan lives. This legislation would provide faster treatment to Alaskans who suffer a cardiac arrest by increasing the availability of automated external defibrillators (AEDs).

Each year, 250,000 people die in the United States as a result of sudden cardiac arrest. The most important treatment for more than half of these patients is immediate defibrillation; an electrical shock intended to restore a more normal cardiac rhythm. For each minute a person remains in cardiac arrest, their chances of survival decrease by approximately 7% to 10%.

AEDs have evolved significantly over the past years and the current generation of devices is much safer and easier to use. These new devices have the ability to discern between shockable and nonshockable rhythm; for that reason, it is literally impossible to shock a person who does not require it.

Businesses and municipalities are interested in making AEDs more accessible in the workplace and in locations where large groups gather for the life safety of their employees and the public.

Currently, the Good Samaritan provision in Alaska law (AS 09.65.090) gives immunity from civil liability for any trained individual who uses an AED. However, this immunity does not apply to those individuals and organizations that make the devices accessible in the workplace. As a result, these devices have not been made readily available for emergency use. SB 160 removes this impediment by extending the Good Samaritan immunity to owners and operators of public and private facilities.

With Senate Bill 160, I am encouraging the proliferation of this life saving technology in Alaska.

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Sectional Analysis
SB 160, Civil Liability for Defibrillator Use

Section 1

Generally, Section 1 established a new section in regard to civil liability. This section replaces the current civil liability immunity deleted in Section 2.

AS 09.65.087(a)

This subsection broadens the civil liability immunity for those who use or attempt to use an automated external defibrillator (AED) device in a perceived medical emergency. However, this immunity requires than an appropriate emergency medical services agency is immediately notified.

AS 09.65.087(b)

This subsection also extends immunity to those who acquire or provide the AED under certain conditions.

These conditions are as follows:

(1) Notification of the local emergency medical response authority within 30 days following placement of the device.
(2) Proper maintenance and testing of the device.
(3) Provision of a means of notifying the local emergency medical response authority that an emergency exists.
(4) Provision of appropriate training to the employee or agent who used the device in a perceived medical emergency.

Further conditions A,B,C, and D in subsection 4 address other situations where the immunity is maintained.

AS 09.65.087(c)

This subsection maintains the current definition of "appropriate training" as having completed an AED training course from the American Heart Association, the American Red Cross, or another AED training course approved by the Department of Health and Social Services.

<u>Section 2</u>

Deletes AS 09.65.090(e) and (f)

FISCAL NOTE

STATE OF ALASKA
2003 LEGISLATIVE SESSION

Fiscal Note Number: 1
Bill Version: SB 160
(S) Publish Date: 4/14/03

Revision Date/Time (Note if correction):
Title "An Act relating to civil liability for use or attempted use of an automated external defibrillator; . . ."
Sponsor Senator Olson
Requester Senate HESS Committee

Dept. Affected: Law
BRU Civil Division
Component Special Litigation
Component No. 2213

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0
CAPITAL EXPENDITURES						
CHANGE IN REVENUES ( )						

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other (Specify Type--Do not abbreviate)						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2003) cost: 0.0
Check this box (X) if funding for this bill is included in the Governor's FY 2004 budgetpro posal: [ ]

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: *(Attach a separate page if necessary)*

This bill would protect from civil liability persons who use automated external defibrillators (AED), and persons who provide the AED for use, so long as certain specified responsibilities are fulfilled.

Passage of this legislation is not anticipated to have a fiscal impact on the Department of Law.

Prepared by: Joan M. Kasson
Division Attorney General's Office
Phone (907) 465-5370
Date/Time 4/9/03 1:13 PM

Approved by: Kathryn Daughhetee for Gregg D. Renkes, Attorney General
Agency Department of Law
Date 4/9/2003

(Revised 9/2002 OMB)

Every year more than three million volunteers contribute their time and talents to help our organization defeat heart and blood vesse[l] disease- and save lives.

American Heart Association®

Fighting Heart Disease and Stroke

Northwest Affiliate
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Anchorage, AK 99503
907.263.2044 888.276.0858
Fax 907.263.2045
www.americanheart.org

Your American Heart Association Supports Senate Bill 160

The American Heart Association supports Senators Olson, Therriault, Wilken, Dyson, Davis, Seekins, Bunde, Cowdery, Green, and Wagoner's Senate Bill 160, a bill that would amend Alaska's Good Samaritan Law to reduce the liability risk associated with both using and providing automated external defibrillators (known as "AEDs").

Each year, 250,000 people die in this country from sudden cardiac arrest. Cardiac arrest is the stopping of the regular heart rhythms, usually because of interference with the electrical signal that regulates the heartbeat. When cardiac arrest occurs, the heart starts to beat chaotically and cannot pump blood. Brain death and permanent death start to occur in just four to six minutes after someone experiences cardiac arrest. This means that when a person goes into cardiac arrest, every second counts. To increase the odds of a victim's survival, the American Heart Association has outlined a four-step plan called the "chain of survival."

Defibrillators play a critical part in this chain of survival. The four links in the chain are (1) early access, which means recognizing that a cardiovascular emergency exists and immediately calling Emergency Medical Services; (2) early CPR, which means giving CPR promptly and properly when necessary; (3) early defibrillation, which means having immediate access to a properly working AED, and; (4) early advanced care, which means having qualified paramedics with up-to-date Advanced Cardiac Life Support Training.

