

POWER TO SAVE A LIFE

Early Defibrillation Program



LEGAL AND RISK MANAGEMENT
CONSIDERATIONS

PHILIPS

Disclaimer

The most effective method to limit liability and risk is to develop a well planned, effectively implemented, and consistently managed program based on your organization's needs. Philips Medical Systems recommends that, before you plan your early defibrillation program, you consult your legal counsel regarding the extent of legal protection that may apply to your organization.

This document is not a substitute for advice from your legal counsel; it is intended as a guide in your consultations with counsel and risk management professionals. Legal requirements vary from state to state and locality to locality, and as early defibrillation programs become more widespread, legal and risk considerations will change with time. Sample insurance language included in this document may not be appropriate for your organization.

Legal and Risk Management Considerations

EARLY DEFIBRILLATION PROGRAM

Table of Contents

Overview	1
Legislation	1
Federal Protection and Support	1
Good Samaritan Laws	3
State Protection	4
Local Activities	5
Risk Management	5
Legal Considerations	9
Insurance	11
Incidental Medical Malpractice	12
Medical Director Coverage	14
Insurance Company Philosophy	15

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Overview

It is only natural that concerns regarding liability and risk management may arise in your organization regarding establishing an early defibrillation program. Naturally this is a topic to be discussed with your legal counsel. However, you should also be aware that there is growing consensus that institutions that cater to an at-risk population that are *not* prepared to respond to a cardiac emergency with a defibrillator may be at increased liability.^{1,2,3,4} Philips Medical Systems offers limited product indemnification for purchasers and users of Philips HeartStart automated external defibrillators (“AEDs” or “defibrillators”). However, you should still implement a strong risk management program designed to capture Good Samaritan protections and evaluate your own insurance program for appropriate coverage.

Legislation

Federal Protection and Support

The significance of automated external defibrillator use in responding to victims of sudden cardiac arrest (SCA) can be seen in the types of Federal legislation passed over the last few years. This overwhelming legislative and funding support has bolstered the acceptance of defibrillator usage within both corporate and community programs. Federal actions in support of early defibrillation have included:

- **The Sudden Cardiac Arrest (SCA) Act.** In 1999 President Clinton signed into effect The SCA Act, which covers federal employees in federal buildings by stating "any person who

¹ Ginsburg W. Prepare to be shocked: The evolving standard of care in treating sudden cardiac arrest. *American Journal of Emergency Medicine* 1998;16:315-31

² Lazar R. Defibrillators enter the business marketplace. *Occupational Health and Safety* 1997;66:86,88.

³ Lazar R. Understanding legal issues. National Center for Early Defibrillation. <http://www.early-defib.org>. 2000.

⁴ Lazar R. Liability no barrier. National Center for Early Defibrillation, *Journal of Emergency Medical Services*, Supplement, March 2002.

provides emergency medical care through the use of an automated external defibrillator is immune from civil liability for any personal injury or wrongful death resulting from the provision of such care."

- **Cardiac Arrest Survival Act (CASA) of 2000.** The Act is further discussed in the section below. However, in addition to the Good Samaritan protections established, funding guidelines were finalized by the General Services Administration and DHHS in May 2001, urging the implementation of early defibrillation programs in federal buildings. Congress has approved \$1 million for implementation of such programs in federal buildings.⁵
- **The Rural Access to Emergency Care Act.** This Act authorizes \$12 million in 2003 (\$25 million over 3 years, 2003-2005) for the federal government to expand access to early defibrillation in rural areas.⁶
- **OSHA's December 2001 Technical Information Bulletin** urges employers to consider making automated external defibrillators available in the workplace.⁷
- **The Community AED Act.** This Act authorized \$30 million in 2003 for communities to establish PAD programs. It was signed into law as of June 12, 2002.⁸
- **The Teaching Children to Save Lives Act.** This act funds defibrillator training and training equipment purchases through state departments of education.

⁵ Cardiac Arrest Survival Act of 2000, Pub.L. 106-505, Title IV, Subtitle A, 114 Stat.2314, 2336 (2000).

⁶ Rural AED Act, Pub.L. 106-505, Title IV, Subtitle B, 114 Stat.2314, 2340 (2000).

