

**Department of State Health Services
Council Agenda Memo for State Health Services Council
February 24, 2011**

Agenda Item Title: Amendments to rules concerning automated external defibrillators (AED) for public access defibrillation and emergency medical services (EMS) operator and operator instructor training and certification

Agenda Number: 4.a.v

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The EMS Trauma Systems Coordination Unit, located in the Regulatory Services Division, is responsible for regulation of EMS and designation of trauma hospitals. The unit coordinates with the Patient Quality Care Unit, which performs inspections, site surveys, and investigations and provides technical assistance regarding EMS. There are approximately 1800 EMS-related complaints received per year and staff conduct comprehensive investigations on approximately 80% of those complaints. Each year, the unit conducts around 1300 surveys of EMS providers.

Funding for the EMS Trauma Systems Coordination Unit is provided through general revenue and fee funds.

Key Health Measures:

The proposed amendments clarify the lay responders' purpose and role in AED use, the physician's role and responsibilities, and the fundamentals for effective AED utilization.

The effectiveness of the rules are exhibited by:

- the successful planning, organization and training of lay responder groups that provide sudden cardiac response;
- the facilitation of clear direction and technical advice to lay responders and local EMS regarding training and lay response to sudden cardiac arrest;
- a diminished need for technical advice from DSHS staff to public inquiries on sudden cardiac arrest response and training programs; and
- a better understanding of the organizational structure of DSHS.

The revised rules are expected to heighten awareness of AED training standards and operational guidelines. The impact of the rule changes can be assessed by monitoring stakeholder feedback regarding clarity of training and use guidelines.

Summary:

The purpose of the amendments is to address the training and use of AEDs by non-professional individuals and lay response groups, correct outdated DSHS references and revise the reference to the electronic processing website. The amendments also comply with the four-year review of rules required by Government Code, Section 2001.039.

Health and Safety Code, Chapter 779, directs DSHS to adopt rules establishing the minimum requirements for AED training. The amended language expands on notice requirements after purchase and use of an AED, and further explains physician involvement in AED training.

The rules affect the individuals, lay responder groups and local EMS personnel who interact with public access defibrillation programs in their service areas.

Summary of Input from Stakeholder Groups:

Members of the Governor's EMS and Trauma Advisory Council (GETAC) reviewed the proposed rules at the May and August meetings.

Feedback has consisted of questions about the role of local EMS medical directors for medical consultation regarding the training and use of AEDs. The rule comments received resulted in no changes to the rule and no unresolved issues remain. No comments were received concerning the operator instructor training and certification rule.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.a.v

Approved by Assistant Commissioner/Director: Kathryn C. Perkins, R.N., M.B.A. **Date:** 2/2/2011

Presenter: Maxie Bishop **Program:** EMS and Trauma Systems **Phone No.:** 512.834.6737

Approved by CCEA: Carolyn Bivens **Date:** 2/2/2011

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 157. Emergency Medical Care
Subchapter C. Emergency Medical Services Training and Course Approval
Amendment §157.41
Subchapter D. Emergency Medical Services Personnel Certification
Amendment §157.49

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §157.41, concerning automated external defibrillators (AED) for public access defibrillation, and §157.49, concerning emergency medical services operator and operator instructor training and certification.

BACKGROUND AND PURPOSE

The amendments to §157.41 are necessary to clarify training and use guidelines, required by rule per Health and Safety Code, §779.002(b), for those who acquire an AED for non-professional use or by groups not licensed, certified or registered under Health and Safety Code, Chapter 773. It includes new language, per Health and Safety Code, §779.008, specifically stating it does not apply to AED use in hospitals licensed under Health and Safety Code, Chapter 241. This amendment clarifies physician involvement in training, adds after-use notification requirements, and defines lay responder, public access defibrillation and sudden cardiac arrest, which are not addressed in the current version of the rule. Under guidelines and procedures for use, this new language elaborates on procedural areas upon which a typical lay responder group should focus.

The amendments to §157.49 are necessary to update rule language to correct language referring to Texas Department of Health, Board of Health, and Bureau of Emergency Management which were changed during the department reorganization after the rule was readopted in 2004. Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 157.41 and 157.49 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed

SECTION-BY-SECTION SUMMARY

Amendments to §157.41 include a change to the rule title by adding “for public access defibrillation.” The amendments define the terms lay responder, public access defibrillation and sudden cardiac arrest. Physician involvement in training and consultation is clarified. A requirement for users to notify the local EMS after use of an AED was added to comply with a statutory directive in Health and Safety Code, §779.004. Under the existing guidelines and procedures for use, additional language was added to describe fundamental aspects of nationally recognized standards as they relate to AED use procedures.

Section 157.49(b)(1) was amended by correcting the agency name to Texas Department of State Health Services; in subsection (b)(2), the Texas Board of Health (board) was replaced with department; subsection (e) was revised by replacing "bureau chief" with "department"; and subsection (o) was revised by replacing the names "the Texas Online Authority" and "Texas Online" with "texas.gov" to reflect the updated website for electronic transactions.

FISCAL NOTE

Renee Clack, Section Director, Health Care Quality Section, has determined that for each year of the first five years the sections are in effect, there will be no fiscal implications to the state or local governments as a result of enforcing or administering §157.41 and §157.49 as proposed.

