Department of Health and Mental Hygiene
Maryland State Department of Education
Maryland State School Health Council

MARYLAND STATE SCHOOL HEALTH SERVICES GUIDELINES

Chain of Survival: Emergency Preparedness for Sudden Cardiac Arrest in Schools

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Thanks to the following individuals for their contributions to the development of this document.

Donna Behrens
Director, School Based Health Centers
Governor's Office for Children, Youth and Families

Cheryl DePinto, Chief
School and Adolescent Health
Center for Maternal and Child Health
Maryland State Department of Health and Mental Hygiene

Mark Gardner
Lieutenant
Baltimore County Fire Dept

Steve Hull
Risk Management Officer
Maryland Association of Boards of Education

Jackie LaFiandra
Assistant Attorney General
Maryland State Department of Education
Office of the Attorney General

Donna Mazyck
Health Services Specialist
Maryland State Department of Education

Laurel Moody
Health Services Specialist
Baltimore County Public Schools

Lisa Myers
Program Development Director
Maryland Institute for EMS

Carole Pinckney
Health Services Supervisor
Prince George's County Schools

Michele Prumo
Chair, MSSHC
Health Services Coordinator
Baltimore County Public Schools

Maura Rossman
Medical Consultant
School Health Services
Baltimore City Health Department

Sarah M. Settee
Assistant Attorney General
Educational Affairs Office
MIEMSS

Lisa Spencer
Loss Control Specialist
Maryland Association of Boards of Education

Vicki Taliaferro
Health Services Specialist
Maryland State Department of Education

Patricia Wince
Coordinator, School Health
St. Mary's Co. Schools

Introduction

According to the American Heart Association (AHA), 220,000 Americans die each year of sudden cardiac arrest. However, the AHA also estimates that 50,000 of these deaths could be prevented with prompt notification of 911 and early initiation of cardiopulmonary resuscitation (CPR). Although sudden cardiac arrests (SCA) occur more commonly in adults, an estimated 5000 to 7000 children (without symptoms) die suddenly in the United States each year, (sudden infantile death syndrome (SIDS) deaths are excluded from this estimate).[1] Research suggests that a majority of sudden cardiac deaths in children and adolescents are directly related to undetected cardiac anomalies. In children and adolescents the most common cardiac problems that may result in SCA are:

- Long QT Syndrome which is a lengthening of the time it takes the heart to recover to baseline cardiac rhythm following each heartbeat;
- Wolff-Parkinson White Syndrome which results in electrical signals reaching the heart prematurely because of the development of extra pathways;
- Cardiac myopathy which is a thickening, stretching, or constricted movement of the heart muscle; and
- Commodio cordis that results from a blunt impact to the chest during the repolarization phase of the cardiac cycle.

In adults, ventricular fibrillation is the most common cause of SCA. Ventricular fibrillation is an abnormal chaotic heart rhythm that prevents the heart from pumping blood. The current treatment for SCA is the "chain of survival" which delineates the four links needed to increase the victim's chance of survival. The four links are:

- Early access to care – calling 911 or emergency medical services (EMS);
- Early CPR;
- Early defibrillation; and
- Early advanced care by EMS and hospital personnel.

Purpose

These guidelines provide a framework for local school systems (LSSs) and schools to ensure that a "chain of survival" is present in schools and buildings.

[1] Berger S, Dhala A. Griedberg DZ. Sudden cardiac death in infants, children and adolescents.3 Pediatric Clinics of North America, Vol. 467 (2), April 1999; p. 221.

Implementation of the "Chain of Survival" in Schools

Each school should have a current plan that includes procedures on how to manage SCA in students and adults who work at and/or routinely visit schools for a variety of reasons including school-sponsored events.

In 1990, the School Health Standards (Code of Maryland Regulation 13A.05.05.05-.15) were adopted and requires that "At least one adult in each school other than the designated school health services professional and the school health services aide shall be currently certified both in the First Aid Program of the American National Red Cross or its equivalent and in Adult and/or Pediatric Cardio-Pulmonary Resuscitation (CPR). Thus, one certified person should be available on-site during the regular school day and at all school-sponsored athletic events."

All CPR certified individuals are trained on when to activate the "chain of survival" which means that these trained individuals shall perform the actions or links that increase a victim's chance of survival. Each year, all LSSs in Maryland certify that their schools meet the School Health Standards that includes having a certified individual in each school to respond to SCAs.

To save an individual experiencing a SCA, each set of actions or links in the chain of survival must be performed as soon as possible. If any link in the chain is weak, delayed or missing the chance of survival is lessened. All public schools in Maryland have the first two links in place. The decision to implement an automatic external defibrillator (AED) program is made at the LSS level and can best be made by assessing the school environment and the risk of SCA within the school setting. Since implementation of an AED program is a local decision, this document identifies the issues that need to be considered by each LSS to adequately and safely implement an AED program.

The Planning Team

Schools need a comprehensive emergency response plan, which is coordinated with the local EMS agency. If a decision is made to include AED as part of the school's emergency plan, it is imperative that adequate planning and support for the program be available.

It is important to have a team of key staff develop policies for the AED program. If an AED program is being implemented in one school, the LSS should consider implementing the program for all schools in the system. Members of the planning team should include:

- Associate superintendent or principal;
- A Maryland Institute for Emergency Medical Services (MIEMSS) representative;
- A designated AED program coordinator;
- A risk management representative;
- The school health services coordinator;
- The athletics director/coordinator of physical education;
- A physical security or facilities representative;
- A local health department representative;
- Local EMS representative;

- The physician providing medical oversight;
- The school-based health center coordinator; and
- The LSS's attorney/legal counsel.

Per Section 13-517 of the Education Article, Annotated Code of Maryland (Appendix B) MIEMSS is responsible for the coordination and training of all AED programs in Maryland. **Before implementing the MIEMSS approved program, LSSs must assess and consider the following factors:**

Assessment

The decision to implement an AED program should be based on a thorough assessment. The assessment should consider:

- The relative effectiveness of the school's current emergency plan in dealing with SCA and other emergencies, and how the use of AEDs would fit with the rest of the emergency plan;
- The types of activities and events conducted in the school buildings and the populations in attendance;
- The types of policies and procedures that are already in place to support student and staff wellness (required physical exams, injury prevention efforts, etc.);
- The attention currently given to the use of protective sports equipment and equipment safety measures;
- The availability and response times for EMS including 911 access and AED availability among first responders such as police, ambulance, and fire;
- Response time to the school does not exceed five minutes for more than 10% of responses.[2] Review response time data for the local EMS to reach school and use data to determine need for AED;
- Identification of medical oversight [3]; and
- Willingness and capability of personnel to respond to cardiac emergencies and to provide CPR and defibrillation [4].

Liability

As previously stated, all activities desiring to initiate an AED program must submit an application to MIEMSS, complete the MIEMSS training program, and comply with MIEMSS requirements (*See Appendix C). Section 13-517 of the Education Article protects LSSs against civil liability for an act or omission in the provision of AED provided the LSS is in compliance with the requirements of the MIEMSS AED program. Additionally, Section 5-518 of the Courts and Judicial Proceedings Article could also limit the liability of a LSS in such a circumstance (See Appendix D).

The AED statute, Section 13-517(n)(3) of the Education Article, provides an individual immunity from civil liability for "any act or omission" in the provision of AED if:

[2] 2001 National Center for Early Defibrillation
[3] 2001 National Center for Early Defibrillation
[4] 2001 National Center for Early Defibrillation

- The individual is acting in good faith while rendering AED to a person who is a victim or reasonably believed by the individual to be a victim of sudden cardiac arrest;
- The assistance or aid is provided in a reasonably prudent manner;
- The AED is provided without fee or other compensation; and
- The individual is providing AED in accordance with the requirements of the law at an authorized facility, has successfully completed an AED training course and is authorized to provide AED, and is using an AED obtained by a prescription issued by a health care provider.

The immunity does not apply if the conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct. Thus, it appears that if the employee's actions in the use of the AED fall within the range of requirements as stated in the law, the LSS employee should be protected against individual civil liability.[4]

In addition to the immunity provided by the AED statute, there are other protections that may be available to LSS employees. Pursuant to § 4-106 of the Education Article and § 5-518 of the Courts and Judicial Proceedings Article, LSS employees acting within the scope of their employment, without malice and gross negligence, are not personally liable for damages resulting from a tortious act or omission for which a limitation on liability is provided for the local board of education under § 5-518 of the Courts and Judicial Proceedings Article. Each local board has immunity for claims against it greater than $100,000, or claims greater than the amount of the local board's limit on its comprehensive liability insurance policy.

Schools must consider a plan for implementation. If schools decide to implement an AED program, they must ensure that an adequate number of CPR/AED trained staff are available and that there are enough AEDs to adequately cover the entire school. Having only one AED for a large high school may be insufficient, as may be having one for only one athletic team. It would be prudent to assure students, families, and others who use the school building that it is equipped with sufficient AEDs to have a successful AED program.

Another major LSS decision is to decide whether all school buildings in the district will have an AED program. The LSS must answer the question, "Is the AED program a standard of care all individuals using school buildings can expect, or is it sufficient for one school to have the program while another school does not have the program?" It is highly recommended that the LSS's legal counsel be consulted regarding this issue.

It is imperative that LSSs confers with their legal counsel to fully review liability issues with regard to an AED program.

Numbers and Locations

If the LSS decides to implement an AED program upon completion of the assessment then the number of AEDs required to implement a successful program must be determined. The following factors must be considered in determining the required number of AEDs:

4 The State of Maryland has a Good Samaritan Act (Section 5-603 of the Courts and Judicial Proceedings Article 5) that may provide some immunity from liability in certain circumstances.

- Size and physical layout of the buildings;
- Number and ages of individuals in the building (staff, students and visitors);
- Types and locations of athletic events;
- Types and locations of curricular, extracurricular, and school-sponsored events; and
- Design features that might be unique to the facility.

It is generally recommended that the time from when the individual "drops" to the time the shock is performed should be less than three (3) minutes. The following locations should be considered in determining where to place the AEDs:

- Cafeteria;
- Auditorium/Gymnasium;
- Health Suite; and
- Populated spots in large or multi-building sites

AEDs should be placed in easily accessible, well-marked locations, ideally near telephones.[5] Tamper-proof cabinets with an alarm can be purchased to store the AEDs. Additionally, a rapid and effective communication system, especially for events held at remote locations, should be developed. Training drills should be planned and conducted to test the communication system.

Cost and Funding

AEDs are readily available from a number of manufacturers and cost from $1,500 to $3,000 each. Electrodes and batteries must be replaced periodically based on manufacturer's suggested shelf life. The pads must be replaced after each use and cost from $50 to $150. There are several funding sources to include parents and organizations that wish to donate AED equipment. *The Automatic Defibrillation in Adam's Memory Act* (Public Law 108-41, July 1, 2003) authorizes the federal government to establish an information clearinghouse that provides information to increase public access to defibrillation in schools. When established, the clearinghouse will serve as a good resource for schools interested in establishing AED programs. It is important to know that the law does not mandate AED programs in schools.

It would be prudent to set some parameters regarding the type of AED to be used, so that training is standard.

Maintenance

If an AED program is being considered, the LSS must address the issues related to maintenance of the AED equipment. Most AED units conduct a self-test every day or week and signal when the battery is low or a problem is detected. This means that electrodes and batteries must be replaced periodically. The AED must also be inspected regularly to ensure no alarm signal is present and that the batteries and electrodes are present and within the expiration date. LSSs need to answer the following questions:

[5] 2001 National Center for Early Defibrillation

- Who will be responsible for checking the equipment?
- How will the safety checks and maintenance be documented?
- Where will the documentation be kept? and
- How will the AED units be made accessible but kept secure to prevent tampering or theft?

Training/Turnover

Training on the proper use of AEDs is coordinated and provided through MIEMSS. LSSs must determine who will be trained and must keep records of that training and any subsequent training that takes place. Consideration must be given to expected turnover or transfer of staff. Adequate staff must be trained at each site. This means that at least one trained individual must be available for the entire school day and for all school- sponsored events. LSSs should also consider the following when training is being planned:

- Will training be conducted during the regular workday? If this is not possible, staff should be paid for time spent in the training during their non duty-hours.
- Will the scope of work or job title of individuals receiving AED training be changed to reflect the responsibility for providing AED services and operating AED equipment?
- Will the employee have the ability to decline assignment?
- How will compensation be made for on-call time or overtime?
- Who will be trained for extracurricular events including school-sponsored trips or athletic events away from school and after school?

After-School Events and School-Sponsored Field Trips

Because school buildings are open to the public for after school events, the LSS will need to address AED coverage during after-school hours including school-sponsored and school-approved events. A determination must be made as to who will be trained and responsible for using the AEDs at these events.

The LSS is not responsible for providing AED services to organizations that use the school buildings after school such as PTA's, churches, Boy Scouts, and other organizations. To avoid confusion, schools should make it very clear in their agreements with these organizations that the school is not responsible for providing AED services.

School-Based Health Centers

School-based health centers (SBHCs) are separate health clinics located within a school. In Maryland, a local health department or local health organization sponsors the majority of the SBHCs. Care in a SBHC requires the consent of a parent or guardian. Supplies, equipment, and staff are present in the SBHC and serve students who are enrolled and have a signed consent. An AED may be part of the equipment used in the SBHC. If an AED is present, it should be addressed in the overall emergency plan for how to handle SCA in students and adults using the SBHC. The SBHC should have a written policy that articulates:

- Maintenance of the equipment;
- Responsibility for maintenance of the AED before and after it has been used;

- o AED training requirements to include who is trained, how often the training occurs, and who on the staff is or should be trained, and refresher training;
- o Directions for operating the AED;
- o Who is the sponsoring health care provider (required by COMAR);
- o Storage;
- o Documentation requirements; and
- o The AED program coordinator

The school administrator must be notified of the presence of an AED device in the SBHC. If an AED is included in the SBHC's emergency response plan, the use and availability of the device within the greater school environment must be discussed with the school administrative team and the school health supervisor. The discussions should include whether the SBHC's AED is the only device available to the school. The AED located in the SBHC may not be sufficient to ensure a timely response for the larger school population. If the AED is made available to the school population, location of the AED must be considered especially if the SBHC is not centrally located in the school.

AED Application Process

The MIEMSS process for applying for an AED program and the training component are located at Appendix D of this document. Each facility must have a sponsoring health care provider and the **sponsoring health care provider** will be required to qualify for a certificate. AEDs are medical devices that must be used under the advice and consent of a health care provider and only by individuals with proper training and certification. Medical oversight is a required component of the program[6] and can be provided by the local director of emergency medical services, the county health officer, or any licensed health care provider in Maryland.