⁷ OSHA Trade News Release, December 2001: "OSHA encourages Defibrillator Use to Revive Workers with Cardiac Arrest" www.osha.gov/media/oshnews/dec01/trade-20011217A.html

⁸ Community Access to Emergency Defibrillation Act of 2002, Pub.L. 107-188, sec. 159, 116 Stat.594, 634 (2002).

Good Samaritan Laws

On November 16, 2000, President Clinton signed into law the Cardiac Arrest Survival Act (CASA) of 2000. This law accomplished two important things on a national level. The first is that it established guidelines for the placement of defibrillators in Federal buildings (42 USC § 238p). The second is that it addressed liability regarding emergency use of automated external defibrillators (42 USC § 238q).

In addition, all 50 states now have “Good Samaritan Laws,” some limiting the liability of companies or institutions purchasing automated external defibrillators, physicians providing oversight, and persons providing training in defibrillator use.

By outlining the requirements needed to obtain Good Samaritan protection (e.g., notification of local emergency response personnel of placement of the devices, maintenance and testing of the devices and provision of appropriate training to employees or agents most likely to use devices) organizations can move forward with the development and implementation of their Risk Management plan for use of defibrillators.

In addition, all 50 states now have “Good Samaritan Laws,” some limiting the liability of companies or institutions purchasing automated external defibrillators, physicians providing oversight, and persons providing training in defibrillator use.

Under most Good Samaritan laws, lay people are protected if they perform CPR, even if they have had no formal training in it, as long as they are voluntarily and genuinely trying to help and are not engaging in gross misconduct. Many of these laws are being amended to incorporate defibrillators as well. Applicable laws for your state can be found on the Internet. Go to the website of The National Conference of State Legislatures

(<http://www.ncsl.org/programs/health/aed.htm>) and click on "Public User".⁹

It is important to evaluate carefully the protections in your state with legal counsel; some states provide limited liability protection while others provide more broad or comprehensive protection. Understanding the degree of protection available is critical to an analysis of the corporation's potential liability exposures and need for insurance coverage.

State Protection

Several states are also considering legislation to require automated external defibrillators in state buildings, schools, exercise facilities, pools and public places where people gather. Two examples of states passing legislation requiring the implementation of early defibrillation programs are New York and Illinois.

- New York has passed legislation budgeting purchase credit for a defibrillator to new business owners. New York also requires certain public and private swimming facilities to retain a defibrillator and train lifeguards in defibrillator use. New York also requires defibrillators to be placed in schools.
- Illinois requires physical fitness facilities owned or operated by parks, local governments, and schools – as well as golf courses -- to implement written emergency medical response plans that include access to at least one automated external defibrillator (AED) during hours of operation. The "Physical Fitness Facility Medical Emergency Preparedness Act" affects public and private elementary and secondary schools, trade schools, colleges, and universities. It specifies the need for defibrillator access at swimming pools; stadiums; track and field facilities; athletic fields; and

⁹ Automated External Defibrillators and PAD Programs. An URMIA White Paper An URMIA R&D Committee Project, Sept 2001

basketball, tennis, and volleyball courts. (Facilities in hospitals, hotels, motels, and other facilities that do not employ instructors or others to assist members, guests, or the general public are exempt from the law.)

Since most funding and legislative action will occur at the local and state level, it is important to be aware of and support the legislative activities occurring in your city and state.

For more information, check the provisions of your state's legislation. A good place to start is the National Center for Early Defibrillation Web site (<http://www.early-defib.org>), which includes a detailed article, "Understanding Legal Issues," written by an attorney specializing in EMS topics. The article discusses state and federal laws, with links to referenced legislation.

Local Activities

Most communities have building codes/regulations related to installation of medical equipment. As you begin to develop a plan, check with local EMS or fire officials to ensure that all requirements are met.

Risk Management

Even with government support of Good Samaritan legislation, some organizations and lay users may still be concerned about risk and liability. The most effective method to limit liability and risk is to develop a well planned, effectively implemented, and consistently managed program based on careful analysis, rational criteria, and applicable state and federal laws.

Although most risk managers will want to see a plan that provides an assessment of the optimal number of defibrillators for the best response coverage, they also recognize it may not be possible from a financial point of view to initially implement the entire, comprehensive plan. In such cases, a documented phased implementation plan is advisable, with the initial

defibrillators being placed in the areas at highest risk for SCA, as identified by the site survey.