While all four links in the chain are important, early defibrillation is often called the critical link in the chain of survival because it is the only way to successfully treat most cardiac arrests. In fact, for every minute without defibrillation, the odds of survival drop seven to ten percent. A cardiac arrest victim who is not defibrillated within eight to ten minutes has virtually no chance of survival.

Senate Bill 160 will improve the chain of survival in Alaska in several ways. First, by eliminating the threat of civil liability for people and businesses that acquire or provide an AED, the bill will help increase strategic AED placement around Alaska. Because every second counts after a victim suffers cardiac arrest, the more AEDs that are placed in strategic areas in the community, the stronger the chain of survival.

Additionally, by requiring that a person who acquires or provides the AED follow some common sense safety requirements, the bill ensures the responsible placement of AEDs. These requirements include (1) the acquirer or provider of the AED notify

Please remember the American Heart Association in your will.

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the local emergency response agency of the location of the device; (2) that the device be properly maintained and tested – just as one would test, for example, a smoke or carbon monoxide detector; (3) that there is a way to notify local EMS within a reasonable proximity to the AED – for example, making sure that there is a phone reasonably close to the device, and; (4) that the acquirer or provider of the AED provide appropriate training for its employees, because trained rescuers can deliver the treatment more quickly than those who are totally unfamiliar with the device.

The bill also eliminates the threat of civil liability for individuals who use or attempt to use the AED on a victim in an emergency. The bill recognizes that while AED training is important, AEDs are easy to use, and the machine discerns between shockable and nonshockable heart rhythms. Because it is virtually impossible to shock a person that does not need it, the bill omits the current requirement that all users of the device be properly trained before they use or attempt to use the device in an emergency situation.

This proposed bill strengthens the American Heart Association's chain of survival by removing liability barriers to AED placement and use, and by ensuring that those persons who provide AEDs have followed basic, common sense protections. The American Heart Association commends these laudable goals, and fully supports Senate Bill 160.

Please remember the American Heart Association in your will.

National Center for Early Defibrillation
Community Resources to Help Save Lives

Because so many more can survive...

New Virginia law strengthens immunity for AED users and purchasers

April 3, 2003

Virginia has joined a handful of states that specifically provide legal liability protection to purchasers of automated external defibrillators (AEDs) and untrained persons who use AEDs in good faith. The bill also encourages laypersons to seek formal training in cardiopulmonary resuscitation (CPR) and AED use. HB 1860, introduced by John M. O'Bannon, R-Henrico, received unanimous support from the Virginia General Assembly and was signed by Governor Mark Warner. On April 2, the Assembly supported the Governor's recommendation to confirm the law. It will take effect on July 1.
<?xml:namespace prefix = o ns = "urn:schemas-microsoft-com:office:office" />
All states now have Good Samaritan legislation designed to encourage use of AEDs by the public, and the federal Cardiac Arrest Survival Act provides additional protection, but Virginia's legislation provides an added measure of encouragement by specifically addressing immunity for those who have not received training. Other states with similar legislation include Pennsylvania and Rhode Island.

The Virginia law is designed to reduce barriers to bystander intervention in sudden cardiac emergencies. Sudden cardiac arrest is the leading cause of death among adults in the U.S. Of the 1,000 people who suffer SCA each day, fewer than 10% survive. With more rapid intervention, including the use of AEDs by untrained bystanders, many more lives could be saved.

For more information, click here.

For a copy of the legislation, click here.

For information on liability issues related to AED programs, click here and here.

National Center for Early Defibrillation
Community Resources to Help Save Lives

Because so many more can survive...

Middle school staff member saved by school's AED

March 15, 2003

When Dexter Grady, a janitor at East Hampton (Long Island) Middle School, volunteered to get trained to use the school's new Automated External Defibrillator (AED), he never imagined that he would be the recipient of the machine's life-saving capabilities.

<?xml:namespace prefix = o ns = "urn:schemas-microsoft-com:office:office" />

On his dinner break yesterday, Dexter, 37, joined some local men who regularly gather in the school gym for pick-up basketball games. Shortly after playing, Grady collapsed in sudden cardiac arrest. Thanks to the quick action of bystanders who called for help and used the AED to defibrillate his heart, Grady is expected to be released from the hospital sometime next week.

The legislation that prompted the middle school to have an AED on site was inspired by the efforts of Karen and John Acompora, of nearby Northport, parents of Louis Acompora, who died from sudden cardiac arrest three years ago, almost to the day. Louis, then 15, had been hit in the chest by a ball during a lacrosse game and an AED was not immediately available.. To prevent other such tragedies, Governor George Pataki signed "Louis's Law" last year, which mandates the placement of AEDs in New York schools.

Judging from Grady's experience, the law seems to be working.

For more information, click here.