Another important individual in the process is the program coordinator. The program coordinator/designee conducts scheduled maintenance checks of the unit according to the manufacturer's instructions to include verifying placement, battery installation, checking status/service indicator light and exterior components, and checking supplies.

Additionally, a thorough post-event review must be conducted and documented[7] every time the AED is used.

Protocols/Policy

A protocol/policy must be developed by the LSS and reviewed by MIEMSS and the LSS's legal counsel. A sample protocol is at Appendix E of this document. Items that may be included in the protocol/policy are:

Purpose
Location of the AEDs
Training

- Who is trained

[6] COMAR 30.06.03.02
[7] COMAR 30.06.04.02B

- What is included in the training
- How often should training be conducted
- How to operate the AED
- What is protocol
- Telephone instructions
- What to tell EMS when they arrive
- Post resuscitation care
- Refresher training
- Training for turnover – new people
- Where protocol will be kept
- How often protocol is updated

Equipment (that will accompany the AED unit) [8]

- AED operating instructions
- Certificate issued by MIEMSSS in a place where it is readily available
- Each AED and all equipment and supplies will be in accordance with the standards as established by the device manufacturer and the Federal Food and Drug Administration;
- Disposable gloves
- 2 sets of defibrillator chest pads
- 2 pocket face masks
- 2 safety razors
- 1 absorbent towel
- 2 one way valve barrier device
- 5 – 4x4 gauze pads
- 1 extra AED battery or a long life lithium battery (5-year shelf life)
- cables
- Maryland Facility AED Report Forms for cardiac arrest (available on line or from local EMS office)
- An AED in a closed, intact case
- *MIEMSS recommends a semi-automated AED*

How the emergency system is activated

- How is EMS activated?
- Who responds
- A rapid and effective communication system[9]

Post Event

- Post event documentation
- Who to call
- When to call parent
- Event forms
- Where to send
- Review data

[8] COMAR 30.06.04.02 D
[9] COMAR 30.06.02.01G

- Give feedback to team
- Conduct post incident debriefing

Maintenance

- who will check
- What will be checked
- How often
- How will inspection be documented
- Annual system inspection

Conclusion

It is imperative that schools establish a "chain of survival" to be prepared for a SCA. This begins with providing and maintaining CPR training for identified staff. If a LSS desires to include an AED program as part of the "chain of survival," it must seriously consider the planning and other factors required to establish and maintain a viable AED program. These guidelines will provide the planning team with a valuable tool to assist in making this most critical decision.

RESOURCES

- Manufacturers of approved AEDs can be found on the following Web sites: **http://unix32.nysed.gov:9210/rscs/chaps/ Health%20Services/AED-Manufacturers.doc**
- Information about potential funding sources is available from the National Center for Early Defibrillation at web site: **http://www.early-defib.org/03_06_05.html**
- MIEMSS
- American Heart Association
- Accopora @ www.la12.org
- National Safety Council
- School Health Standards

APPENDICES

A. Checklist for Schools

B. MIEMSS Training Packet (Includes Section 13-517 of the Education Article, Annotated Code of Maryland; and Code of Maryland Regulations 30.06.01-.05)

C. Sample AED Policy

D. November 13, 2001 Memo from the Office of the Attorney General

APPENDIX A
AED Program Checklist for Schools

The following elements are essential in the planning and support of an AED program:

- Compliance with MIEMSS requirements for an AED program;
- A core emergency response team of trained personnel, including the school nurse, and a method to activate the team;
- A well-defined emergency plan that clearly states all policies and procedures relative to the use of an AED;
- Strategic placement and availability of the AED unit(s);
- A rapid and effective communication system, especially with regard to events held at remote locations;
- Initial training, periodic refresher sessions, and systematic refresher training of appropriate staff in CPR, including the use of AEDs;
- Regular maintenance of the AED unit(s) according to the manufacturer's specifications;
- Periodic testing and repair/replacement of non-functioning units;
- Reporting the use of an AED to the collaborating emergency health care provider, who in turn is required to report to the regional Emergency Medical Services Council; and
- Health care provider oversight.

APPENDIX B

MIEMSS Training Packet

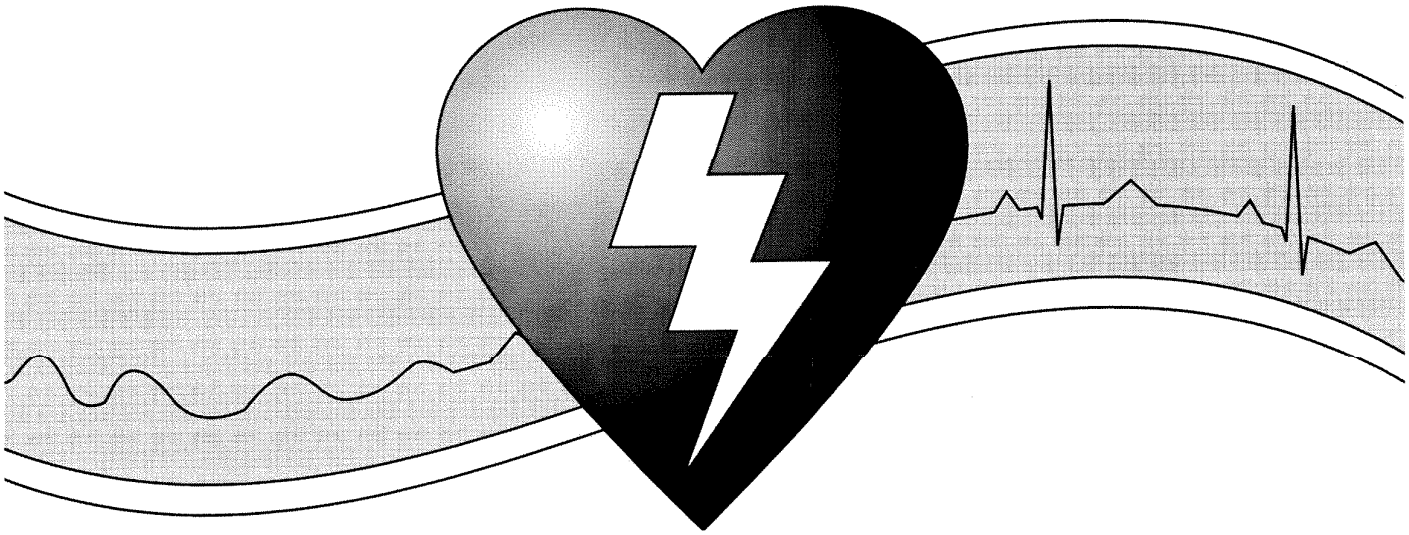
Includes Section 13-517 of the Education Article, Annotated Code of Maryland; and Code of Maryland Regulations 30.06.01-.05

STATE OF MARYLAND
Maryland Institute for Emergency Medical Services Systems
653 West Pratt Street Baltimore, Maryland 21201-1536

Maryland Facility

AED

Automated External Defibrillator



Program

"A Vital Link in the Chain of Survival"

"I'm living proof that we get second chances
and the second time around is better than the first."

- Lance Armstrong

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State of Maryland

Maryland Institute for Emergency Medical Services Systems

653 West Pratt Street
Baltimore, Maryland
21201-1536

Robert L. Ehrlich, Jr.
Governor

Donald L. DeVries, Jr., Esq.
Chairman
Emergency Medical Services Board

Robert R. Bass, MD
Executive Director
410-706-5074
FAX 410-706-4768

TO: Maryland Facility AED Program Applicants

FROM: Richard L. Alcorta, MD, FACEP
State EMS Medical Director
MIEMSS

RE: Automated External Defibrillator (AED)

The Maryland Institute for Emergency Medical Services Systems (MIEMSS) is pleased your organization has decided to become an integral part of the Maryland Emergency Medical Services (EMS) System. Maryland's EMS system is a cooperative, multidisciplinary, consensus-based program of integrated resources, agencies, hospitals, and dedicated individuals such as you.

Each year in the United States an estimated 250,000 people suffer from sudden cardiac arrest. Ventricular Fibrillation is the most common cause of death from sudden cardiac arrest and can be treated with early defibrillation that restores the heart to a normal rhythm.

MIEMSS has established requirements for the use of the AED in your facility. The enclosed items outline the requirements of the program and the application that must be submitted to MIEMSS prior to institution of an AED Program in your facility.

You are a vital link in the chain of survival by providing rapid defibrillation, the major determinant of successful resuscitative attempts. Your prompt response combined with immediate access to EMS advanced life support personnel will optimize the victim's chances of survival and recovery. I thank you for your interest in the AED program and should you have any questions please do not hesitate to contact Lisa Myers, MIEMSS Office of Program Development, at (410) 706-4740.

Maryland Facility AED Program Requirements

Introduction

The Maryland Institute for Emergency Medical Services (MIEMSS) is pleased to provide you with information about Maryland's automated external defibrillator (AED) Program. The law is intended to apply to a broad range of circumstances: an authorized facility may be a single organization located at one place or a business that operates at several locations (sites). Authorized facilities with multiple sites must determine that each site meets the requirements noted below with an asterisk ("*").

Because the AED is an advanced medical device that should be used only in an emergency by persons who are trained to use the device, specific requirements have been developed for authorized facilities that wish to set up an AED Program. The enclosed information will provide you with a basic understanding of what is needed for an authorized facility to implement an AED Program. Specific regulatory requirements are contained in the AED regulations (see appendix C).

This packet of materials is intended to provide an overview of the requirements of the statute and regulations concerning the use of AEDs at authorized facilities. It is not intended to replace a careful reading of the statute and regulations. Should any discrepancies exist between these materials and the text of regulations, the regulations are binding. Facilities operating AEDs without a valid certificate of authorization or renewal are in violation of Maryland State law.

Program Requirements

The following is a list of the requirements that an authorized facility must meet in order to participate in the AED Program:

1. **Personnel:** Each authorized facility must have a sponsoring physician who agrees to provide medical oversight for the program. One sponsoring physician is all that is required to oversee an authorized facility that has multiple AED sites. To qualify, the physician must be licensed in the state of Maryland. The sponsoring physician is required to complete specific duties outlined in the AED regulations. Each authorized facility's program must also have a designated CPR and AED-trained AED coordinator who is responsible for implementing and administering the program, maintaining necessary records and documentation, reporting use of the AED, facilitating required inspection and maintenance, and other associated program tasks.
   MIEMSS recommends that the number of AED trained individuals at a facility be sufficient to permit the provision of AED care within 5 minutes of an incident.

2. **Registration*:** MIEMSS will register each authorized facility with its closest jurisdictional emergency medical services (EMS) operational program. It is the responsibility of the facility's AED coordinator to contact its closest jurisdictional

(*) Authorized facilities with multiple sites ensure that each site meets the requirement noted.

EMS operational program at the time of AED Program approval to establish an efficient working relationship with the jurisdiction. Collaboration between EMS and AED authorized facilities will help EMS respond appropriately to emergency calls from authorized facilities.

3. **Links to 911*:** It is essential to notify "9-1-1" ***immediately*** when an AED is used at an authorized facility. Therefore, each authorized facility must have an effective means of communicating with "9-1-1," ideally a telephone. In situations when no telephone is available, another means of immediate notification to "9-1-1" should be available, e.g., a two-way radio contacting the facility's switchboard operator who notifies "9-1-1."

4. **Equipment and Maintenance*:** Because most reported AED malfunctions result from failure to perform user-based maintenance of the AED, it is required that authorized facilities adhere to the AED manufacturer's guidelines for maintenance, inspection, and repair of AEDs. This includes daily inspection of the AED and associated equipment, restocking of equipment as needed, replacement/recharging of batteries as needed, and other necessary procedures.
   It is required that this equipment list be kept with each AED daily inspection record.

Required Equipment (Keep with AED at All Times)

- 2 sets of defibrillator chest pads
- 2 pocket facemasks
- disposable gloves
- 2 safety razors (for shaving patient's chest **if necessary** for proper defibrillator pad contact)
- 1 absorbent towel
- 5- 4x4 gauze pads
- 1 extra battery set, if the AED uses replaceable batteries other than long life lithium batteries
- cables (if your AED has removable cables)
- Maryland Facility AED Report Forms for Cardiac Arrests
- A ready-to-use AED should be kept in a closed, intact case with no visible signs of damage that would interfere with its use.

5. **Quality Assurance*:** Documentation of all necessary equipment maintenance, repairs, inspections, etc., is required. Additionally, documentation of all authorized AED user personnel must be maintained. For quality purposes, the following records must be maintained:

(*) Authorized facilities with multiple sites ensure that each site meets the requirement noted.

- A log showing the dates of performance of manufacturer-recommended maintenance, as well as the name of the company performing the maintenance.
- Repairs performed on the AED, as well as the date and name of the company performing the repairs.
- Dates and frequency of routine safety inspection of the AED, documentation of a properly functioning AED, and the individual inspecting the AED (a sample record for daily inspection is included in Appendix A). Documentation must be available verifying the stocking of all required equipment (see checklist above).
- Documentation of all personnel authorized to operate AEDs, including dates of initial training (both AED and CPR), and subsequent required refresher training, as well as current recognition from a MIEMSS- approved AED training program (a form is included in Appendix A).
- Documentation showing the name, address, and telephone number of the sponsoring physician and verification that the physician meets the required qualifications.
- Completed "Maryland Facility AED Report Form for Cardiac Arrests" for each incident requiring AED operation, even if the AED was not discharged (a form is included in Appendix A).
- Mandatory FDA medical products reporting form in the event of an AED malfunction (a form is included in Appendix A; forms may also be accessed at: http://www.fda.gov/medwatch/report/hcp.htm).

6. **Use of an AED*:** Each authorized facility must determine that individuals who will be using the AED meet certain criteria. These criteria include the following:

    - AED operators have knowledge of and immediate access to the Maryland AED protocol mandatory for AED use included in this packet.
    - AED operators and AED coordinators have met all requirements for initial and subsequent refresher training in CPR and AED use through a MIEMSS-approved AED training course prior to using an AED.
    - AED operators are at least 18 years of age, with the exception of persons between the ages of 16 and 18, who need the written permission of a parent or legal guardian.

7. **Compliance:** Entities participating in the AED Program are expected to meet all Program regulatory requirements, in order to provide the safest environment possible for everyone. MIEMSS may perform a compliance review of an authorized facility upon information that the facility has failed to comply with Program requirements. Therefore, it is essential that records are efficiently maintained on MIEMSS forms (included in Appendix A) and are immediately available should inspection become necessary.

(*) Authorized facilities with multiple sites ensure that each site meets the requirement noted.