The requirements of the early defibrillation program can be incorporated into the company's Emergency Response Plan. In addition, your organization may find it useful to have a written Risk Management Plan that specifically addresses the risk-related goals and the requirements of the laws governing early defibrillation programs.

Whether in a separate Risk Management Plan or as part of your company's Emergency Response Plan, the following issues related to the early defibrillation program must be formally addressed in order to mitigate risk:

- The program's collapse-to-shock or call-to-shock response goal and implementation plan for achieving it

Your site survey will have identified optimal defibrillator locations to achieve a response interval (the time from collapse to arrival of the responder with the defibrillator) of no more than three minutes and a call-to-shock interval (the time it takes designated responders to be notified, get the defibrillator, reach the victim's side, apply the pads, and deliver the first shock) of no more than five minutes. These goals will help determine how many defibrillators are required, as well as where they should be placed.

If it is not possible to purchase all of the required defibrillators at once, you can develop a plan for phased defibrillator purchase and placement, including how many units are to be initially purchased, where they will be located, the projected timeline for future purchases, and the location of those devices when available. Consult with your lawyer and purchasing personnel for the best approach.

- **Coordination with local EMS**

Be sure to inform your local emergency medical services (EMS) provider (e.g., fire station) that the corporation is implementing an early defibrillation program. Most EMS providers will be happy to work with you on relevant aspects of the plan. They can also provide any applicable registration forms.

Register each defibrillator (with its specific location) with your EMS provider. Under CASA and many state Good Samaritan laws, your immunity is partially dependent upon your notifying your local emergency response personnel of the most recent placement of the defibrillator.
- **Policies and Procedures for the early defibrillation program**

Your emergency response plan should allow you to track defibrillator use for quality management purposes. Developing a data-tracking plan to capture and review incidents, response times and outcomes will allow you to evaluate what you are doing well and what needs to be improved. It can answer questions related to the adequacy of your chosen defibrillator locations, training, communication call systems, etc. Conducting a Critical Incident Debriefing session with your Medical Director and EMS representative after defibrillator use can be instrumental in evaluating any necessary changes in rescue practice.
- **Prescription to purchase and medical supervision**

The U.S. Food and Drug Administration (FDA) currently regulates defibrillators as prescription devices. While the FDA does not detail the precise nature and scope of medical direction, the FDA's Center for Devices and Radiological Health (CDRH) requires manufacturers of automated external defibrillators to sell the devices only on the order of a physician.

For most organizations, the prescribing physician is typically the Medical Director for the program. In addition, the FDA required 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.

- Regular maintenance and testing

Incorporate the manufacturer's maintenance and testing recommendations (if any) for the defibrillators into your Risk Management Plan and/or Emergency Response Plan. Typically, these are specified in the Instructions for Use provided with each defibrillator.

Immunity from liability under CASA and many state Good Samaritan laws is in part based on proper maintenance of the defibrillator. The plan should identify who will be responsible for defibrillator maintenance, what documentation will be required, and how that documentation will be archived. Maintenance activities include checking the inventory of necessary supplies as well as procedures for returning a defibrillator to service after a use. Periodic evaluation of the maintenance standards and documentation reflecting accomplishment of those standards can be added to your quality assurance program.

- Initial and ongoing training

Another requirement for immunity from liability is providing defibrillator training to your employee(s) or agent(s) who are reasonably expected to use the defibrillator. The training plan must ensure that expected users of the defibrillator are trained and address the training of new users who join between scheduled training sessions. It should also include how responders will receive ongoing training.

In addition to providing training on the operation of the defibrillator, the training program must include cardio-pulmonary resuscitation (CPR). The guidelines of most of

the national training organizations state that trainees should receive refresher training at least every two years.

There are several national and regional training organizations that offer standardized training programs in CPR and defibrillator use. Large companies may want to have one or more employees become certified as a CPR/defibrillator trainer. Alternatively, you can contract with a training organization to conduct all of your initial and refresher courses.

Conducting periodic drills will help ensure that your staff is ready to respond to an emergency and helps to document the adequacy of your emergency response plan.

Legal Considerations

The allegation that a person or entity failed to meet the appropriate standard of care is the basic premise of a negligence-based or malpractice lawsuit. Given the Good Samaritan protections and your strong risk and quality programs as developed above, the question now becomes, what remaining exposures to liability do you have? Because local and regional requirements may vary, Philips suggests working with your legal counsel to help balance and evaluate the risks of implementing an early defibrillation program and to weigh such variables as the Good Samaritan protections, duty and standard of care, number of defibrillators and responders and training requirements.