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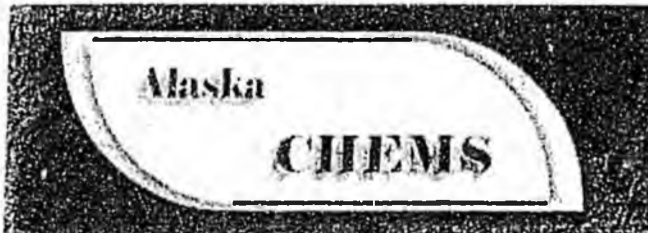

EMS AED
Emergency Medical Services Programs

Automated External Defibrillators in Alaska

Revised 02/25/2003

Automated external defibrillators (AEDs) are an essential tool in the treatment of out-of-hospital cardiac arrest. Over the years, the devices have become safer, more reliable and more maintenance free. The new technologies used in these devices make them suitable for use by anyone who has had basic training in their use.

AEDs are most effective when implemented as part of an overall strategy which considers each link in the "Chain of Survival:"

- Early access to the emergency medical system (EMS and 9-1-1 system)
- Early cardiopulmonary resuscitation (CPR)
- Early defibrillation when indicated
- Early advanced emergency treatment

In 1998 legislation was passed that redefined the use of an automated external defibrillator as a basic life support skill and provided, through the Good Samaritan Law, some immunity from civil liability to properly trained personnel who use AEDs in a resuscitation attempt and who activate the EMS system. The text of the statute is available below.

Files of interest (click to download):

- Civil Liability for Emergency Aid (AS 09.65.090)
- Regulations for Approving AED Training Programs (7 AAC 26.585)
- Federal Register - AED Requirements for Federal Buildings
- Answers to Frequently Asked Questions about the AEDs in Alaska

Approved Training Programs

In Alaska's Good Samaritan Law (AS 09.65.090) "properly trained" to use an AED means " that the individual has completed an automated external defibrillator training course from the American Heart Association, the American Red Cross, or another automated external defibrillator training course approved by the Department

of Health and Social Services."

The following programs have been approved by the Department of Health and Social Services in accordance with 7 AAC 26.588

- BLS for Health Care Providers-**American Heart Association**
- CPR for the Professional Rescuer-**American Red Cross**
- The CPR component of **Medic First Aid-Advanced**
- Basic Life Support for Professionals (BLSPRO)-**EMP America**
- CPR for the Professional Rescuer-**American Safety & Health Institute**
- **Respond Systems** AED/CPR

AED Placement

It is important for emergency medical dispatchers to know the locations of AEDs so they can direct rescuers to the device when emergency medical services personnel are en route. The Section of Community Health and EMS has developed a simple form that can be completed and faxed to the Section at 465-4101. The Section will fax copies of the form to the appropriate Regional EMS Office, Emergency Medical Dispatch center, and the nearest emergency medical services agency.

Model AED Placement Notification. pdf

Rural AED Act Grant Program

On July 15th, the Section of Community Health and EMS submitted an application to the Health Resources and Services Administration for over $2,100,000 in automated external defibrillators and related training. The grant was written and submitted in response to the announcement in the May 23rd Federal Register that 12.5 million dollars were available nationwide in federal fiscal year 2002 under the Rural Access to Emergency Devices Grant Program.

Following the program's announcement, the Section of Community Health and EMS notified all emergency medical services agencies and other agencies known to be interested, including the Alaska Department of Public Safety and the Alaska Department of Transportation and Public Facilities, that it would be submitting a statewide application on behalf of eligible agencies statewide. Twenty-one "Community Partnerships" encompassing 77 communities and over 175 agencies responded with information about AED needs and provided letters of commitment. The total number of AEDs requested was 637.

In October, the Section of Community Health and EMS received word from the Health Resources and Services Administration (HRSA) that Alaska had been awarded $237,703 to implement the Rural Automated External Defibrillator (AED) Grant program.

The Section will solicit updated applications for funding from community partnerships included within the funded grant application and will distribute the available funds based on expert reviews of the applications.

Rural AED List Server

The Section of Community Health and Emergency Medical Services has developed an internet list server to facilitate communications regarding this important issue

Join Alaska Rural AED List Server

TOP

Emergency Medical Services Programs

New On-Line Course Approval
Click HERE For the On-Line System

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New EMS Regulations
EMS Funding, Billing, and Reimbursement
Training Info and Schedules
Letters of Solicitation
Discussion Forum
EMS Downloads
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AHELP Alaska Health Education Library Project
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Alaskan Exposure
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Virginia Out To Widen Use Of Life-Saving Devices

By Shirley Adams, Special to Stateline.org

March 31, 2003

About 1,000 Americans die every day from sudden cardiac ; them could survive if they immediately received a jolt of elec machine called a defibrillator, to reset their heart.

Special automated defibrillators, designed for use by layper: training, have been available since the early 1980s. Over th years, the units have improved to the point where good Sam training at all, have used them successfully to save lives.

Virginia is at the forefront of states that are accelerating efforts to take advantag technological advances. The national movement envisions that widespread avai automated external defibrillators, or AEDs, can do for sudden cardiac arrests wh extinguishers do for fires.

Delegate John M. O'Bannon, R-Henrico, sponsored legislation this year to remo widespread access to AEDs. His bill will give legal protection to untrained people machines in good faith.

The legislation earned the unanimous support of the General Assembly and Gov has signed it. Warner asked lawmakers to make it effective immediately and the Assembly will consider his request when it reconvenes in Richmond on Wednes one-day "veto session."