8. **Application Process*:** Facilities that wish to participate in the AED Program, must complete the enclosed application (included in Appendix A), include the $25 fee, and return it to MIEMSS. Instructions for the application process are included below. MIEMSS may perform inspection of the facility, any sites, equipment, and records to determine that Program applicants meet the AED Program requirements. AED Program applicants meeting the Program requirements will be approved by the EMS Board for a period of 3 years. Applicants not meeting the requirements will be denied and will be given a written explanation stating the reason for denial. Applicants that have been denied may re-apply, or may file an appeal within 20 days of receipt of the EMS Board's decision stating the reason that the Board should reconsider its decision. Applicants filing an appeal will be granted a hearing before the EMS Board or the Office of Administrative Hearings.

9. **Instructions for AED Program Application Process:** Please fully complete and submit the enclosed application according to the AED application instructions in Appendix A along with the $25 application fee, made payable to **"MIEMSS,"** to:

Lisa Myers, Director of Program Development
MIEMSS AED Program
653 West Pratt Street
Baltimore, Maryland 21201

Incomplete applications will not be processed until all information has been submitted.

10. **AED Information:** US Food and Drug Administration AED reports are available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm.

(*) Authorized facilities with multiple sites ensure that each site meets the requirement noted.

Maryland Facility AED Protocol

Indications

- Sudden cardiac arrest (patient without signs of circulation and not breathing).

Contraindications

- Children under age 8 (estimate based upon information available to individual operating AED).
- Patient is breathing, responsive, speaking, or making intentional movements.

Potential Adverse Effects/Complications

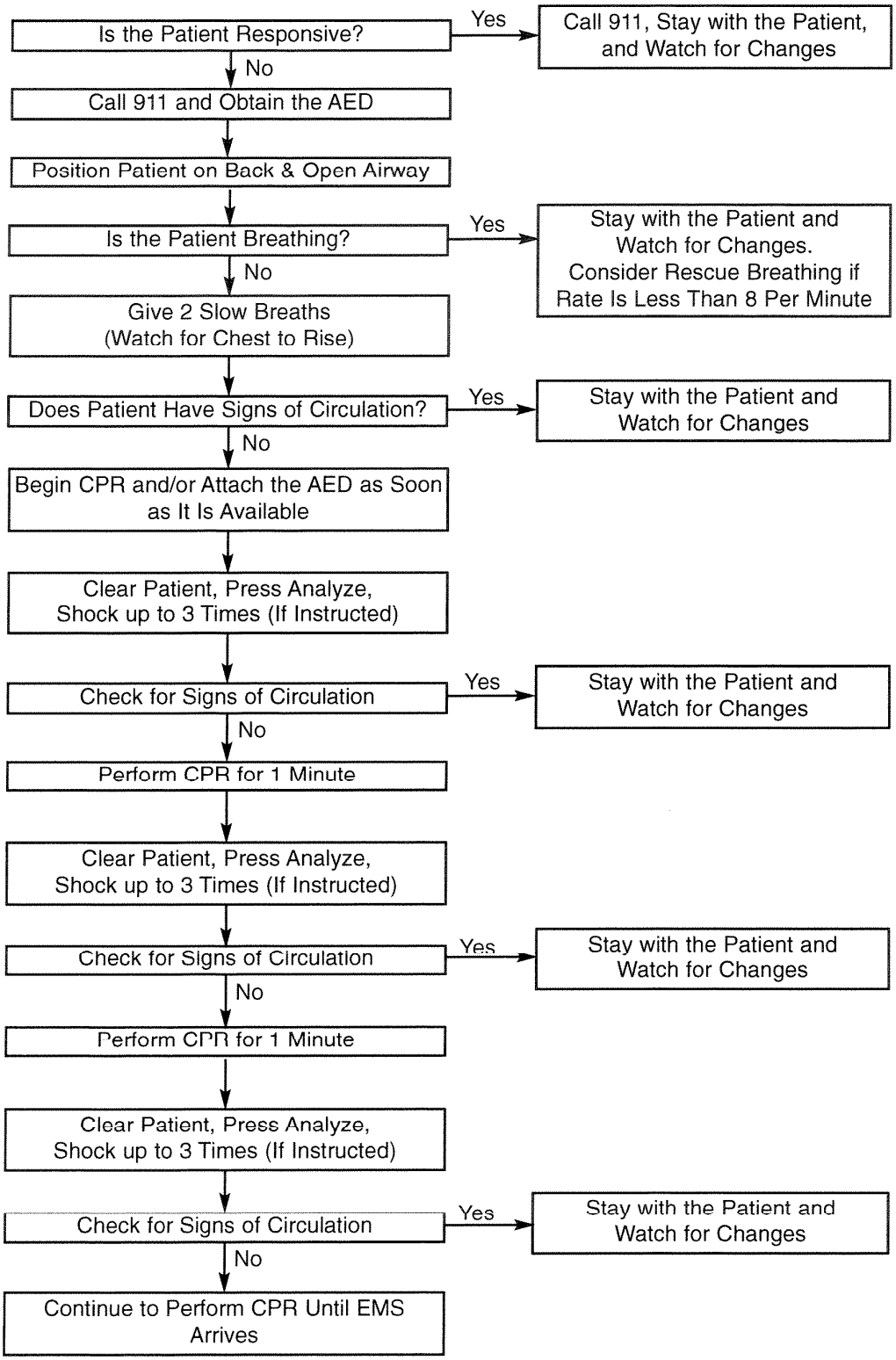
- Burns to the skin.
- Deactivation of the patient's implanted pacemaker.
- Injury to the patient, self, and/or bystanders.

Precautions/Critical Concepts

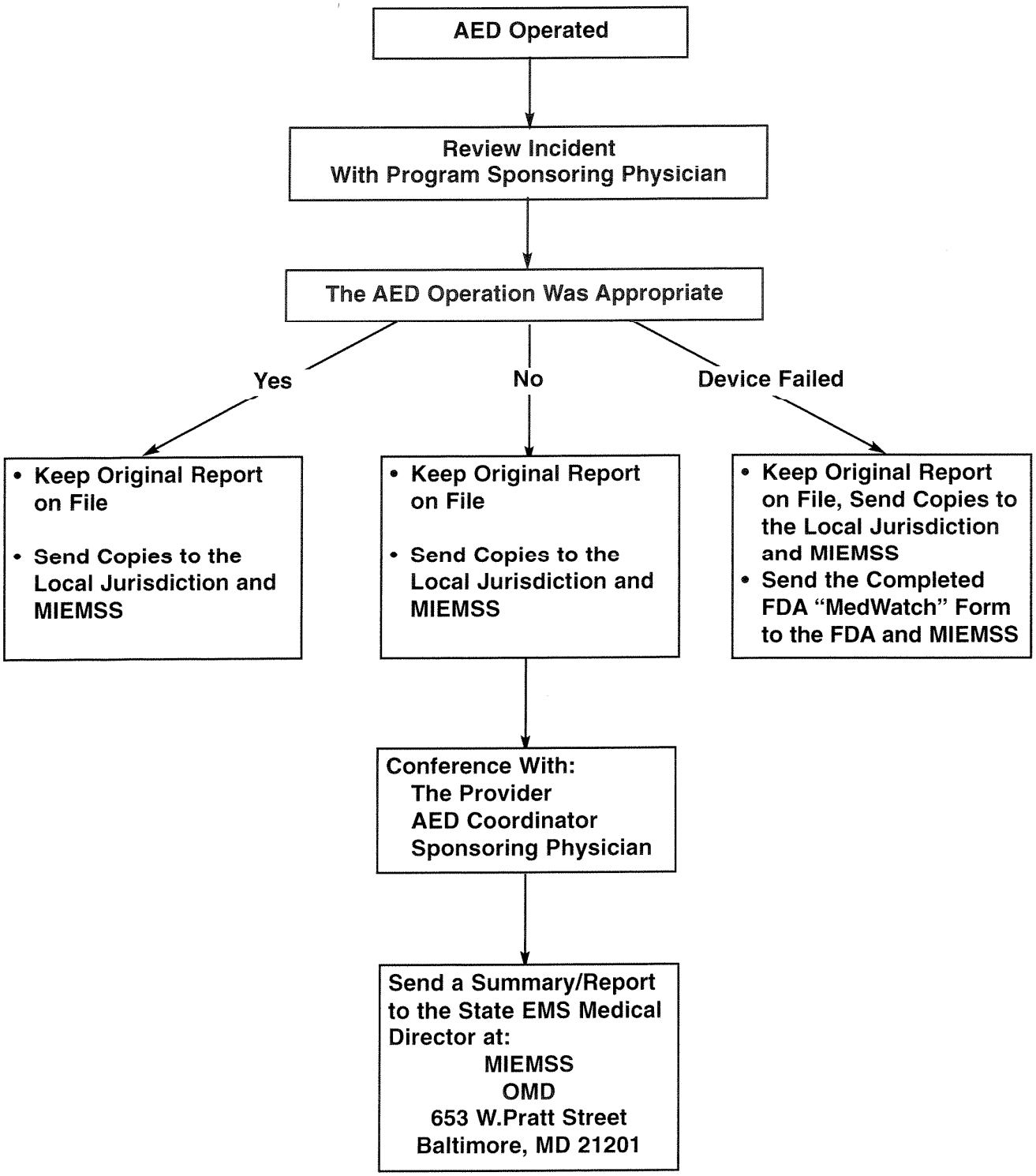
- **Wet conditions** – Make sure the patient and environment are dry (this includes removing nitroglycerin paste from the chest with a dry cloth).
- **Metal surfaces** – Make sure the patient is not touching any metal surfaces.
- **Combustible materials or hazardous (explosive) environment** – Remove the patient, if possible, from an area that presents a hazard.
- Do not touch the patient while the AED is assessing, charging, or shocking the patient.
- Ensure the patient is "clear" (no one is touching the patient) when the shock is delivered.
- If the patient has an internal pacemaker/defibrillator, position the pad one hand's width (approximately 5 inches) from the pacemaker/defibrillator site. If the patient has a nitroglycerin patch, position the pads away from the patch.
- Never defibrillate while moving the patient.
- Location of the AED(s) should provide optimal accessibility to the maximum number of individuals and authorized operator(s) at the facility. Upon placement of the AED, please consider the following:

  1. No obstacles are in the way of the AED.
  2. Avoid locked doors preventing quick access to the AED.
  3. Areas of the facility with large numbers of high risk individuals.
  4. Length of time and distance to access the AED.
  5. The AED is placed in a location clearly visible to the authorized operators.

Automated External Defibrillator Algorithm



Automated External Defibrillator Quality Review Procedures



APPENDIX A

Enclosed Forms

The following forms are included in appendix A of this packet and may be copied for authorized facilities to use when implementing an AED program:

- Application for participation in AED Program (return to MIEMSS)
- Application Form Instructions
- List of AED Site Location Types
- Multiple AED site form (facilities with more than one AED site, complete and return to MIEMSS)
- AED Sponsoring Physician Directory
- List of Approved AED TRaining Programs
- Operator Training Recognition Form
- Permission slip for minors to operate AED
- MIEMSS Maryland Facility AED Report form and Instructions for completion (return **a copy** to MIEMSS for each cardiac arrest incident)
- FDA mandatory equipment malfunction reporting form (submit to FDA with a copy to MIEMSS for any AED malfunction)
- AED daily safety inspection record

Additional forms may be downloaded from the MIEMSS web-site http://miemss.umaryland.edu/AED

STATE OF MARYLAND
MARYLAND INSTITUTE FOR EMERGENCY MEDICAL SERVICES SYSTEMS
653 West Pratt Street • Baltimore, Maryland 21201 – 1536 • (410) 706-4740

APPLICATION FOR PARTICIPATION IN MARYLAND FACILITY AED PROGRAM

Name of Applicant _____

Applicant Address: _____

_____

Name of Primary Facility: _____

Facility Address: _____

_____

Facility County: _____ **Number of AEDs:** _____

Number of Sites: _____ *(please complete multiple site form for more than 1 site)* _____

Facility Location

Type(s): _____

Number of Employees: _____ **Number of Employees Currently Trained in AED Use:** _____

Total Anticipated Number of Employees to be Trained in AED Use: _____

AED Coordinator: _____ **Phone:** (____) _____ - _____
(Name) (Title)

AED Coordinator Address: _____
(If different than Facility Address)

Coordinator's AED Training Program: _____ **Date Completed:** ___/___/___

Name of Sponsoring Physician: _____ **Maryland License #:** _____

Address: _____ **Phone:** (____) _____ - _____
(If different than Facility Address)

Describe: AED Type, Brand, and Year: _____
(MIEMSS recommends use of semi-automated AEDs)

Are there any unusual hazards at your facility? ..... ❑ Yes ❑ No (over)

If "Yes", please check all that apply: ..... ❑ Combustible Materials ❑ Wet Surfaces
❑ Metal Surfaces ❑ Other

Describe AED safety measures developed for any hazards: (*please use additional pages as needed*)

_____

_____

_____

_____ **Please check if this application is for renewal of an existing AED Program. If yes, please indicate current certificate expiration date** _____/_____/_____.

Your signature on this application represents the commitment by your facility to follow MIEMSS Maryland Facility AED Protocol, developed to provide maximum safety to all individuals concerned in the event of a cardiac emergency, and to the best of your knowledge, assures that all information in this AED application packet is true. Return completed application and $25 check (payable to "MIEMSS"), to Lisa Myers, Director of Program Development, at the above address.

AED Coordinator: _____ **Date:**_____/_____/_____
(Signature)

Sponsoring Physician: _____ **Date:**_____/_____/_____
(Signature)

For MIEMSS use Only
Application Approved/Denied/Renewed (circle one) by EMS Board Date: _____/_____/_____ **Cert. #** _____

MIEMSS Reviewer _____ **Date:** _____/_____/_____

AED Application Instructions

Please complete both sides of the application as well as the multiple sites form if necessary. Incomplete applications cannot be processed and will be returned to the applicant.