In the event of a lawsuit, the person initiating the lawsuit (e.g., sudden cardiac arrest victim) is called the plaintiff and the person/organization being sued (e.g., lay responder or AED purchaser) is called the defendant.

The plaintiff would have to successfully prove four essential legal elements in order for a negligence claim to succeed.

These are:

- A. Duty: The defendant must owe a legal duty to the plaintiff
- B. Breach of Duty: Failure to fulfill that duty by not meeting to the applicable standard of care
- C. Causation: Breach of duty by the defendant caused the resulting injury to the plaintiff
- D. Damage: Plaintiff's injury

If the allegation pertains to plaintiff harm as the result of the use of a defibrillator, there are two likely scenarios. The first is that Good Samaritan protection exists, the second is that Good Samaritan protections would have existed but for the lack of following the statutory requirements to obtain that protection.

- 1) When there is an established risk management program in place that takes into account the federal and state Good Samaritan requirements as well as the risk and quality recommendations noted above, an organization should strictly follow its program and meet all its duties and applicable standards of care. This will make it easier to argue successfully that there was no breach of duty and the Good Samaritan protections apply.
- 2) However, if there has been a breach in the standard of care by the defibrillator acquirer (e.g., training was not provided to employees), then a breach of duty could be found. If this breach of duty is found to have caused the plaintiff's injury, it is possible that the four components of legal liability will have been met concurrent with finding that the legal requirements for immunity were not met. This can result in organizational or individual liability.

Another area of concern revolves around the failure to provide a defibrillator. If your organization has not completed a risk analysis or survey and does not have an emergency response plan in place (addressing the use or non-use of defibrillators)

then you may be at risk for a negligence claim if a person is injured and alleges that you had a duty to provide life-saving equipment and failed to do so.

When analyzing this exposure, you should ascertain whether or not there is a statutory or regulatory requirement that a defibrillator be in place. If there is no such requirement, then you should evaluate what your peer groups (other similar organizations) are doing with respect to defibrillator use. If you are an organization that caters to an at-risk or high-risk clientele, and other similar organizations are implementing an emergency response plan with defibrillators, this could become the standard of care for your industry. If this were to occur, not having such a plan including defibrillators could become a breach of duty, exposing you to liability.

Insurance

Given the above, organizations and their employees will want to know if they have coverage for claims alleging negligence in the use of or non-use of defibrillators.

Insurance involves the transfer of risk from a person or organization to an insurance carrier. When you purchase insurance, you receive an insurance policy or contract that describes what risks are being transferred to the carrier and what risks you are agreeing to retain on your own.

We all retain a certain amount of risk. It is important to identify our risk exposures and the risks we want to retain, before there is a loss. For each risk retained, evaluate how severe it might be. At this time, any actual liability risks associated with implementing an early defibrillation program may be small.¹⁰ However, it makes sense from many perspectives to make sure

¹⁰ Lazar, Understanding Legal Issues, www.early-defib.org.

your program is designed to capture your Good Samaritan protections.

Work with your insurance carrier and legal counsel to evaluate your insurance policy, referring to any endorsements that you might have received at or after your policy was originally issued. A carrier can amend an insurance policy (add, exclude, or remove coverage) by adding an attached document called an endorsement.

There is no national uniformity to insurance policy or endorsement wording. Therefore, there is no one place or single policy clause to which you can refer if you want to know if you have coverage for your use or non-use (for example, if you decide not to purchase a defibrillator) of the device.

The place to begin your analysis of coverage will be with your Commercial General Liability Policy (CGL). With the exception of auto, workers compensation and professional liability exposures, CGL insurance covers the majority of liability exposures faced by an organization. The provision of health care as a business is covered under a Professional Liability (PL) policy. However, for non-healthcare organizations, the CGL policy often includes coverage for incidental healthcare liability or medical malpractice exposures.

Incidental Medical Malpractice

Incidental medical malpractice is an exposure created by the offering of healthcare services by an entity not engaged primarily in the offering of such services. A manufacturing business, for example, might have such an exposure by virtue of the fact that it employs an industrial nurse to handle first aid type claims or it has one or more defibrillators on-site.