MICRO-BUSINESSES AND SMALL BUSINESSES IMPACT

Ms. Clack determined that for each year of the first five years the sections are in effect, there will be no fiscal implications to small or micro-businesses as a result of enforcing or administering §157.41 and §157.49 as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

Ms. Clack determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of these sections. The public benefit anticipated is clarity of lay responders' purpose and role in AED use, a better understanding of the physician's role and responsibilities and better clarity regarding the fundamentals for effective AED utilization, and to correct outdated references.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Jane Guerrero, Office of EMS/Trauma Systems Coordination, Health Care and Quality Section, Division of Regulatory Services, Department of State Health Services, Mail Code 1876, P.O. Box 149347, Austin, Texas 78714-9347, (512) 834-6700, or by email to Jane.Guerrero@dshs.state.tx.us. Comments will be accepted for 30 days following the publication of the proposal to the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services, General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by the Health and Safety Code, Chapters 773 and 779; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Chapter 1001, Health and Safety Code. Review of the rules implements Government Code, §2001.039.

The amendments are authorized by Government Code, Chapter 531; and Health and Safety Code, Chapters 773, 779, and 1001.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§157.41. Automated External Defibrillators for Public Access Defibrillation.

(a) Purpose. The purpose of this rule is to establish minimum standards and requirements for training of lay responders **[persons]** using automated external defibrillators (AED).

(b) Excluded. [Exemption.] This section shall not apply to persons who are licensed, certified or registered under the Texas Health and Safety Code, Chapter 773, or to hospitals licensed under Health and Safety Code, Chapter 241.

(c) Definitions.

(1) Automated External Defibrillator (AED)--An electronic medical device approved by the United States Food and Drug Administration which is capable of recognizing the presence or absence of cardioventricular fibrillation or rapid cardioventricular tachycardia; is capable of determining, without interpretation of cardiac rhythm by an operator, whether defibrillation should be performed and, on determining that defibrillation should be performed, automatically charges and requests the operator to deliver an electrical impulse to an individual's heart.

(2) Cardiopulmonary Resuscitation (CPR)--A life saving procedure involving closed chest compressions and artificial respiration to an individual who is pulseless and apneic or who is experiencing agonal respiration.

(3) Lay Responder--A non-EMS-professional trained to respond to specific medical emergencies such as sudden cardiac arrest.

(4) Public Access Defibrillation--A comprehensive, integrated community approach to the use of AEDs by trained lay responders.

(5) Sudden Cardiac Arrest--A condition of sudden, unexpected loss of heart function, breathing and consciousness, usually resulting from an electrical disturbance in the heart that disrupts its pumping action and causes blood to stop flowing to the rest of the body.

(d) Training required.

(1) A person acquiring and/or using an AED shall successfully complete a training course in CPR and AED operation in accordance with the guidelines established by the device's manufacturer and as approved by the American Heart Association, the American Red Cross, other nationally recognized associations, or the medical director of the local emergency medical services provider.

(2) The person shall maintain that training in accordance with the guidelines established by the training association.

(3) A licensed physician shall be involved in the training program to ensure compliance with the requirements of this chapter. Physician involvement may be in the form of medical consultation or general oversight of the course.

(e) Notification required.

(1) A person or entity that acquires an AED shall immediately notify all local emergency medical service providers of the existence, physical location and type of device.

(2) A person or entity that uses an AED shall notify the local emergency medical service (911) provider after the AED is used.

(f) Guidelines and procedures for use. Use of an AED shall be in accordance with the guidelines established as nationally recognized standards and shall be in accordance with the manufacturer's operating procedures. The person or entity that acquires the AED should assure:

(1) AED prescription, purchase, use and maintenance records are retained;

(2) continuous involvement with the medical consultant and local EMS;

(3) appropriate placement of AED;

(4) maintenance of the AED;

(5) a core of trained users is maintained;

(6) liability exemption information is retained;

(7) the guidelines used are approved by the American Heart Association, the American Red Cross, other nationally recognized associations, or the medical director of the local emergency medical services provider;

(8) after-use procedures are developed and followed; and

(9) quality improvement procedures are developed and followed.

§157.49. Emergency Medical Services Operator and Operator Instructor Training and Certification.

(a) (No change.)

(b) Provision of medical information.

(1) An EMS information operator may provide medical information to a member of the public during an emergency call if the information operator has successfully completed an EMS information operator training program approved by the Texas Department of State Health Services (department) and holds a certificate issued under the provisions of this section or holds equivalent credentials recognized by the department; and

(2) An EMS information operator may provide medical information to a member of the public during an emergency call if the information provided conforms to the protocol and medical direction for delivery of the information adopted by the department [**Texas Board of Health (board)**] under the provisions of subsection (c) of this section.

(c) – (d) (No change.)

(e) Recognition by equivalent credentials. Upon written request to the department [**bureau chief**] and submission of its program's curriculum, the department may approve credentials issued by an emergency medical dispatch certification agency, organization, or by another state as being equivalent to EMS information operator certification.

(f) – (i) (No change.)

(j) EMS information operator instructor certification.

(1) – (3) (No change.)

(4) Retesting.

(A) A certificant who does not pass the department's written examination may retest after:

(i) submitting an application to retest; **[:]** and

(ii) (No change.)

(B) (No change.)

(k) – (n) (No change.)

(o) For all applications and renewal applications, the department [**(or the board)**] is authorized to collect subscription and convenience fees, in amounts determined by texas.gov [**the Texas Online Authority**], to recover costs associated with application and renewal application processing through texas.gov [**Texas Online**].