1. **Applicant name and address.** The name and address of the organization, entity, business, etc. applying to the Maryland Facility AED Program.
2. **Name of primary facility** or location where AED will be located **if different than applicant name and address.** Please indicate the total number of sites and complete the multiple sites form if there will be more than one site address where AEDs will be located.
3. **Number of AEDs.** Indicate the number of AEDs that will be located at the primary facility. If multiple sites will be included, indicate the number of AEDs per site on the multiple site form.
4. **Facility county.** Indicate the county of the primary facility. If multiple sites will be included, indicate the county of each site address on the multiple sites form.
5. **Facility location type.** From the list of AED Site Location Types, please list the facility location type for the primary facility. Please choose as many location types as apply. If multiple sites will be included, indicate the location type of each site address on the multiple sites form.
6. **Number of employees.** Please list the number of employees or estimate of the number of individuals that are typically present during the hours of operation at the primary facility and each AED site address if applicable. Use the multiple sites form if needed.
7. **Number of employees trained.** Please list the number of employees or estimate of the number of individuals that are typically present during the hours of operation at the primary facility and each AED site address if applicable who have been trained to use an AED. Use the multiple sites form if needed.
8. **Anticipated number of employees to be trained.** Please list the number of employees or estimate of the number of individuals that are typically present during the hours of operation at the primary facility and each AED site address if applicable who will been trained to use an AED. Use the multiple sites form if needed.
9. **AED coordinator.** Please list the name of the individual that will be responsible for the AED Program. The AED coordinator is the person that will receive the program approval notification and certificate and all other communications and notifications from MIEMSS. Please include the mailing address for the AED coordinator if different from the primary facility address as well as the current telephone number and extension.
10. **AED coordinator training program.** In order for the application to be processed and the facility approved for AED use, the AED Coordinator must have completed a nationally recognized AED training course. Please see appendix A for a list of current nationally recognized training programs. **Please list the name and date of completion of the nationally recognized training program (e.g., AHA Heartsaver AED) and not the name of the individual or company where training was received.**

11. **Sponsoring physician.** Please include the name, address, telephone number and Maryland license number of the AED program sponsoring physician for your facility.
12. **AED type.** Please list the type, brand, and year of the AED purchased. The only AED purchase requirement for participation in the Maryland Facility AED Program is that the AED is an FDA approved device.
13. **Hazards.** Please list any hazards that may exist at your facility and precautions in place to address them.
14. **Renewals.** Please indicate if the application is for renewal of an existing AED program and list the current certificate expiration date.
15. **Signatures.** The AED coordinator and sponsoring physician must both sign and date the application. Applications that are not signed and dated or are incomplete will be returned.
16. **Submission of forms.** Mail the application, multiple sites form and $25 check payable to MIEMSS, to Lisa Myers at MIEMSS 653 West Pratt Street, Baltimore Maryland 21201.

Application processing and approval takes approximately 2-4 weeks.

AED Site Location Type

Residential
Senior Living Housing
Other

Transportation Related
Airport – BWI
Airport – Other
Bus Station
Train Station
Street / Highway
Public Transportation
Other

Building
Government Admin. Building
Public Building (non – Gov't)
Industrial Place and Premises
Restaurant / Bar
School / Educational Facility
Church
Hotel / Motel
Retail Stores (enclosed mall)
Retail Store (not in enclosed mall)
Jail / Correctional Facility
Convention Center
Courthouse
Other

Recreation
Stadium
Racecourse / Racetrack
Amusement Park
Theatre / Cinema
Health Club
Golf Course
Public Beach
Park
Museum
Other

Medical Facilities
Rehab Facility (outpatient)
Physician or Dentist Office
Dialysis Center
Urgent Care Facility
Other

Mobile Units
Law Enforcement Officer Vehicles
Emergency Roadside Assistance
Other

Multiple AED Sites

1. Name of Site _____

Address _____

City _____ **State** _____ **Zip Code** _____

County *(if different than main facility)* _____

Telephone (area code) + Number _____

# of Individuals Trained _____

# of AEDs _____ **Location Type** _____

2. Name of Site _____

Address _____

City _____ **State** _____ **Zip Code** _____

County *(if different than main facility)* _____

Telephone (area code) + Number _____

# of AEDs _____ **Location Type** _____

# of Individuals Trained _____

3. Name of Site _____

Address _____

City _____ **State** _____ **Zip Code** _____

County *(if different than main facility)* _____

Telephone (area code) + Number _____

# of AEDs _____ **Location Type** _____

# of Individuals Trained _____

Facilities with an AED at more than one site must provide the above information for all sites. Please complete and return this form to MIEMSS with the facility application form and $25 fee.

AED Sponsoring Physician Directory

The following individuals and entities may be available to provide medical oversight to facility AED programs. Facilities are not required to utilize physicians from this list. Physician fees and service terms are negotiated exclusively between facilities and physicians.

1. Mark Milner, MD (301) 214-4344 (Montgomery County Only)

2. David Hexter, MD (410) 392-7005 (Cecil County Only)

3. Dewitt Charles Fortenberry, MD (301) 879-2836

4. Andrew Pollak, MD (410) 328-6040

5. Cliff Turen, MD (410) 328-6040

6. Arjun Chanmugam, MD (410) 955-8708

7. Eric Nager, MD (410) 625-9491

8. Mid Atlantic Cardiovascular Associates
Contact: Dr. Stephen Pollock (410) 583-1170

9. LifeLinkMD (202) 955-0000
Offers services to Medtronic Physio-Control LIFEPAK 500 customers.

10. MD Solutions (206) 781-8770
Offers service to Heartstream FR2 customers but will accept customers that have previously purchased from other companies.

11. Rescue One (301) 570-6675
Complementary physician oversight for facilities receiving training through this company.

12. Lifework, Inc. (410) 418-4989
Medical Direction, training, and AED sales.

13. Complient (410) 404-0680
Offers AED sales and services, including physician oversight to facilities regardless of brand of AED previously purchased.

14. CSI Cardiac Science Total Management Solution (410) 908-8793
Medical direction and other services available to facilities for Cardiac Science or other AED brands.

15. First Response (301) 780-3424
Offers medical direction and training to facilities regardless of AED brand purchased.

Last Updated on 11/10/03

Automated External Defibrillator Training Programs

1. American Safety & Health Institute
   8324 Corporate Way
   New Port Richey, Florida 34653
   Contact Gregg Rich (727) 817-1140 x204

2. American Red Cross
   4700 Mount Hope Drive
   Baltimore, Maryland 21215
   Contact Bob Hoguet (410) 764-7000 x7100

3. American Heart Association
   4217 Park Place Court
   Glen Allen, Virginia 23060
   Contact Kami Hodges (804) 965-6561

4. National Safety Council of Maryland
   17 Governor's Court
   Baltimore, Maryland 21244
   Contact Patricia Raven (410) 298-4770

5. Maryland Fire & Rescue Institute
   University of Maryland
   Special Programs Section
   College Park, Maryland 20742
   Contact Elizabeth Harman (301) 226-9940

6. EMP America
   500 Danebo Avenue
   Eugene, Oregon 97402
   Contact William Rowe (541) 344-7099

Programs out of state will direct you to the local contact person in your area.

AED Operator Training Recognition

Please complete and maintain the following information for each AED authorized operator at your facility.

Operator Name: _____

Age: _____ **Title:** _____

Name of AED Training Program: _____

Date Completed: _____ **Refresher Training:** ____**Yes** ____ **No**

Name of Refresher Course: _____ **Date:** _____

Name of CPR Training Program: _____

Date Completed: _____ **Refresher Training:** ____ **Yes** ____ **No**

Name of Refresher Course: _____ **Date:** _____

Signature of Operator _____ **Date:** _____

Signature of AED Coordinator _____ **Date:** _____

The above signatures verify that AED operator is currently recognized by a MIEMSS approved AED Program.

Permission for Minor* to Operate Automated External Defibrillator (AED)

I, (please print name of parent or guardian) _____,

give permission for my child (please print name of minor) _____,

to operate an automated external defibrillator, in the event of an emergency at

(please print name of work facility) _____,

during his/her time on duty.

Signature of parent or guardian _____

Date _____

***A minor is defined as an individual between the ages of 16 and 18.**

CONFIDENTIAL

For Official Use Only
M-CAPD #_____
Facility CA Form #_____
MAIS Form #_____

MARYLAND FACILITY AED REPORT FORM FOR CARDIAC ARRESTS

To be completed immediately after a cardiac arrest occurs at your facility or the facility AED is put on a patient
Form should be filled out by the main caregiver at the scene & the Facility AED Operator and returned to MIEMSS **within 48 hours**
Please Return Completed Form with your AED Summary Report and copy of FDA Incident Form (if applicable) to:
Maryland Institute for Emergency Medical Services Systems (MIEMSS)
653 West Pratt Street Baltimore MD 21201 Attention: Epidemiology / M-CAPD Study
Fax: (410) 706-4366

1.Facility Name: _____

2.Incident Location: _____
Street address

_____
City *State* *ZipCode* *County*

3. Date of Incident: ___ ___/___ ___/___ ___
Mo. *Day* *Yr.*

4.Estimated Time of Incident: _____:_____ a.m. /p.m. 4a.Estimated Time that 911 Call was placed: _____:____ a.m. / p.m.
Hr. *Min.* *Hr.* *Min.*

5. Name of Patient:_____
First *Middle* *Last*

6. Patient Gender: Male[ ] Female[ ] 7. Estimated Age of Patient: _____Yrs.

8. Did the patient collapse (become unresponsive)? Yes[ ] No[ ]

8a. If Yes, what were the Events immediately prior to the collapse (check all that apply):
Difficulty Breathing [ ] Chest Pain [ ] No Signs or Symptoms[ ] Drowning [ ]
Electrical Shock [ ] Injury [ ] Unknown [ ]

8b.Was someone present to see the person collapse? Yes[ ] No[ ]
If yes, was that person a trained AED Employee? Yes[ ] No[ ]

8c. After the collapse, at the time of Patient Assessment and just prior to the Facility AED pads being applied,
Was the person breathing? Yes[ ] No[ ]
Did the person have a pulse? Yes[ ] No[ ]

9. Was CPR given prior to 911 EMS arrival? Yes[ ] Go to #9a No[ ] Go to #10
9a.Estimated time CPR Started: _____:_____a.m. / p.m.
Hr. *Min.*
9b. Was CPR started prior to the Arrival of a Trained AED Employee? Yes[ ] No[ ]
9c.Who Started CPR? Bystander[ ] Trained AED Employee[ ]

10. Was a Facility AED brought to the patient's side prior to 911 EMS arrival? Yes[ ] No[ ]
10a. If No, Briefly describe why and skip to question 17:_____
10b. If Yes, Estimated Time (based on your watch) Facility AED at patient's side: _____:_____a.m. /p.m.
Hr. *Min.*

TURN OVER and COMPLETE BOTH SIDES

CONFIDENTIAL

11. Were the Facility AED Pads put on the patient? Yes[ ] No[ ]

11a. If Yes, Was the person who put the AED pads on the patient a:
Trained AED Facility Employee[ ] Untrained AED Facility Employee[ ] Bystander[ ]

12. Was the Facility AED turned on? Yes[ ] No[ ]

12a. If Yes, Estimated Time (based on your watch) Facility AED was turned on: _____:_____a.m. /p.m.
Hr. Min.

13. Did the Facility AED ever shock the patient? Yes[ ] No[ ]

If Yes,
13a. Estimated time (based on your watch) of 1st shock by facility AED: _____:_____a.m. / p.m.
Hr. Min.
13b.If shocks were given, how many shocks were delivered prior to the EMS ambulance arrival? #_____

14. Name of Person operating the Facility AED:_____
First Middle Last

14a. Is this person a trained AED employee? Yes[ ] No[ ]
14b. Highest level of medical training of person administering the Facility AED:
Public AED Trained [ ] First Responder AED Trained [ ] EMT-B [ ] CRT/EMT-P [ ]
Nurse/Physician [ ] Other Health Care Provider [ ] No Known Training [ ]

15. Was there any mechanical difficulty or failure associated with the use of the Facility AED? Yes[ ] No[ ]
15a. If Yes, Briefly explain and attach a copy of the completed FDA reporting form (required by Federal law).

_____

_____

16. Were there any unexpected events or injuries that occurred during the use of the Facility AED? Yes[ ] No[ ]

16a. If yes, Briefly explain:_____

_____

17.Indicate the patient's status at the time of the 911 EMS arrival:

Hr. Min.
17a. Pulse restored: Yes [ ] No [ ] Don't Know [ ] If Yes, Time Pulse Restored: __ __:__ __
17b. Breathing restored: Yes [ ] No [ ] Don't Know [ ] If Yes, Time Breathing Restored: __ __:__ __
17c. Responsiveness restored: Yes [ ] No [ ] Don't Know [ ] If Yes, Time Patient Responsive: __ __:__ __

18. Was the patient transported to the hospital? Yes[ ] No[ ]
18a. If Yes, How was the patient transported? EMS Ambulance[ ] Private Vehicle[ ] Other_____

Report Completed by:_____
Please Print Name *Date*

_____
Signature *Date*

_____ _____
Title *Office Phone*

Make/Model of the Facility AED that was used?_____
Manufacturer Make *Model #*

RETURN TO MIEMSS WITHIN 48 HOURS FOLLOWING INCIDENT: FAX (410) 706-4768
PLEASE FORWARD QUESTIONS TO YOUR FACILITY AED COORDINATOR
JANICE WHITE AT MIEMSS (410) 706-4366

Maryland Facility AED Report Form for Cardiac Arrests

All facilities registering with MIEMSS for Public AED use will be required to fill out a Facility AED Report Form when:

1. A suspected Cardiac Arrest occurs at your facility whether or not the AED was applied; OR
2. Any time the Facility AED pads are put on a person (regardless of the person's medical condition). This includes the use of a Facility AED for any reason by either an authorized employee or an unauthorized person.

WHEN DOES THE REPORT NOT NEED TO BE FILLED OUT?

The report does not need to be filled out for non-cardiac related false alarms when the AED is retrieved but the pads are not applied. (Example: A customer feels ill and the AED is brought to the patient's side. The caregiver at the scene does not put the AED pads on the patient because the patient is not suspected of having a cardiac arrest.)

WHO SHOULD FILL OUT THE REPORT?

The report form should be filled out immediately after an incident occurs at your facility ***by the main Facility Caregiver at the scene and the Facility AED Operator*** (if a different person). The main Facility Caregiver at the scene is defined as the facility employee who begins the resuscitation process prior to the Facility AED operator arriving. In some circumstances, the Facility Caregiver and the Facility AED Operator may be the same person. If the person initiating resuscitation is not a facility employee, then the Facility AED Operator should be the person who fills out the form. The facility is not responsible for tracking down bystanders who are active in the resuscitation process. However, the report form should accurately reflect that a bystander and not a facility employee initiated the CPR process. The Facility AED Coordinator should review the report and help clarify any questions that the caregiver may have concerning the report.

WHAT IS THE TIME FRAME FOR FILLING OUT THE REPORT & SENDING IT BACK TO MIEMSS?

The report should be ***filled out immediately following the incident*** so that the information is still fresh in the mind of the main Facility Caregiver and the Facility AED Operator. If the caregiver has questions about the form, he/she will have 48 hours to consult with the Facility's AED Coordinator. The AED Coordinator is responsible for seeing that the report is ***returned to MIEMSS within 48 hours following the incident.***

WHO WILL SEE THIS REPORT?

This is a confidential report. The AED Coordinator should keep the original copy on file at the facility and a copy should be sent to MIEMSS for quality control purposes. ***It will be viewed only by the main Facility Caregiver at the incident, the Facility AED operator (if different from the main Facility Caregiver), the Facility AED Coordinator, and MIEMSS.*** MIEMSS will use the report for quality assurance and research purposes only.