Without an emergency clause, the legislation would take effect July 1.

"Widespread access to AEDs will be a step in the right direction," said O'Bannor thousand deaths a day from ventricular fibrillation are way too many. I think we'll go down."

Unlike heart "attacks," which occur when something blocks adequate blood flow muscle, sudden cardiac arrests are almost always an electrical problem.

Normal pumping is regulated by electrical signals that stimulate each part of the the right time. When those signals suddenly become chaotic (a condition called fibrillation), the heart quivers unproductively, and no blood is pumped. With little person loses consciousness and stops breathing; death follows in minutes.

In the October 2002 issue of The New England Journal of Medicine, a team of d underscored the scope of the challenge: "Though highly reversible with the rapid defibrillator, ventricular fibrillation is otherwise fatal within minutes, even when ca resuscitation (CPR) is provided immediately."

AEDs are different in many ways from traditional full-function defibrillators -- the in medical dramas on television and used in real life by highly trained emergency

full-function defibrillators are complicated and can kill if administered improperly.

Currently, state law tightly restricts access to both full-function defibrillators and ,
bill will lift the restrictions on AEDs, which are specifically designed for public-acc

"Widespread access to AEDs will be a step in the right directior
Virginia Del John M. O'Bannon (R)

Anyone who can find the big green "ON" button, and follow a few simple instruct
public-access AED. A recording in the machines begins providing clear verbal in
as the power is turned on. They actually sound quite bossy, but the authoritative
helps rescuers stay focused.

Instead of using bulky paddles, AEDs have self-adhesive, palm-size pads that ai
unit by an electrical cord. The person attempting the rescue places the pads on i
After the pads are on, the operator does not need to touch the patient unless the
them to do so.

Several scientific studies have tested the safety and effectiveness of AEDs.

A 1999 research project, for example, timed and evaluated two groups -- sixth-g
no prior training, and emergency medical professionals -- as they used AEDs in
emergencies. All of the children understood and followed the instructions succes

When the study was published in Circulation, a medical journal for heart speciali
researchers made the following conclusion: "During mock cardiac arrest, the spe
untrained children is only modestly slower than that of professionals."

Many people compare modern public-access AEDs to fire extinguishers, which a
to save lives that they are found in almost every public place. In some ways, AEI
dangerous than fire extinguishers.

Fire extinguishers are not idiot-proof. If operators point the nozzle at themselves
fire, they will be hurt by the blast of chemicals. Fire extinguishers can also be us
malicious harm -- by bludgeoning someone, for instance.

AEDs are not idiot-proof, either. Before the unit delivers a shock, it sounds a cau
alarm and issues emphatic orders, "Do NOT touch the patient!"

If operators disobey the defibrillator's orders, they can be hurt.

Unlike fire extinguishers, AEDs would be extremely difficult to use to cause mali
units refuse to even charge up unless their sensors indicate that they are proper
person who is not breathing and whose heart is in fibrillation.

In 1997, Florida became the first state to enact a law encouraging broad public a
trained non-medical personnel such as police officers and firefighters. Currently,
taken similar steps.

What makes Virginia unusual is that its law will expand legal protection for purch
to untrained AED users acting in good faith. Only a handful of states, such as Pe
Rhode Island, provide such protection from liability.

This protection will be important as AEDs become more prevalent in public place
defibrillators were recently installed at all service plazas along the Pennsylvania
Illinois Legislature just passed a law requiring golf courses, school gymnasiums
government-owned physical fitness facilities to have access to at least one AED
operation.

Under current Virginia laws, public-access AEDs (which do not need trained ope

much the same as full-function defibrillators (which definitely do need trained op

O'Bannon's bill will update these laws so that:

AED units can be placed in locations where untrained good Samaritans might us

Purchasers will not be required to complete registration paperwork and pay a st

Purchasers will not be responsible for preventing use of the AEDs by untrained

Anyone who makes a good-faith effort to use an AED in a life-threatening situati from liability.

O'Bannon said he would be thrilled with even a small increase in the number of who receive emergency treatment in time to prevent irreversible brain damage.

He noted that his bill not only promotes the availability of AEDs but also urges pe life support training.

"The AEDs are great -- no doubt about it," O'Bannon said. "But realistically, there times when CPR and other skills that are taught in basic life support classes will patient is to have the best possible chance for a full recovery."

EMAIL THIS STORY

PRINT VERSION OF THIS STORY

Issues to Watch

Healthcare

States to Watch

Florida Pennsylvania Virginia

National Center for Early Defibrillation
Community Resources to Help Save Lives

Because so many more can survive...

This section was written by Richard Lazar, Esq., a legal expert on emergency medical services topics, who serves as an advisor to the National Center for Early Defibrillation.

If you are like most people considering the implementation of an AED program, you probably have questions about laws and regulations affecting early defibrillation programs and whether or not there are any liability risks. Let's take a look at the federal and state law and regulatory framework within which early defibrillation programs operate, and review the nature and limited scope of any negligence liability risk associated with community-based early defibrillation programs[1].