Sample incidental malpractice wording that can be found or placed into your policy via endorsement includes:

- “The definition of bodily injury is expanded to include injury resulting from providing or failure to provide any medical or professional health care services or furnishing or dispensing drugs or medical supplies. However, the coverage excludes any insured in the business or occupation of providing healthcare services.”
- “The definition of bodily injury is expanded to include injury resulting from providing or failure to provide any medical or professional health care services including the use of Public Access Defibrillators/Automatic External Defibrillators.”
- “The definition of who is insured is amended to read ‘any employee specifically trained in the use of Public Access Defibrillators / Automatic External Defibrillators.’”

Insurance carriers employ underwriters to evaluate risks, determine which risks will and will not be covered (often on a per-client basis), and develop the associated premiums. This means that even within one insurance company, risks can be viewed differently. Whereas one underwriter may agree to cover a specific risk for one insured, it may not be covered for another.

Since different carriers and underwriters handle this exposure in different ways, it is a good idea to ask your agent or broker the following questions:¹¹

Do we have coverage for incidental healthcare liability or incidental medical malpractice?

If YES:

- Will it provide a defense and indemnification (payments to the plaintiff that we are legally required to pay) for allegations of providing or failing to provide medical or professional healthcare services?

¹¹ This insurance-related discussion assumes that you do not provide professional health care services as your business. If your organization is a medical office, hospital, or other such entity, the insurance-related issues are different.

- Will it provide coverage for my employees as well as the organization? If you have volunteers on staff that may utilize the defibrillator, will volunteers be covered as well? Most CGL policies include coverage for volunteers.
- Are any of my employees excluded? Keep in mind that the definition of employee will probably not include temporary or leased workers or contracted personnel (e.g., your Medical Director). The policy may also exclude healthcare personnel such as EMTs or nurses. Conversely, the policy may only include incidental malpractice coverage for specific employees such as law enforcement or security personnel or those trained in the use of defibrillators. As a result, your Medical Director will need to have his/her own coverage, and you may need to purchase separate professional liability coverage for your employed or volunteer nurses, EMTs or other health care providers.

If NO:

- Can this coverage be added to or expanded in my policy by endorsement? If the initial response is that coverage can not be added, then request an explanation as to the underwriter's concerns. Your specific underwriter may not have had much exposure to the use of defibrillators; providing educational material or a copy of your Risk Management Plan may make a significant difference in how the exposure is viewed. You can also climb the chain of command and seek an opinion as to the carrier's acceptance of this risk by higher level management

Medical Director Coverage

The Medical Director of an early defibrillation program should have professional liability coverage through his/her own standard medical malpractice policy. If not, he/she may be able to obtain such coverage through the EMS system. As part of the

Medical Director contracting process, you should ask to see proof of insurance.

Insurance Company Philosophy

The good news is that many insurance companies already offer coverage for defibrillation responders through their CGL policy's Incidental Malpractice clause. If this is the case, then there will likely not be an associated increase in premiums for many policyholders.

Other insurance companies support the acquisition, placement, and use of defibrillators in appropriate circumstances, provided that:

- defibrillator use is permitted by state law
- the individual using the defibrillator has been suitably trained
- the defibrillators are maintained according to the manufacturer's requirements
- appropriate CPR and EMS resources are available and used.

In this case, specific underwriting will be accomplished with the underwriter asking to review specified documents, such as your risk analysis or Risk Management Plan. An associated premium may be charged if an additional endorsement for coverage has to be added to your policy.

Some carriers have decided to provide such coverage for their larger clients, where this exposure is a small part of the entire package, but not for their smaller clients, where the premium obtained is not sufficient to cover an unknown exposure.

Lastly, other carriers will not yet consider providing any coverage for this exposure. They are still researching the types of claims that may arise by having or not having a defibrillator.

As a result, it is paramount that you ask the questions above and determine if you have coverage or if it can be added. If coverage is not in place through your current carrier, then you must decide if, given the federal and state protections, and the strength of your program you want to accept this risk as an uninsured exposure or if you want to change insurance carriers in order to obtain coverage elsewhere. If you decide to change carriers remember that while another carrier may provide coverage for your early defibrillation program, it may also exclude coverage for another organizationally inherent risk that could be of more significance to your financial stability.

Working with your legal counsel and insurance carrier, you can balance the potential risks with the benefit of saving lives through an early defibrillation program