WHAT IS THE RESPONSIBILITY OF THE FACILITY'S AED COORDINATOR REGARDING THE REPORT FORM?

1. The Facility AED Coordinator should answer any questions the main caregiver/AED operator has when filling out the form. Any further questions should be directed to Janice White at MIEMSS (410) 706-4193.
2. The Facility AED Coordinator is responsible for seeing the form is fully completed. The AED Coordinator must return to MIEMSS within 48 hours of the incident:
   - A copy of the Facility AED Report Form
   - A copy of the AED Summary Report (internal report generated from the facility AED) and
   - A copy of the FDA Incident Form (if applicable).
3. The Facility AED Coordinator is responsible for keeping on file at the facility: the original AED Report Form, a copy of the AED Summary Report and a copy of the FDA Incident Form (if applicable). Because these are confidential reports, the facility file should be in a secure room and locked.

WHERE DO I SEND THE MIEMSS REPORTS?

The forms can be returned to MIEMSS by either Fax or Express Mail.

MIEMSS Fax: (410) 706-4366 OR Express Mail to MIEMSS: 653 West Pratt Street
Baltimore MD 21201
Attention: Epidemiology / M-CAPD Study

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

Mfr Report #
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
- ☐ Death: ____ *(mo/day/yr)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability
- ☐ Congenital Anomaly
- ☐ Required Intervention to Prevent Permanent Impairment/Damage
- ☐ Other: ____

3. Date of Event *(mo/day/year)*	4. Date of This Report *(mo/day/year)*

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

C. SUSPECT MEDICATION(S)

1. **Name** *(Give labeled strength & mfr/labeler, if known)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # *(if known)*	7. Exp. Date *(if known)*	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC#** *(For product problems only)*
– –

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Type of Device**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mo/day/yr)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mo/day/yr)*	7. If Explanted, Give Date *(mo/day/yr)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mo/day/yr)*

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3500A (9/03)

Medication and Device Experience Report

(Continued)

Refer to guidelines for specific instructions.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA USE ONLY

Page ____ of ____

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☐ User Facility ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mo/day/yr)*

7. **Type of Report**
☐ Initial
☐ Follow-up # ____

8. **Date of This Report** *(mo/day/yr)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. **Report Sent to FDA?**
☐ Yes ____ *(mo/day/yr)*
☐ No

12. **Location Where Event Occurred**
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. **Report Sent to Manufacturer?**
☐ Yes ____ *(mo/day/yr)*
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other: ____

4. **Date Received by Manufacturer** *(mo/day/yr)*

5.
(A)NDA # ____
IND # ____
PLA # ____
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 15-day
☐ 10-day ☐ Periodic
☐ Initial ☐ Follow-up # ____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. **Device Manufacture Date** *(mo/yr)*

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other: ____

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

AED Daily Safety Inspection Record for: (month)_____

Date (Daily)	Inspector Initials	Carrying Case Intact	Battery Charged; "Ready for Use"	All Equipment is in Carrying Case

***Please complete a separate record for each AED.**

APPENDIX B

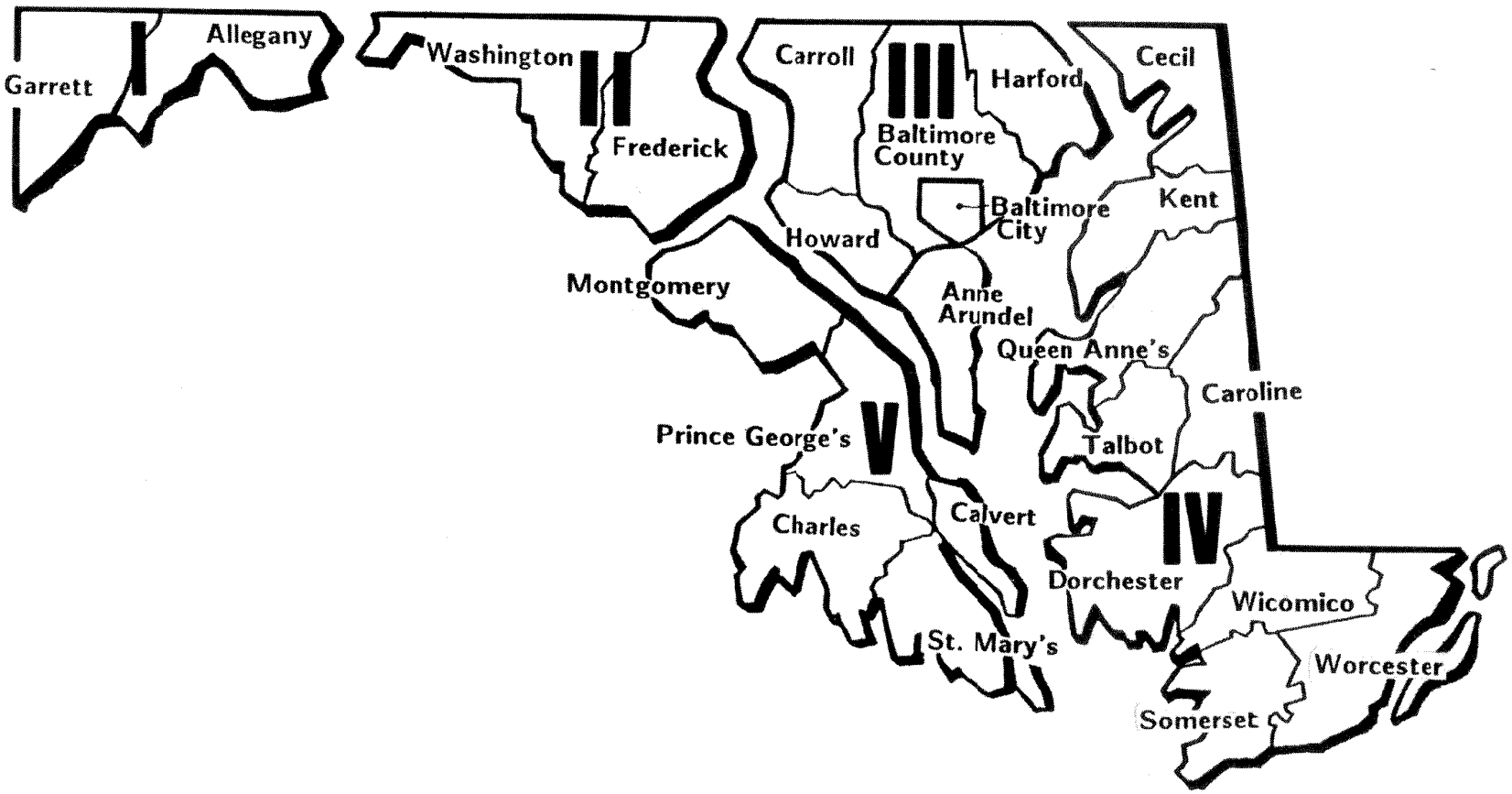
The Maryland EMS System

Maryland's Emergency Medical Services (EMS) System is coordinated by the Maryland Institute for Emergency Medical Services Systems (MIEMSS). The EMS system is comprised of educated career and volunteer fire and rescue personnel, as well as several levels of certified/licensed EMS providers. Basic life support care is provided by First Responders and Emergency Medical Technician-Basics, while Cardiac Rescue Technicians and Emergency Medical Technician-Paramedics provide advanced life support care. EMS is accessed by dialing 9-1-1, the universal link to multiple emergency resources across the state, Emergency Medical Dispatchers answer 9-1-1 calls, medically prioritize them, and dispatch the appropriate fire, law enforcement and emergency medical units based on the medical needs identified. Upon arrival at the scene, the EMS provider initiates care based on the Maryland Medical Protocols for EMS Providers and then determines and transports the patient to the most appropriate hospital, trauma center, or specialty center based on the type and severity of the injury or illness and the incident location.

Maryland's EMS System is divided into five EMS regions across the state. Regional boundaries are based on geographic considerations and traditional EMS delivery areas (see attached map). The regions are further divided into jurisdictions (23 counties, Baltimore City, and Annapolis) addressing needs specific to the patients and providers in that area. Each region has a "regional" medical director, and each jurisdiction has a "jurisdictional" medical director responsible for medical oversight in his/her area. The MIEMSS regional administrators act as liaisons between MIEMSS and local EMS agencies, hospitals, and the community.

Through the cooperation of prehospital providers, jurisdictional authorities, hospital administrators and medical staff, MIEMSS, and government agencies, Maryland has one of the premier systems in the world.

MARYLAND EMS REGIONS



APPENDIX C

SUBTITLE 06 AUTOMATED EXTERNAL DEFIBRILLATOR PROGRAM
CHAPTER 01 DEFINITIONS.

01 Definitions.

A. In this subtitle, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Approved training program" means an organization, business, association, or agency that has been approved by MIEMSS to provide AED training for individuals who will operate the device at authorized AED facilities.

(2) Authorized Facility.

(a) "Authorized facility" means an organization, business, association, or agency that meets the requirements of the EMS Board for providing automated external defibrillation.

(b) "Authorized facility" may include multiple sites.

(3) "Automated external defibrillator (AED)" means a medical heart monitor and defibrillator device that:

(a) Is cleared for market by the federal Food and Drug Administration;

(b) Recognizes the presence or absence of ventricular fibrillation or rapid ventricular tachycardia;

(c) Determines, without intervention by the operator, whether defibrillation should be performed;

(d) On determining that defibrillation should be performed, automatically charges; and

(e) Either:

(i) Requires operator intervention to deliver the electrical impulse, or

(ii) Automatically continues with delivery of electrical impulse.

(4) "Cardiopulmonary resuscitation (CPR) training" means training in adult cardiopulmonary resuscitation which, at a minimum, includes:

(a) Patient assessment;

(b) Mouth-to-mouth breathing;

(c) Mouth-to-mask breathing;

(d) Chest compressions; and

(e) Relief of foreign body airway obstruction on an unconscious and conscious patient.

(5) "Event (code) summary" means the electronic report of an AED operation produced by an AED.

(6) "Facility" means an agency, association, corporation, firm, partnership, or other entity.

(7) "Medical direction" means the medical oversight, including quality assurance, planning, and education, provided by a sponsoring physician to an authorized facility.

(8) "Nationally recognized AED instructor training program" means an organization determined by MIEMSS to:

(a) Be nationally recognized as having the resources, experience, and expertise to:

(i) Set minimum standards for the instruction in operation of an AED, and

(ii) Provide adequate quality assurance of its instruction and instructors;

(b) Have a valid, reliable instrument for the evaluation of the training of persons in instruction in the use of an AED; and

(c) Have affiliates, members, or persons whom it officially recognizes as meeting its standards in at least 26 states, and whose members meet specified qualifications.

(9) "Nationally recognized AED training program" means an organization determined by MIEMSS to:

(a) Be nationally recognized as having the resources, experience, and expertise to:

(i) Set minimum standards for training in the operation of an AED, and

(ii) Provide adequate quality assurance of its instruction and instructors;

(b) Have a valid, reliable instrument for the evaluation of the training of persons in the operation of an AED; and

(c) Have affiliates, members, or persons whom it officially recognizes as meeting its standards in at least 26 states and whose members meet specified qualifications.

(10) "Operate" means to use or attempt to use an AED to defibrillate an individual whether or not any electrical impulse is delivered.

(11) "Public safety answering point (PSAP)" has the meaning stated in Article 41, § 18-101(f)(5), Annotated Code of Maryland.

(12) "Response" means the removal of the AED from its storage location for the purposes of rendering care whether or not the care is actually rendered.

(13) "Site" means a building, plant, unit, branch, vehicle, or other ancillary location that is part of or affiliated with a facility.

(14) "Sponsoring physician" means a physician who:

(a) Is licensed to practice medicine under Health Occupations Article, Title 14, Annotated Code of Maryland;

(b) Provides medical direction to an authorized facility; and

(c) Meets the qualifications established by the EMS Board.

.02 Criteria for Authorization of Facilities.

To be eligible for authorization, or renewal of authorization, to operate an AED under this subtitle, an authorized facility shall:

A. Have a sponsoring physician:

(1) Who meets all requirements of COMAR 30.06.03.02B; and

(2) Whose duties and responsibilities meet the requirements of COMAR 30.06.03.02C;

B. Designate an AED coordinator who shall:

(1) Either:

(a) Be certified or licensed in Maryland as an EMS provider other than a first responder or emergency medical dispatcher; or

(b) Have successfully completed either:

(i) An AED training course, incorporating CPR training, provided by an approved AED training program, or

(ii) An AED training course provided by an approved AED training program and, before enrollment in the AED training course, CPR training;

(2) Successfully complete refresher training for CPR and AED required under COMAR 30.06.05; and

(3) Be responsible for implementing and administering the AED program at the authorized facility in compliance with this subtitle;

C. Provide an orientation to the operation, maintenance, and location of the authorized facility's AEDs to all individuals who will be authorized to operate an AED for the authorized facility;

D. Implement a quality assurance and maintenance program at each site at which the AED is operated which meets the requirements of COMAR 30.06.04;

E. Adopt written operational policies and procedures regarding the operation and maintenance of the AED at each site at which an AED is operated which shall be subject to and available for inspection by MIEMSS;

F. Place all AEDs in locations which comply with the requirements of the AED protocol in COMAR 30.06.03.03;

G. Have a telephone or other communication service available at all times at each site at which an AED is operated, for the notification of the public safety answering point;

H. Submit data or other information concerning the AED program which may be periodically requested by MIEMSS; and

I. Require that all individuals operating an AED for the facility:

(1) Follow the protocol in COMAR 30.06.03.03 whenever operating an AED for the facility; and

(2) Are 18 years old or older, except that an individual who is 16 or 17 years old may be authorized to operate an AED with written permission from a parent or legal guardian [.] ; and

J. Provide scenario-based practice drills for all individuals operating an AED for the facility every 12 months at a minimum unless providing AED refresher training consistent with the requirements of an approved AED training program annually.

.03 Application and Authorization Process

A. A facility that operates AEDs as of October 1, 1999, may continue until MIEMSS has completed the authorization process with respect to that facility, if the facility applies to be an authorized facility within 90 days of the adoption of this regulation.

B. A facility seeking authorization or renewal of authorization shall:

(1) Submit an application and all required documentation to MIEMSS on the form required by MIEMSS; and

(2) Pay the required fee of $25 for:

(a) Initial authorization, or

(b) Renewal.

C. MIEMSS may make the inspection and require the verification as necessary to ensure that an applicant meets the requirements of this chapter, including an inspection of the facility, any sites, equipment, and records.

D. MIEMSS shall issue a certificate of authorization or renewal to a facility that meets the requirements of Regulation .01 of this chapter.

E. The certificate of authorization or renewal is valid for a period of 3 years.

.04 Denial of Authorization.