Federal and state laws and regulations

The purchase and use of AEDs occurs within a complex maze of federal and state laws and regulations. At the federal level, the U.S. Food and Drug Administration (FDA) oversees the manufacture of AEDs because they are medical devices. At the state level, various regulatory agencies oversee the use of AEDs. Both the FDA and state regulatory agencies determine who can use AEDs and how they may be used.

Federal regulatory oversight

The FDA is the federal regulatory agency responsible for ensuring that medical devices like AEDs are safe and effective. To achieve this goal, the FDA imposes device labeling requirements on AED manufacturers. Labels must describe the indications and conditions for AED use. Currently, AEDs are viewed by the FDA as restricted, prescription devices. This means AED labeling must indicate that the device may only be used under certain conditions: the user must be trained and under the supervision of a physician. In addition, AEDs must come with directions so they can be used safely in the manner intended, that is, to resuscitate victims of sudden cardiac arrest. All AEDs sold in the marketplace today are evaluated and cleared by the FDA.

Certain aspects of current federal law are unclear. For example, FDA regulations do not detail the precise nature and scope of medical direction or training required to use AEDs. Of some help on the question of medical oversight is a statement contained in a consumer information document published by the FDA's Center for Devices and Radiological Health (CDRH) which states that "a physician who oversees the PAD (Public Access Defibrillation) program at a facility must write a prescription for the AED in order for the facility to purchase it."[2] This suggests an AED prescription is device specific rather than patient specific. On the issues of training this same document states:

For direct links to individual state laws on AEDs, click here.

PDF Documents:

State Legislative Activity Related to AEDs

Characteristics of State AED Laws

Summary of AED Related Legislation in 107th Congress

Cardiac Arrest Survival Act of 2000

Airport Medical Assistance of 2000

FAA Final Rule

Rural AED Act

Rural AED Act Summary

Public Health Improvement Act

Word Documents:
Cardiac Arrest Survial Act of 2000

patient specific. On the issued of training this same document states:

> Public access refers to accessibility for trained users to use AEDs in public places. Public access does not mean that any member of the public witnessing a sudden cardiac arrest should be able to use the device. AEDs are to be used only by individuals with the proper training and certification in accordance with state and local laws. [3]

To the extent training is required--a question of debate in both legal and public policy circles--the CDRH document suggests training standards are governed by state and local laws rather than federal law.

The FDA is reviewing whether AEDs should remain prescription devices and whether more extensive use of these devices should be permitted. It is likely federal requirements affecting the sale and use of AEDs will change in the near future.

Federal law

Laws recently passed by the U.S. Congress could have a dramatic impact on the pace at which early defibrillation programs are adopted.

The Cardiac Arrest Survival Act (CASA)[4] requires the U.S. Secretary of Health and Human Services to establish guidelines for placing AEDs in federal buildings. These guidelines are to include recommendations on the appropriate placement of AEDs including procedures for the following:

- Implementing appropriate training courses in the use of such devices, including the role of cardiopulmonary resuscitation;
- Proper maintenance and testing of the devices;
- Ensuring coordination with appropriate licensed professionals in the oversight of training of the devices;
- Ensuring coordination with local emergency medical systems regarding the placement and incidents of use of the devices[5].

When published, these guidelines and recommendations may lead to community-based early defibrillation programs founded on more uniform state AED laws, regulations and training requirements.

An important provision of the CASA provides certain AED users with conditional Good Samaritan legal liability immunity for any harm resulting from the use or attempted use of the device[6]. AED acquirers receive similar immunity if certain requirements are met. AED trainers and medical oversight physicians do not receive immunity under this law. How CASA immunity and AED immunity under state law (see state Good Samaritan law section below) will apply in specific situations remains a complex and unanswered question.

The Rural Access to Emergency Devices Act[7](also called the Rural AED Act) was passed by Congress along with the CASA. This law authorizes the appropriation of $25 million in grants to certain "community partnerships" for the purchase of AEDs and for AED training.

The Airline Passenger Safety Act[8], enacted in April 1998, requires the Federal Aviation Administration (FAA) to review the contents of medical kits carried on commercial airplanes. Administrative rules proposed by the FAA as required by this law would mandate that every commercial aircraft be equipped with specified life-saving equipment and appropriately stocked first-aid and medical kits, including AEDs, and

that flight crew members be trained in their use. It is estimated that 1,000 persons die each year due to cardiac arrest suffered on international commercial airline carriers. More and more airlines are equipping their fleets with AEDs.

State regulatory oversight

User classes

State laws and regulations are not uniform. Some states do not oversee the use of AEDs. Other states do, but the scope of oversight varies widely. State laws and regulations affecting early defibrillation programs address two key elements. The first element relates to those individuals specifically permitted to use AEDs, known as "user classes." User classes may include the following groups:

- Emergency medical responders such as paramedics and emergency medical technicians (EMTs)
- Public safety emergency responders, such as firefighters and police officers
- Targeted emergency responders, such as security guards, industrial first aiders, flight attendants, ship crews, ski patrol, lifeguards, non-hospital healthcare facility workers, nursing home personnel, retirement community personnel, athletic trainers, etc.
- Trained citizen responders, such as friends, relatives and co-workers of people with identified heart problems

States vary in their approaches to authorizing AED use. Some allow a broad range of individuals to use the devices. For example, California allows anyone to use an AED if the individual meets certain training and competency requirements and if there is medical oversight. A Florida law says "an automatic external defibrillator may be used by any person for the purpose of saving the life of another person in cardiac arrest," if the individual is trained in CPR and proficient in AED use.