A. MIEMSS may deny an application if it finds that the applicant fails to meet the requirements of this chapter.

B. Notice of Denial.

(1) MIEMSS shall issue a written notice of denial to an applicant that includes the reasons for denial.

(2) The notice shall conform to the requirements of State Government Article, § 10-207, Annotated Code of Maryland.

C. An applicant denied approval may file an appeal with the EMS Board under Regulation .05 of this chapter.

D. If an applicant does not file a timely appeal under Regulation .05 of this chapter, the decision is final.

E. If an application is denied, the applicant may reapply under this chapter.

.05 Compliance

A. MIEMSS may initiate a compliance review of an authorized facility upon information that the authorized facility has failed to comply with this subtitle.

B. MIEMSS shall give written notice of the compliance review to the authorized facility.

C. In the course of its compliance review, MIEMSS may:

(1) Inspect all:

(a) Sites where the authorized facility maintains an AED,

(b) Records relating to the AED and supplemental equipment,

(c) Records relating to the CPR and AED training of all personnel authorized to operate an AED at the facility,

(d) Records relating to the operation of an AED, and

(e) Equipment related to the AED; and

(2) Interview employees of the authorized facility regarding the AED program.

D. If MIEMSS finds that an authorized facility has failed to comply with this subtitle, MIEMSS may:

(1) Suspend the facility's authorization;

(2) Revoke the facility's authorization;

(3) Refuse to renew a facility's authorization; or

(4) Take other action as appropriate.

E. Within 30 days after the conclusion of the compliance review, MIEMSS shall provide its findings, decision and any proposed action in writing to the:

(1) Authorized facility; and

(2) EMS Board.

F. The report shall:

(1) Conform to the requirements of State Government Article, § 10-207, Annotated Code of Maryland; and

(2) Contain the reasons for the decision and the proposed action.

G. Upon receipt of the report and proposed action, an authorized facility may file an appeal with the EMS Board under Regulation .05 of this chapter.

H. If an applicant does not file a timely appeal under Regulation .05 of this chapter, MIEMSS' proposed decision is final.

.06 Procedure for Appeals.

A. An applicant or authorized facility may appeal a disputed decision by filing a notice of appeal to the EMS Board with the Executive Director of MIEMSS not later than 20 days after receipt of the decision.

B. The appeal shall state with specificity the reasons why the disputed decision should be modified.

C. An applicant or authorized facility that files an appeal shall be granted a hearing before the:

(1) EMS Board; or

(2) Office of Administrative Hearings, if the Board so elects and notifies the applicant or authorized facility.

D. An appeal hearing shall be governed by COMAR 28.02.01.

E. If the hearing is conducted by the Office of Administrative Hearings, COMAR 30.02.06.22 and .23 also apply.

F. An applicant or authorized facility which has participated in a hearing under this regulation may seek judicial review of the EMS Board's final action under State Government Article, § 10-222, Annotated Code of Maryland. The EMS Board shall be party to the proceeding.

.07 Confidentiality of Records

MIEMSS shall maintain the confidentiality of records referred to in this subtitle in accordance with:

A. Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland;

B. Health Occupations Article, Title 10, Subtitle 5, Annotated Code of Maryland; and

C. State Government Article, Title 10, Subtitle 6, Part III, Annotated Code of Maryland.

SUBTITLE 06 AUTOMATED EXTERNAL DEFIBRILLATOR PROGRAM
CHAPTER 03 MEDICAL DIRECTION AND PROTOCOL

.01 Scope.

This chapter governs the requirements for medical direction of authorized facilities.

.02 Authorized Facility Sponsoring Physician.

A. Each authorized facility shall have a sponsoring physician.
B. A sponsoring physician shall meet the following qualifications:
(1) Be licensed to practice medicine in Maryland;
(2) Be knowledgeable in the operation of the AEDs available at the facility; and
(3) Possess current knowledge of the:
(a) Maryland EMS System,
(b) AED Protocol in COMAR 30.06.03.03, and
(c) AED quality assurance process in COMAR 30.06.04.
C. The sponsoring physician shall perform the following duties:
(1) Be responsible for providing medical direction for the operation of AEDs at the authorized facility;
(2) Require that all personnel operating an AED for the authorized facility meet the training requirements of COMAR 30.06.05;
(3) Oversee the quality assurance program as required in COMAR 30.06.04;
(4) Liaise with the local EMS jurisdictional operational program medical director and the State EMS Medical Director; and
(5) Require that all personnel in the AED program are following the protocol required in Regulation .03 of this chapter when operating the AED.
D. The authorized facility shall notify the office of the State EMS Medical Director immediately of any change of its sponsoring physician.

.03 Protocol.

All personnel in the AED program at an authorized facility shall have access to and follow the following protocol when operating an AED:
[(See table on next page.)] Table (proposed for repeal)

Indications

b5 Sudden cardiac arrest-Patient [with no pulse] without sign of circulation and not breathing.
Contraindications
b5 Children under age 8 (estimate based upon information available to individual operating AED).

b5 Patient is breathing, responsive, speaking, or making intentional movements.

Potential Adverse Effects/Complications
b5 Burns to skin.

b5 Deactivation of patient's implanted pacemaker.

b5 Injury to patient, self, and/or bystanders.

Precautions/Critical Concepts

b5 Wet conditions-Make sure the patient and environment are dry (this includes removing nitroglycerin paste from the chest with a dry cloth).

b5 Metal surfaces-Make sure patient is not touching any metal surfaces.

b5 Combustible materials or hazardous (explosive) environment-Remove patient, if possible, from area which presents hazard.

b5 Do not touch patient while AED is assessing, charging, or shocking patient.
b5 Ensure patient is "clear" (no one is touching patient) when shock button is pushed.

b5 If patient has internal pacemaker/defibrillator, position pad 1 hand's width (approximately 5 inches) from the pacemaker/defibrillator site. If patient has a nitroglycerin patch, position patches away from the patch.

b5 Never defibrillate while moving patient.

b5 Location of AED(s) should provide optimal accessibility to the maximum number of individuals and authorized operator(s) at the facility. Upon placement of AED consider the following: 1. No obstacles in the way of AED. 2. Avoid locked doors preventing quick access to AED. 3. Areas of facility with large numbers of high-risk individuals. 4. Length of time and distance to AED. 5. The AED is placed in a location clearly visible to the authorized operators.

SUBTITLE 06 AUTOMATED EXTERNAL DEFIBRILLATOR PROGRAM
CHAPTER 04 QUALITY ASSURANCE AND MAINTENANCE

.01 Scope.

This chapter governs the requirements for quality assurance and maintenance for authorized facilities.

.02 Quality Assurance and Maintenance.

A. Each authorized facility shall have a quality assurance and maintenance program consistent with the requirements of this regulation.

B. An authorized facility shall implement a quality assurance program which, at a minimum, provides for:

(1) Review by the authorized facility's sponsoring physician of each incident in which an AED was operated or there was a response with an AED to determine the appropriateness of the operation of the AED or the AED response; and

(2) For each incident in which the sponsoring physician determines that the use of the AED was inappropriate:

(a) A conference among the individual operating or responding with the AED, the AED coordinator, and the sponsoring physician, and

(b) Submission of a report to the State EMS Medical Director summarizing the conclusions of the review and conference;

(3) Reporting each incident as required by s B(5) of this regulation;

(4) Compliance with all requirements of the federal Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992; and

(5) Remedial action as necessary to resolve any issues of compliance with this subtitle.

C. An authorized facility shall adopt written procedures for the implementation and administration of the quality assurance and maintenance program which has been approved by the authorized facility's sponsoring physician.

D. An authorized facility shall maintain:

(1) The certificate issued by MIEMSS in a place where it is readily available;

(2) Each AED and all related equipment and supplies in accordance with the standards established by the device manufacturer and the federal Food and Drug Administration;

(3) Supplemental equipment with the AED at all times as follows:

(a) [3] 2 sets of defibrillator chest pads,

(b) 2 pocket facemasks,

(c) Disposable gloves,

(d) 2 safety razors, for shaving patient's chest, if necessary for proper defibrillator pad contact,

(e) 1 absorbent towel,

(f) 5-4x4 inch gauze pads,

(g) 1 extra battery set , if the AED uses replaceable batteries other than long life lithium batteries,

(h) Cables, if the AED has removable cables, and

(i) Maryland Facility AED Report Forms for Cardiac Arrest;

(4) All AED storage areas, equipment, and supplies clean and sanitary;

(5) Each AED in a closed, intact case with no visible signs of damage that would interfere with its use;

(6) Written records of :

(a) The dates and frequency of manufacturer recommended maintenance as well as the name of the company performing maintenance,

(b) All repairs performed on the AED, as well as the date and service company performing the repairs,

(c) Dates and frequency of routine safety inspection of the AED, documentation of properly functioning AED, and the individual inspecting the AED,

(d) Completion of training requirements and current proficiency in AED operation for personnel authorized to operate AEDs for the authorized facilities, including dates of initial CPR and AED training, [and] subsequent required refresher training, and practice drills

(e) The name, address, and telephone number of the sponsoring physician and verification that the physician meets the required qualifications,

(f) Completed MIEMSS Maryland Facility Cardiac Arrest Form for each incident in which the AED was operated or there was an AED response, and

(g) Completed FDA AED malfunction form for each incident in which an AED malfunctioned.

E. An authorized facility shall conduct and maintain written logs of daily safety inspections of all supplemental and AED equipment, including assurance of adequate battery charge, per the manufacturer's guidelines.

F. An authorized facility shall submit:

(1) A report for each incident in which an AED is operated or there was an AED response, on the Maryland Facility AED Report Form for Cardiac Arrests, including any event (code) summary, recording, or tape created by the AED:

(a) To the office of the State EMS Medical Director, and

(b) If the PSAP is accessed, to the local jurisdictional EMS operational program; and

(2) If the AED fails when operated, in addition to submitting the required report to the federal Food and Drug Administration, a copy of the report to the State EMS Medical Director.

G. An authorized facility shall ensure the confidentiality of any medical records maintained by the authorized facility in accordance with Health- General Article, Title 4, Subtitle 3, Annotated Code of Maryland.

SUBTITLE 06 AUTOMATED EXTERNAL DEFIBRILLATOR PROGRAM
CHAPTER 05 TRAINING REQUIREMENTS

.01 Training Requirements.

Each individual who operates an AED for an authorized facility shall:

A. Either:

(1) Have successfully completed:

(a) An AED training course, incorporating CPR training, provided by an approved AED training program;

(b) An AED training course provided by an approved AED training program, and CPR training before enrollment in the AED training course; or

(c) An AED and CPR training program in another state which authorizes the individual to provide AED in another state; or

(2) Be certified or licensed in Maryland as an emergency medical services provider other than a first responder or emergency medical dispatcher;

B. Either:

(1) Receive refresher training consistent with the requirements of an approved AED training program; or

(2) Maintain current certification or licensure in Maryland as an emergency medical services provider other than a first responder or emergency medical dispatcher; and

C. Receive refresher CPR training every 2 years unless included in the refresher AED training course or emergency medical services provider continuing education [.] ;and

D. Participate in scenario-based practice drills every 12 months at a minimum unless receiving AED refresher training consistent with the requirements of an approved AED training program annually.

.02 Approval of an AED Training Program.

A. To be eligible for approval or renewal of approval, a training program shall:

(1) Submit an application on a form approved by MIEMSS, along with a complete description of the course curriculum;

(2) Be:

(a) A nationally recognized AED training program, or equivalent as determined by MIEMSS;

(b) A Maryland Higher Education Commission accredited post-secondary institution; or

(c) An emergency services training academy operated by any city, county, or municipal government;

(3) Use instructors who:

(a) Either have:

(i) Successfully completed a nationally recognized AED instructor training program, or

(ii) Been approved by MIEMSS as emergency medical services instructors; and

(b) Provide proof of current proficiency in AED instruction;

(4) Use a nationally recognized AED training curriculum, including any curricula developed by the American Heart Association, the American Red Cross, the National Safety Council, or the United States Department of Transportation, which, at a minimum, includes the following training objectives:

(a) Briefly define, explain, describe, or identify the importance of AED and the principles of early defibrillation;

(b) Explain the components of an appropriate response to sudden cardiac arrest and how early defibrillation fits into the concept;

(c) Briefly define, explain, describe, or identify the rationale that supports the concept of early defibrillation;

(d) Briefly describe or identify the types of AEDs that are available;

(e) Describe or identify the indications for the AED;

(f) Describe or identify contraindications to the AED;

(g) Briefly explain or identify how the automated analysis of cardiac rhythm occurs;

(h) Briefly explain or identify how these devices respond to ventricular fibrillation and rapid ventricular tachycardia;

(i) Explain or identify what modifications to CPR procedures are necessary when the AED is being operated;

(j) Describe or identify the appropriate age guidelines;

(k) Explain or identify the procedural steps for performing AED;

(l) Given a minimum of three patient care scenarios in which the AED is indicated, properly demonstrate use of the device and explain why the device is appropriate or not appropriate; and

(m) Define, explain, describe, or identify site-specific hazardous environment safety precautions and considerations for AED use;

(5) Provide training in the Maryland protocol for public access defibrillation;

(6) Require and provide refresher AED training which addresses all of the cognitive and psychomotor skills objectives as required in the initial training consisting of a minimum of:

(a) 4 hours [annually] every 2 years for an AED training course incorporating CPR; and

(b) 3 hours [annually] every 2 years for an AED training course which does not incorporate CPR;

(7) Have a medical director; and

(8) Maintain a quality control program including instructor evaluation and review.

B. MIEMSS shall approve each AED training program which meets the requirements of s A of this regulation.

C. Each approval or renewal of approval shall be:

(a) Valid for 1 year; and

(b) Renewed for an additional year at the end of that period without making further application, if the training program continues to meet the requirements for approval in compliance with this subtitle.

.03 Denial.

A. MIEMSS may deny an application for approval as a training program if it finds that the applicant does not meet the requirements of Regulation .02 of this chapter.

B. Notice of Denial.

(1) MIEMSS shall issue a written notice of denial to an applicant that includes the reasons for denial.

(2) The notice shall conform to the requirements of State Government Article, § 10-207, Annotated Code of Maryland.

C. An applicant denied approval may file an appeal with the EMS Board under Regulation .05 of this chapter.

D. If an applicant does not file a timely appeal under Regulation .04 of this chapter, MIEMSS' decision is final.

E. If an application is denied, the applicant may reapply under this chapter.

.04 Procedures for Appeals.

A. An applicant may appeal a disputed final decision by filing a notice of appeal to the EMS Board with the Executive Director of MIEMSS not later than 20 days after receipt of MIEMSS' decision.

B. The appeal shall state with specificity the reasons why the disputed decision should be modified.

C. An applicant that files an appeal shall be granted a hearing before the:

(1) EMS Board; or

(2) Office of Administrative Hearings, if the Board so elects and notifies the applicant or facility.

D. An appeal hearing shall be governed by COMAR 28.02.01.

E. If the hearing is conducted by the Office of Administrative Hearings, COMAR 30.02.06.22 and .23 also apply.

F. An applicant which has participated in a hearing under this regulation may seek judicial review of the EMS Board's final action under State Government Article, § 10-222, Annotated Code of Maryland. The EMS Board shall be party to the proceeding.

APPENDIX D

(2) Notice of any delegation of authority made under this section shall be published in the Maryland Register.

(3) The EMS Board may not delegate its authority to promulgate and revise regulations, hear contested cases, or designate the provider review panel to the Executive Director of the Institute.

(4) The EMS Board may delegate to the Office of Administrative Hearings the authority to hear contested cases and issue recommendations. (1997, ch. 201, § 1; 1998, ch. 46; 2000, ch. 61, §§ 1, 6; ch. 174.)

Effect of amendments. — Chapter 61, Acts 2000, approved Apr. 25, 2000, and effective from date of enactment, substituted "of" for "or" following "Director" in (m) (3) (now (n) (3)).

Chapter 174, Acts 2000, effective Oct. 1, 2000, added (a) (15); and inserted present (g) and redesignated the remaining subsections accordingly.

Editor's note. — Section 5, ch. 61, Acts 2000, provides that "the provisions of this Act are intended solely to correct technical errors in the law and that there is no intent to revive or otherwise affect law that is the subject of other acts, whether those acts were signed by the Governor prior to or after the signing of this Act."

Section 6, ch. 61, Acts 2000, approved Apr. 25, 2000, and effective from date of enactment, provides that "any reference in the Annotated Code rendered obsolete by an Act of the General Assembly of 2000 shall be corrected by the publisher of the Annotated Code, in consultation with the Department of Legislative Services, with no further action required by the General Assembly. The publisher shall adequately describe any such correction in an editor's note following the section affected." Pursuant to § 6 of ch. 61, appropriate changes have been made in (c)(1)(ii) and in the introductory language of (h)(1) and (i)(1).

§ 13-517. Automated External Defibrillator Program.

(a) *Definitions.* — (1) In this section the following words have the meanings indicated.

(2) "Authorized facility" means an organization, business, association, or agency that meets the requirements of the EMS Board for providing automated external defibrillation.

(3) "Automated external defibrillator (AED)" means a medical heart monitor and defibrillator device that:

(i) Is cleared for market by the federal Food and Drug Administration;

(ii) Recognizes the presence or absence of ventricular fibrillation or rapid ventricular tachycardia;

(iii) Determines, without intervention by an operator, whether defibrillation should be performed;

(iv) On determining that defibrillation should be performed, automatically charges; and

(v) 1. Requires operator intervention to deliver the electrical impulse; or

2. Automatically continues with delivery of electrical impulse.

(4) "Certificate" means a certificate issued by the EMS Board to an authorized facility.

(5) "Facility" means an agency, association, corporation, firm, partnership, or other entity.

(6) "Jurisdictional emergency medical services operational program" means the institution, agency, corporation, or other entity that has been approved by the EMS Board to provide oversight of emergency medical

services for each of the local government and State and federal emergency medical services programs.

(7) "Sponsoring physician" means a physician who:

(i) Is licensed to practice medicine under Title 14 of the Health Occupations Article;

(ii) Provides medical oversight to an authorized facility; and

(iii) Meets qualifications established by the EMS Board.

(b) *Established; purpose.* — (1) There is an Automated External Defibrillator Program.

(2) The purpose of the Program is to provide a means of authorizing a facility to make automated external defibrillation available to an individual who is a victim of sudden cardiac arrest if physician services or emergency medical services are not immediately available.

(3) The Program shall be administered by the EMS Board.

(c) *Powers of EMS Board.* — The EMS Board may:

(1) Adopt regulations for the administration of the Program;

(2) Set reasonable fees for the issuance and renewal of certificates and other services it provides under the Program provided that the fees set produce funds to approximate the cost of maintaining the certification program and the other services provided under the Program;

(3) Issue and renew certificates to facilities that meet the requirements of this section;

(4) Deny, suspend, revoke, or refuse to renew the certificate of an authorized facility for failure to meet the requirements of this section;

(5) Approve educational and training programs required under this section that:

(i) Are conducted by any private or public entity;

(ii) Include training in cardiopulmonary resuscitation; and

(iii) May include courses from nationally recognized entities such as the American Heart Association, the American Red Cross, and the National Safety Council;

(6) Approve protocols for the use of an automated external defibrillator;

(7) Require each authorized facility on reasonable notice to produce for inspection:

(i) Maintenance records;

(ii) Training records; and

(iii) Equipment; and

(8) Delegate to the Institute any portion of its authority under this section.

(d) *Distribution of fees paid.* — (1) The EMS Board shall pay all fees collected under the provisions of this section to the Comptroller of the Treasury.

(2) The Comptroller of the Treasury shall distribute the fees to the Maryland Emergency Medical System Operations Fund established under § 13-955 of the Transportation Article.

(e) *Facility certification required.* — (1) Each facility that desires to make automated external defibrillation available shall possess a valid certificate from the EMS Board.

(2) This subsection does not apply to:

(i) A jurisdictional emergency medical services operational program;

(ii) A licensed commercial ambulance service; or

(iii) A health care facility as defined in § 19-114 of the Health-General Article.

(f) *Individual operation requirements.* — (1) Except as provided in paragraph (2) of this subsection, an individual may not operate automated external defibrillation equipment unless it is operated:

(i) Through an authorized facility; and

(ii) In compliance with the requirements of this section.

(2) This subsection does not apply to an individual who:

(i) Satisfies the requirements of § 5-603 (c) of the Courts Article; or

(ii) Has successfully completed an AED training course and is currently authorized to provide automated external defibrillation in the state where the individual resides or works.

(3) This subsection does not limit the right of an individual to:

(i) Practice a health occupation that the individual is licensed, certified, or otherwise authorized to practice under the Health Occupations Article;

(ii) Provide emergency medical services under § 13-516 of this subtitle; or

(iii) Operate an automated external defibrillator that is obtained by a prescription to a known patient issued by a physician licensed to practice medicine under Title 14 of the Health Occupations Article if the individual has successfully completed an educational course and refresher training as required by the EMS Board or the prescribing physician.

(g) *Facility certification — Requirements.* — To qualify for a certificate a facility shall:

(1) Have a sponsoring physician;

(2) Be registered with the closest jurisdictional emergency medical services operational program;

(3) Comply with written protocols approved by the EMS Board for the use of an automated external defibrillator which include:

(i) Notification of the emergency medical services system through the use of the 911 universal emergency access number as soon as possible on the use of an automated external defibrillator; and

(ii) Subsequent reporting of the use of an automated external defibrillator to the closest jurisdictional emergency medical services operational program;

(4) Have established automated external defibrillator maintenance, placement, operation, reporting, and quality improvement procedures as required by the EMS Board;

(5) Ensure that:

(i) Each automated external defibrillator is maintained, operated, and tested according to manufacturers' guidelines; and

(ii) Written records of the maintenance and testing of each automated external defibrillator are maintained as required by the EMS Board; and

(6) Ensure that each individual who operates an automated external defibrillator for the authorized facility:

(i) Has successfully completed an educational training course and refresher training as required by the EMS Board; and

(ii) Is at least 18 years of age, except that an individual who is between the ages of 16 and 18 may be authorized to operate an automated external defibrillator with written permission from a parent or legal guardian.

(h) *Same — Procedures.* — A facility that desires to establish or renew a certificate shall:

(1) Submit an application on the form that the EMS Board requires;

(2) Pay to the EMS Board the application or renewal fee set by the EMS Board; and

(3) Meet the requirements under this section.

(i) *Certificate — Contents.* — (1) The EMS Board shall issue a new or a renewed certificate to a facility that meets the requirements of this section.

(2) Each certificate shall include:

(i) The type of certificate;

(ii) The full name and address of the facility;

(iii) A unique identification number; and

(iv) The dates of issuance and expiration of the certificate.

(j) *Same — Length of validity.* — A certificate is valid for 3 years.

(k) *Use of defibrillator by authorized individual.* — An individual who is authorized to operate an automated external defibrillator at an authorized facility may administer automated external defibrillation to an individual who is reasonably believed to be a victim of sudden cardiac arrest if physician services or emergency medical services are not immediately available.

(l) *Adherence to established protocols.* — An individual who is authorized to operate an automated external defibrillator at an authorized facility shall follow the protocols established by the EMS Board.

(m) *Cease and desist orders.* — The EMS Board may issue a cease and desist order or obtain injunctive relief:

(1) If a facility makes automated external defibrillation available in violation of this section; or

(2) If an individual provides automated external defibrillation in violation of this section.

(n) *Immunities.* — (1) In addition to any other immunities available under statutory or common law, an authorized facility is not civilly liable for any act or omission in the provision of automated external defibrillation if the authorized facility:

(i) Has satisfied the requirements for making automated external defibrillation available under this section; and

(ii) Possesses a valid certificate at the time of the act or omission.

(2) In addition to any other immunities available under statutory or common law, the sponsoring physician of an authorized facility is not civilly liable for any act or omission in the provision of automated external defibrillation.

(3) In addition to any other immunities available under statutory or common law, an individual is not civilly liable for any act or omission if:

(i) The individual is acting in good faith while rendering automated external defibrillation to a person who is a victim or reasonably believed by the individual to be a victim of a sudden cardiac arrest;

(ii) The assistance or aid is provided in a reasonably prudent manner;

(iii) The automated external defibrillation is provided without fee or other compensation; and

(iv) 1. The act or omission occurs while the individual is providing automated external defibrillation in accordance with the requirements of this section at an authorized facility;

2. The individual has successfully completed an AED training course and is authorized to provide automated external defibrillation; or

3. The individual is using an automated external defibrillator obtained by a prescription issued by a physician.

(4) The immunities in this subsection are not available if the conduct of the authorized facility amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct.

(5) This subsection does not affect, and may not be construed as affecting, any immunities from civil or criminal liability or defenses established by any other provision of the Code or by common law to which an authorized facility or an individual may be entitled.

(o) *Opportunity for hearing.* — (1) An authorized facility aggrieved by a decision of the Institute acting under the delegated authority of the EMS Board under this section shall be afforded an opportunity for a hearing before the EMS Board.

(2) An authorized facility aggrieved by a decision of the EMS Board under this section shall be afforded an opportunity for a hearing in accordance with Title 10, Subtitle 2 of the State Government Article. (1999, ch. 167; ch. 702, § 5; 2000, ch. 61, § 1; 2001, ch. 29, § 1.)

Effect of amendments. — Chapter 61, Acts 2000, approved Apr. 25, 2000, and effective from date of enactment, substituted "this article" for "the Education Article" in (f)(3)(ii).

Chapter 29, Acts 2001, approved Apr. 10, 2001, and effective from date of enactment, substituted "subtitle" for "article" at the end of (f)(3)(ii); and substituted "tortious" for "tortuous" in (n)(4).

Subtitle 6. Police Force.

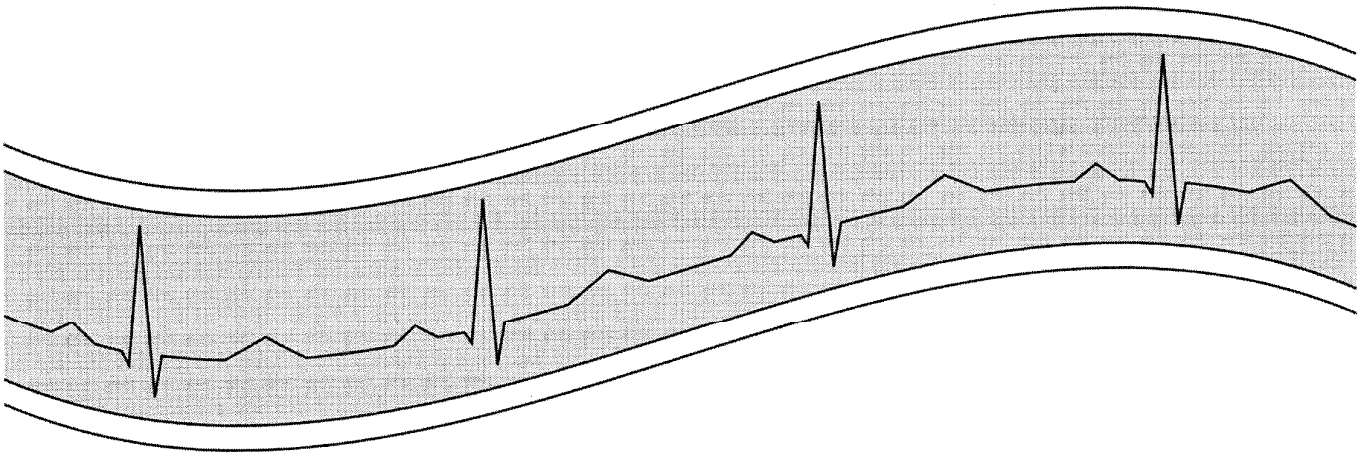
§ 13-601. University of Maryland Police Force; campus security forces or building guards.

(a) *Established.* — There is a University of Maryland Police Force.

(b) *Powers.* — (1) A University of Maryland police officer is and has all the powers of a peace and police officer in this State.

(2) However, a University of Maryland police officer may exercise these powers only on property that is owned, leased, operated by, or under the control of the University of Maryland. The police officer may not exercise these powers on any other property unless:

(i) Engaged in fresh pursuit of a suspected offender;



APPENDIX C

Sample AED Policy

Sample School Automated External Defibrillator (AED) Policy

Purpose:

To provide guidance in the management or administration of a school-based AED program. Check ONE box:

- ❒ For treatment of victims eight years of age and older ONLY.
- ❒ Includes treatment of children under eight years old or under 25 Kg. (55 lbs).

Sudden Cardiac Arrest (SCA) is a condition that occurs when the electrical impulses of the human heart malfunction causing a disturbance in the heart's electrical rhythm called ventricular fibrillation (VF). This erratic and ineffective electrical heart rhythm causes complete cessation of the heart's normal function of pumping blood resulting in sudden death. The most effective treatment for this condition is the administration of an electrical current to the heart by a defibrillator, delivered within a short time of the onset of VF.

An AED is used to treat victims who experience SCA. It is only to be applied to victims who are unconscious, without pulse, signs of circulation and normal breathing. The AED will analyze the heart rhythm and advise the operator if a shockable rhythm is detected. If a shockable rhythm is detected, the AED will charge to the appropriate energy level and advise the operator to deliver a shock.