In contrast, some states restrict the scope of user classes allowed to use AEDs. For example, a shrinking number of states allow only emergency medical responders (e.g., EMTs and First Responders) to use AEDs. In these states, other user classes are not specifically permitted to use the devices. Whether the absence of express state authorization prohibits the use of AEDs by other user classes is an open legal question.

Efforts are underway to encourage states to expand the scope of user classes allowed to use AEDs. Overall, the trend at the state level is to expand groups of individuals allowed to use AEDs.

Conditions of use

Generally, the second element addressed by state AED laws and regulations describes the conditions under which AEDs may be used, known as "conditions of use." These conditions address training, medical oversight, quality assurance, record keeping, and reporting. States vary dramatically in their approach to specifying conditions of use. Some states require very little while a diminishing number specify lengthy and burdensome conditions of use.

Summary of government oversight

It is important that your early defibrillation program follow applicable federal and state laws and regulations. Therefore, your first task as you

begin the process of developing an early defibrillation program is to review the laws and regulations affecting AED use in your state. It is essential to contact your state EMS agency for information about state laws and regulations. A knowledgeable attorney can help you get your program up and running.

Legal liability risk

Individuals, agencies and companies considering the purchase and use of AEDs sometimes fear negligence liability suits. As noted by the AHA, "a potential disincentive to lay users of AEDs . . . is the threat of a personal injury claim."[9] While the public's apprehension is understandable, any actual liability risk associated with early defibrillation programs appears quite small. Still, perceptions and fears must be addressed if widespread AED availability is to become reality.

The following sections provide an overview of negligence liability issues applied to the concept of early defibrillation. Armed with this background information, individuals, agencies and companies considering the purchase and use of AEDs should be reassured that any actual legal liability threat is both small and manageable. *Clearly, the benefits associated with widespread early defibrillation far outweigh liability risks.*

An overview of negligence

For a sudden cardiac arrest victim (or a relative) to successfully sue an AED purchaser or user for negligence, four essential legal elements must be proven. These include duty, breach of duty, causation of injury, and legally recognized damages. A negligence claim cannot succeed if any one of these elements is missing. Because an AED related claim is most likely to focus on the elements of duty and causation, these elements are discussed in detail.

The concept of legal duty

Duty in negligence law is defined as "an obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another."[10]

If a legal duty is found to exist, it is possible for liability to be imposed. In the absence of a legal duty, no liability can be imposed.

A bystander has no legal obligation to provide affirmative medical aid to an ill or injured person, even if the bystander has the ability to help. "[T]he law has persistently refused to impose on a stranger the moral obligation of common humanity to go to the aid of another human being who is in danger, even if the other is in danger of losing his life."[11]

Courts recognize, however, that the existence of certain relationships between a victim and one in a position to render aid may create a duty to provide assistance. Generally, EMS providers, such as paramedics and EMTs, have a legal duty to respond to and treat victims of medical emergencies. Specific responsibilities imposed on these responders vary from state to state and are influenced by court cases, statutes and regulations.

For individuals other than EMS providers, the following section, from the leading statement of general negligence law, outlines the types of relationships which may give rise to a duty to render emergency medical assistance (See Figure 1.)[12] This statement of law is adopted

by many courts and may become more important as the concept of public access defibrillation evolves.

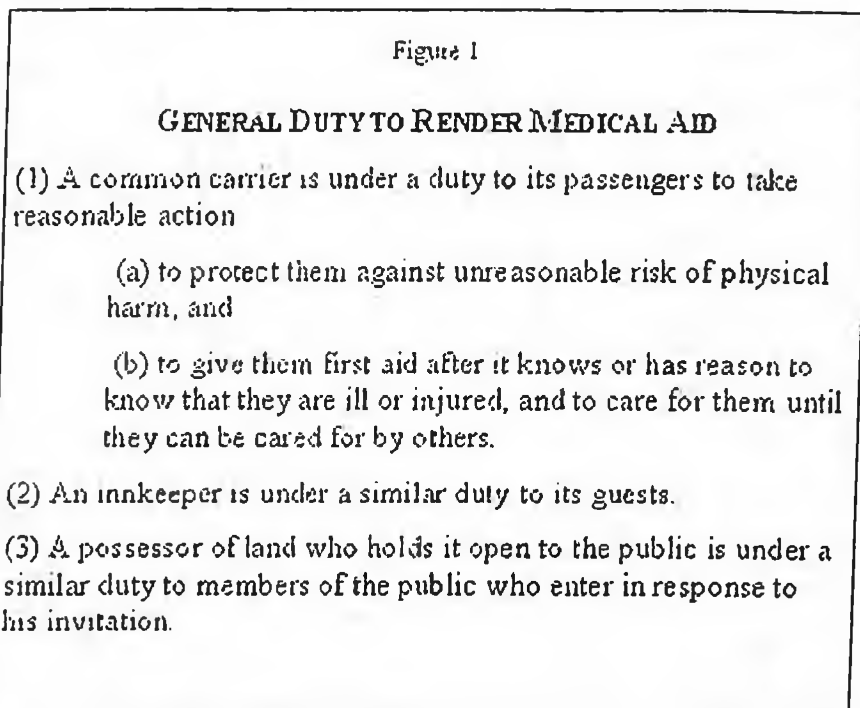
Figure 1

GENERAL DUTY TO RENDER MEDICAL AID

(1) A common carrier is under a duty to its passengers to take reasonable action

(a) to protect them against unreasonable risk of physical harm, and

(b) 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.