System Owner:

Program Coordinator (e.g. school nurse, health care coordinator, athletic director)

Responsibilities:

- Selection of employees for AED training and distribution of AED-trained employee lists as required
- Coordination of training for emergency responders
- Coordinating equipment and accessory maintenance
- Maintain on file a specifications/technical information sheet for each approved AED model assigned or donated to the school
- Revision of this procedure as required
- Monitoring the effectiveness of this system
- Communication with medical director on issues related to medical emergency response program including post-event reviews

Applicable documents: (examples):

- General safety and health standard
- County/State AED Guidelines
- Medical emergency action plan
- Infection control procedure for universal precautions
- State immunity from liability exclusion
- AED Procedure

Medical Control:

The medical advisor of the AED program is _____, M.D. The medical advisor of the AED program has ongoing responsibility for:

- Proving medical direction for use of AEDs
- Writing a prescription for AEDs
- Reviewing and approving guidelines for emergency procedures related to use of AEDs and CPR
- Evaluation of post-event review forms and digital files downloaded from the AED

Authorized AED users:

The AED may be used by:

- Employees including: administrators, nurses, athletic/activities director, athletic trainers and office staff.
- Additional staff as identified by administration. Examples: teachers, coaches, field/game managers and security staff.
- Any trained volunteer responder who has successfully completed an approved CPR/AED training program within the last two years and has a current successful course completion card.

AED-Trained Employee Responsibilities:

- Activating internal emergency response system and providing prompt basic life support including AED and first aid according to training and experience
- Understanding and complying with requirements of this policy
- Following the more detailed procedures and guidelines for the AED program

Volunteer Responder Responsibilities:

- Anyone can, at their discretion, provide voluntary assistance to victims of medical emergencies. The extent to which these individuals respond shall be appropriate to their training and experience. These responders are encouraged to contribute to emergency response only to the extent they are comfortable. The emergency medical response of these individuals may include CPR, AED or medical first aid.

School Office Responsibilities:

The school office staff is responsible for:

- Receiving emergency medical calls from internal locations
- Using an established 9-1-1 checklist to assess emergency and determine appropriate level of response
- Contacting the external community 9-1-1 response team (EMS) if required
- Deploying AED-trained employees to emergency location
- Assigning someone to meet responding EMS aid vehicle and direct EMS personnel to site of medical emergency

Equipment

Approved equipment:

The LIFEPAK® Automated External Defibrillators (AEDs) have been approved for this program. The AED conforms to the state/county standards.

- The AED and first-aid emergency care kit will be brought to all medical emergencies.
- The AED should be used on any person who is at least 8 years of age and displays ALL the symptoms of cardiac arrest. The AED will be placed only after the following symptoms are confirmed:
    - Victim is unresponsive
    - Victim is not breathing, or is breathing ineffectively
    - Victim has no signs of circulation such as pulse and coughing, or movement

NOTE: If AED program includes the treatment of children under eight years old or under 25 Kg. (55 lbs). equip AEDs with Infant/Child Reduced Energy Defibrillation Electrode Starter Kit (includes one pair of electrodes, storage pouch and appropriate safety instructions and labels).

Location of AEDs

During school hours, the AED will be at designated locations. These locations shall be specific to each school but should allow the device to be easily seen by staff. The locations should allow staff members to retrieve the device outside of normal school hours.

After school hours, the AED may be moved from its designated location by an AED-trained athletic trainer to support athletic department activities on a voluntary basis. A trained volunteer would have to be available and willing to support this effort during non-school hours. A visible sign must be left in the place of the AED, with the phone number of the athletic trainer, clearly indicating they have possession of the AED.

Contracted and other community activities are not guaranteed access to the AED as part of standard rental contracts.

Location of AEDs:

- _____
- _____
- _____
- _____
- _____

Additional resuscitation equipment:

Each AED will have one set of defibrillation electrodes connected to the device and one spare set of electrodes with the AED. One resuscitation kit will be connected to the handle of the AED. This kit contains two pair latex-free gloves, one razor, one set of trauma shears, and one facemask barrier device.

Equipment Maintenance:

All equipment and accessories necessary for support of medical emergency response shall be maintained in a state of readiness. Specific maintenance requirements include:

- The main school office shall be informed of changes in availability of emergency medical response equipment. If equipment is withdrawn from service, the main school office shall be informed and then notified when equipment is returned to service.
- The main school office shall be responsible for informing response teams of changes to availability of emergency medical equipment.
- The AED Program Coordinator or designee shall be responsible for having regular equipment maintenance performed. All maintenance tasks shall be performed according to equipment maintenance procedures as outlined in the operating instructions.
- Following use of emergency response equipment, all equipment shall be cleaned and/or decontaminated as required. If contamination includes body fluids, the equipment shall be disinfected according to procedure #_____.

Routine Maintenance:

- The AED will perform a self-diagnostic test every 24 hours that includes a check of battery strength and an evaluation of the internal components.
- A volunteer, assigned by the AED Program Coordinator or designee, will perform a daily AED check following the procedure checklist. The procedure checklist will be initialed at the completion of the daily check. The procedure checklist will be posted with the AED.
- If the OK icon is NOT present on the readiness display, contact the AED Program Coordinator or designee immediately.
    - If the battery icon is visible, the battery or CHARGE-PAK™ charging unit needs to be replaced. You may continue to use the AED if needed.
    - If the wrench icon is visible, the AED needs service. You may attempt to use the AED if needed. If the message CALL SERVICE appears, the AED is not usable. Continue to provide CPR until another AED is brought to the victim or EMS arrives to take over care.
- If the expiration date on the electrode is near, notify the AED Program Coordinator or designee immediately.

Initial Training:

Trained employees:

- Must complete training adequate to provide basic first-aid, CPR and AED that will be provided on site. AED training must be a course approved by the state. Trained employees will also be trained in universal precautions against bloodborne pathogens. The trained employees shall be offered hepatitis B vaccination free of charge. The school office shall maintain training records for the trained employees.
  NOTE: If AED program includes the treatment of children under eight years old or under 25 Kg. (55 lbs), training should include infant/child CPR/FBAO since techniques differ from adult CPR/FBAO.

Volunteer Responders:

- These responders will possess various amounts of training in emergency medical response and their training may be supplied by sources outside of the company. Volunteer responders can assist in emergencies, but must only participate to the extent allowed by their training and experience. Volunteer responders may have training adequate to administer first aid, CPR and use the AEDs deployed throughout the campus. Any volunteer wishing to potentially use one of the AEDs deployed on the campus should have successfully completed a state approved AED course including CPR within the last two years. The school will not maintain training records for the volunteer responders.

Refresher Training:

- Trained employees will renew first-aid and AED training every two years.
- AED-trained employees will refresh AED skills using computer-based training. Each AED-trained employee will have access to AED Challenge™ interactive training software. Every six months each will perform a three-scenario test that will be reviewed by the AED Program Coordinator or designee.
- Volunteer responders should obtain documented renewal training at least once every two years. Volunteer responders are encouraged to periodically refresh their AED skills. This can be accomplished through the use of AED Challenge interactive training software. A copy of AED Challenge software has been placed on the computer in the library. All trained volunteer responders are encouraged to practice anytime.

Medical Response Documentation:

Internal Post-Event Documentation: It is important to document each use of the medical emergency response system. The following forms shall be sent to the AED Program Coordinator or designee within 24 hours of a medical event:

- An accident report form shall be completed by a responding employee for each accident requiring first-aid of any type.
- The AED-trained employee or volunteer responder shall complete a medical event form (9-1-1 form) whenever an AED is used.

External Post-Event Documentation: A copy of AED use information shall be presented within 48 hours of the emergency to the following:

- Medical director of the AED program
- Local EMS, county, state officials as designated in state AED requirements and local regulations
- At a minimum, event information supplied shall include any recorded data, and all electronic files captured by the AED.

Post-Event Review:

Following each deployment of the response team member, or if a volunteer responder uses an AED, a review shall be conducted to learn from the experience. The AED Program Coordinator or designee shall conduct and document the post-event review. All key participants in the event shall participate in the review. Included in the review shall be the identification of actions that went well and the collection of opportunities for improvement as well as critical incident stress debriefing. A summary of the post-event review shall be sent to the environmental health and safety committee. The environmental health and safety coordinator according to the record retention policy shall maintain a copy of the post-event review summary.

System Verification and Review:

The medical emergency response system is ultimately successful if necessary medical assistance is provided to victims in a timely and safe manner. Since actual use of this system procedure is expected to be very infrequent, other measures of effectiveness are required.

Annual System Assessment:

Once each calendar year, the AED Program Coordinator or designee shall conduct and document a system readiness review. This review shall include review of the following elements:

- Training records
- Equipment operation and maintenance records

Approvals

Function	Printed Name	Signature	Date
Medical Director	_____	_____	_____
Program Coordinator	_____	_____	_____

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APPENDIX D

November 13, 2001 Memo from the Office of the Attorney General

#1537

Office of the Attorney General

Maryland State Department of Education
200 St. Paul Place
Baltimore, Maryland 21202
(410) 576-6465

November 13, 2001

TO: Vicki Taliaferro, Health Service Specialist

FROM: Jackie C. La Fiandra, Assistant Attorney General Jackie

SUBJECT: Civil Liability for Using Automated External Defibrillators in Public Schools

You have asked for general advice concerning school system liability for the operation and use of automated external defibrillators ("AED's") in public schools.[1]

Prompted by public interest in early defibrillation and the use of AED's, the federal government and many states, including Maryland, developed laws protecting individuals and entities from civil liability related to the use of AED's. *See generally* Cardiac Arrest Survival Act of 2000, 42 U.S.C. § 238q. In 1999, the Maryland General Assembly enacted legislation establishing an AED program authorizing a "facility" to make AED available to victims of sudden cardiac arrest and establishing provisions for immunity from civil liability under the program. *See* Md. Code Ann., Educ. §13-517. Thereafter, the Maryland Institute for Emergency Medical Services ("MIEMS") promulgated regulations for the AED program.[2] *See generally* COMAR 30.06.01. Together, these Maryland laws provide the legal framework for and govern the AED program in the State.

As mentioned above, § 13-517 of the Education Article authorizes a "facility" to make AED available. The definition of a "facility" in § 13-517 is extremely broad. It defines "facility" as "an agency, association, corporation, firm, partnership, or other entity." Md. Code Ann., Educ. § 13-517(a)(5). Given this expansive definition, I believe that a public school could

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[1]An AED is a specialized medical device that is used to defibrillate victims of sudden cardiac arrest. Maryland regulations define an AED as a medical heart monitor and defibrillator device that is cleared by the federal Food and Drug Administration; recognizes the presence or absence of ventricular fibrillation or rapid ventricular tachycardia; determines, without intervention by the operator, whether defibrillation should be performed; and requires operator intervention to deliver the electrical impulse or automatically continues with delivery of the electrical impulse. COMAR 30.06.01.01B(3). *See also* Md. Code Ann., Educ. § 13-517(a)(3).

[2]The AED program is administered by the Emergency Medical Services ("EMS") Board, the governing body of MIEMS. *See* Md. Code Ann., Educ. §13-503.

be considered a facility under the AED program.

Section 13-517 also sets forth various requirements that must be attained by a facility making AED available. For example, a facility must possess a valid certificate from the EMS Board. In order to qualify for a certificate, the facility must: (1) have a sponsoring physician;[3] (2) register with the closest EMS operational program; (3) comply with written protocols approved by the EMS Board for the use of AED;[4] (4) have established AED maintenance, placement, operation, reporting, and quality improvement procedures; (5) ensure that each AED is maintained, operated and tested according to the manufacturer's guidelines and that written records of such are maintained; (6) ensure that each individual who operates an AED for the facility has successfully completed a training course and refresher training and is at least 18 years old.[5] Md. Code Ann., Educ. § 13-517(g). In conjunction with having a valid certificate, a facility must also be authorized to operate AED's by meeting the criteria set forth in COMAR 30.06.02.01.

With regard to civil liability, § 13-517(n) provides authorized facilities with immunity from civil liability for "any act or omission in the provision of automated external defibrillation" if the authorized facility has satisfied the requirements for making AED available under § 13-517 and the authorized facility possesses a valid certificate at the time of the act or omission.[6] Thus, if a public school, as an authorized facility, satisfies these requirements, I believe that the immunity provided in §13-517 should fully protect a local school system from civil liability for an act or omission in the administration of AED.

Even if a local school system were subject to civil liability for damages resulting from the provision of AED despite the immunity provided in § 13-517, there are other statutory provisions that could limit the liability of the school system.[7] Each local board of education is covered by a "tort claim act."[8] *See* Md. Code Ann., Cts. & Jud. Proc. § 5-518 and Educ. § 4-105. Section 5-

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[3]COMAR 30.06.03.02 lists the qualifications and duties for sponsoring physicians.

[4]COMAR 30.06.03.03 sets forth the protocol for authorized facilities.

[5]An individual who is between ages 16 and 18 may be authorized to operate an AED with the written permission from a parent or legal guardian. Md. Code Ann., Educ. § 13-517(g)(6)(ii).

[6]Section 13-517 also provides immunity from civil liability to the sponsoring physician of an authorized facility and other individuals. For individual immunity, certain factors must be present. *See* Md. Code Ann., Educ. 13-517(n)(3).

[7]Section 13-517 specifically states that the immunities provided therein are in addition to any other immunities available under statutory or common law. Md. Code Ann., Educ. §13-517(n).

[8]The tort claim act also protects a county board employee acting within the scope of his or her employment without malice or gross negligence such that the employee may not be

518 provides each local board with immunity for claims against it greater than $100,000, or claims greater than the amount of the local board's limit on its insurance policy.[9] Thus, a local board of education would generally not be subject to tort liability for any individual claim resulting from the use of an AED beyond the amounts just stated.

In sum, I believe that § 13-517 of the Education Article protects a local school system against civil liability for an act or omission in the provision of AED provided the school system complies with the requirements of the AED program. Additionally, even if a school system were not fully protected by the immunity set forth in § 13-517, I believe that § 5-518 of the Courts and Judicial Proceedings Article could provide a limitation of liability for a school system in such a circumstance. I hope this information is helpful to you. Please contact me if you have any questions or if I may be of further assistance in this matter.

THIS IS NOT AN OFFICIAL OPINION OF THE ATTORNEY GENERAL

Attachments

c: Valerie V. Cloutier

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personally liable for damages resulting from a tortious act or omission. Md. Code Ann., Cts. & Jud. Proc. § 5-518(e). Furthermore, a judgment in tort for damages against a county board employee acting within the scope of employment is levied against the county board and not the employee. Md. Code Ann., Cts. & Jud. Proc. § 5-518(h).

[9]Each local board is required to carry comprehensive liability insurance to protect itself and its agents and employees. Md Code Ann., Educ. § 4-105(a).