(2) An innkeeper is under a similar duty to its guests.

(3) A possessor of land who holds it open to the public is under a similar duty to members of the public who enter in response to his invitation.

Figure 1

Thus, in contrast to the general rule imposing no such duty on bystanders, certain groups may be compelled by law to render a reasonable level of medical aid and to quickly summon outside emergency medical assistance (Figure 2). These groups include common carriers (such as airlines, cab companies, passenger railroads and cruise ship operators), innkeepers (such as hotel and motel operators) and virtually all other commercial business establishments.

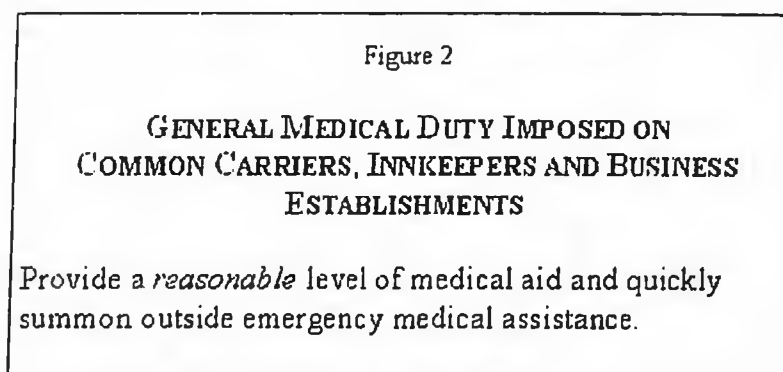
Figure 2

GENERAL MEDICAL DUTY IMPOSED ON COMMON CARRIERS, INNKEEPERS AND BUSINESS ESTABLISHMENTS

Provide a *reasonable* level of medical aid and quickly summon outside emergency medical assistance.

Figure 2

Appellate courts, trial court judges and juries define what is "reasonable," thus establishing the scope of a legal obligation or duty. The degree of reasonableness required under the facts and circumstances of a particular case evolves as society evolves. Action or inaction viewed as reasonable today may be viewed as unreasonable tomorrow.

While early defibrillation programs began to appear in the mid-1990s, only two appellate cases found to date directly address the issue of early defibrillation initiated by non-healthcare professionals and each of these deals with commercial airlines. In one case United Airlines was

sued by the widow of a man who suffered sudden cardiac death on a 1995 domestic flight[13]. The widow alleged that United was liable "because it failed to equip its aircraft with certain medical equipment, including an automatic external defibrillator, and because her husband would have survived if the in-flight emergency medical kit had contained such equipments." The case was recently settled after United unsuccessfully attempted to have the case dismissed on technical grounds.

In another case, Northwest Airlines was sued by a woman alleging her husband died from sudden cardiac arrest because the airline failed to have a defibrillator on board a 1995 flight[14]. The case was dismissed because the woman failed to produce an expert who would testify that the airline had a duty to carry a defibrillator at the time of the incident.

Because they were both dismissed on technical grounds, neither the United nor Northwest Airlines cases offer much guidance on how future appellate courts might address issues surrounding public access defibrillation. Appellate courts examining notions of reasonableness in other medical contexts have, historically, been generally resistant to requiring common carriers, innkeepers and commercial businesses faced with ill or injured patrons to do more than summon an ambulance. Two recent trial court verdicts, however, suggest an evolving trend toward higher standards requiring the protection of customer health and safety in certain business contexts.

Future trial court cases will likely offer insight into society's current view of reasonableness when businesses are faced with ill or injured patrons. Modern advances in AED technology, coupled with low cost and the proven ability of these devices to save lives, may persuade trial and appellate courts to sanction businesses that fail to adopt AED programs. While the likelihood of any type of AED related claim remains extremely small, it appears that common carriers, innkeepers and commercial businesses that adopt AED programs may face a lower legal liability risk than those that fail to adopt such programs.

The concept of causation

A successful negligence lawsuit also requires proof that alleged misconduct caused legally recognized damages such as death or injury. Three possible causation theories include allegations that a death directly resulted from: 1) the failure to purchase and make available an AED; 2) the failure to use an available AED; or 3) the improper use of an available AED.

In all cases involving sudden cardiac arrest leading to sudden cardiac death, the element of medical causation will be extremely difficult to prove. The causation question likely to be considered in early defibrillation cases is whether death could have been prevented with the availability and use of an AED.

Defibrillation delivered as quickly as possible after onset of sudden cardiac arrest has the capacity to greatly improve a victim's chances of survival. Thus, common carriers, innkeepers and commercial businesses that fail to purchase and use AEDs are at greatest risk in terms of proof of causation. However, this relative risk is quite small given the generally poor survival associated with sudden cardiac arrest. Next in order of risk are those situations in which an AED is available but improperly used. This scenario is unlikely because, with proper training, the modern generation of AEDs are both easy to use and difficult to misuse. Companies that purchase and properly use AEDs are at lowest causation risk.

Overall, the prospect of proving causation in early defibrillation cases, while theoretically possible in some circumstances, will be extremely difficult given the life-threatening nature of sudden cardiac arrest. Organizations that carefully adopt and implement AED programs may well be at lowest risk of liability.

Legal risk assessment: A summary

Legal liability risks associated with early defibrillation programs are quite remote. The following factors support this conclusion:

- Only two known appellate cases raise early defibrillation by non-healthcare professionals as an issue. A limited number of relevant trial court verdicts suggest that organizations that adopt AED programs face a lower liability risk than those that do not.
- If sudden cardiac arrest is untreated, the victim will die. As a general rule, an AED used properly can only help.
- Proving medical causation in an early defibrillation case will be extremely difficult.
- Many states possess laws that limit the types and scope of negligence lawsuits permissible against individuals rendering emergency medical care, including tort limitation, Good Samaritan laws and a variety of immunity laws.
- The modern generation of AEDs are both easy to use and difficult to misuse.
- For these reasons, legal liability fears should not deter organizations considering the purchase and use of AEDs.

Minimizing legal liability risk

There are a variety of ways to both manage and allocate even the small legal liability risks associated with early defibrillation programs.

1. Design a careful program

- Implementation: General rules governing negligence cases suggest that organizations that carefully adopt and implement early defibrillation programs face a lower legal liability risk than those that do not.
- Device selection and maintenance: All AEDs on the market have been cleared by the FDA. Because device price, performance, ease-of-use characteristics and recommended maintenance procedures differ by manufacturer, and because technology is advancing rapidly, it is worthwhile to carefully consider all AED options before purchase.
- User identification and training: Many state regulations currently require appropriate training of AED users. It is important that appropriate individuals be identified and trained.
- Site selection: AEDs should be placed in locations that can be reached quickly and easily. If an AED is placed in a locked or secure location, it is important that designated AED users possess keys or other means of accessing the device.

2. Promote Good Samaritan laws
Most states now have laws that protect individuals from legal liability flowing from the provision of emergency medical care. A growing number of states have Good Samaritan laws that specifically protect AED users from legal liability under certain circumstances.

A review of your state's laws will help you determine whether, and to what degree, liability immunity protection exists. For further information

on Good Samaritan laws, see the State AED Laws, the National Immunity/Good Samaritan Law Database, National EMS Info Exchange, NAEMT Online at http://naemt.org/nemsie/immunity.htm, and Emergency Medical Risk Management by Henry and Sullivan.

3. Explore insurance options
Negligence liability risk can be further minimized through the purchase of insurance. Private insurance companies and some AED manufacturers offer indemnification plans that protect AED purchasers from liability claims, except in cases of gross negligence, as long as certain conditions are met. Since these plans vary in scope and are continuously evolving, communities should take the time to investigate insurance options.

Summary

This section addresses laws and regulations affecting the use of AEDs. Both the FDA and state regulatory agencies determine who can use AEDs and how they may be used. State laws and regulations vary widely. Communities that implement AED programs must abide by federal and state laws and regulations and should check with state EMS agencies for information.

This section also addresses the nature and limited scope of any negligence liability risk associated with AED programs. Legal liability fears should not deter those considering the purchase and use of AEDs. Organizations that carefully adopt and implement AED programs will be at lowest risk of liability.

[1]*Note: Information in this chapter is not intended as legal advice. While every effort is made to ensure the accuracy of information, the AED legal and regulatory landscape is evolving rapidly. Legal questions surrounding AED use can be complex. If your community needs specific advice, seek the services of a competent attorney.*
[2]*http://www.fda.gov/cdrh/consumer/AED_PAD.html.*
[3]*Ibid (emphasis added).*
[4]*Public Health Improvement Act, Sections 401-404.*
[5]*Ibid, Section 403.*
[6]*Ibid, Section 404.*
[7]*Public Health Improvement Act, Sections 411-413.*
[8]*Pub. L. 105-170, 49 USC 44701.*
[9]*Circulation. 1995;92:2740-2747*
[10]*W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 53, at 356 (5th ed. 1984).*
[11]*Ibid.*
[12]*Restatement (Second) of Torts § 314A.*
[13]*Somes v. United Airlines, Inc., 33 F.Supp.2d 78 (US District Court, D. Massachusetts 1999)*
[14]*Talit v. Northwest Airlines, Inc., 58 Conn. App. 102, 752 A.2d 1131 (2000).*

AED Legislation : State

Alabama
Alaska
Arizona
Arkansas
California
Colorado

Connecticut
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Delaware
Most recent amendment to Title 16
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New Hampshire
New Mexico
New Jersey
North Carolina
Ohio
Oklahoma
Oregon
Link to ORS 30.800 referred to in bill
Pennsylvania Good Samaritan Law
Rhode Island
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Tennessee:
HB 1158 and HB 1218 are attached in a .pdf file along with the amendment.
HB 2970
Amendment to: HA 1199
SB 2871
Amendment to: SA 1071
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Vermont:

Bill as passed by House and Senate
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