



State of Louisiana
Louisiana Department of Health
Office of the Secretary

March 10, 2021

Via Statutorily Required Email

To: The Honorable Patrick Page Cortez, President, Louisiana Senate
The Honorable Clay Schexnayder, Speaker, Louisiana House of Representatives
The Honorable Chairman Fred H. Mills Jr., Senate Health & Welfare Committee
The Honorable Chairman Larry Bagley, House Health & Welfare Committee

From: Dr. Courtney N. Phillips
Secretary

Re: First Report: Proposed Amendments to LAC 48:V.Chapter 61 – Automated External Defibrillators

Under the authority of the laws of the State of Louisiana and in accordance with the provisions of Chapter 6 of Title 36 of the Louisiana Revised Statutes of 1950, and with the Administrative Procedure Act, La. R.S. 49:950 *et seq.*, the secretary hereby gives notice that rulemaking procedures have been initiated to promulgate amendments to the rules governing the administration of Automated External Defibrillators, LAC 48:V.Chapter 61.

- I. Copy of the rule as it is proposed after amendment, with new proposed language indicated by the underscored text and deleted language indicated by the strike-through type.

See attachment.

- II. A statement of the proposed action.

The proposed rule revisions are necessary to update the Louisiana Administrative Code (LAC).

- III. Specific citation of law authorizing promulgation of the rule.

R.S. 36:254, and R.S. 40:1137.3.

IV. Circumstances which require the amendment of the rule.

R.S. 40:1137.3 was amended to no longer require any person or entity which possesses an Automated External Defibrillator (AED) to notify the LDH OPH Bureau of Emergency Medical Services. The R.S. 40:1137.3 amendments require such notification be made only to a local provider of emergency medical services, such as 911 service, local ambulance service, or the fire department of the acquisition, location, and type of AED.

V. Statement of Fiscal and Economic Impact.

See attachment.

Please contact Stacy Barbary, Stacy.Barbary@la.gov, if you have any questions or require additional information about this matter.

Attachments (2)

Cc: Melissa Mendoza, JD, MPH, Legislative and Regulatory Affairs Director, OPH
LDH
Susan Bailey, MSEM, NRP, Director Bureau of Emergency Medical Services, OPH
LDH
Aliya Rubenstein, JD, MPH, Rulemaking Liaison, OPH LDH
Bethany Blackson, Legislative Liaison, LDH
Catherine Brindley, Editor, *Louisiana Register*, Office of the State Register

NOTICE OF INTENT

Department of Health Office of Public Health

Automated External Defibrillators (LAC 48:V.Chapter 61)

Under the authority of R.S. 36:254(B)(7) and in accordance with R.S. 49:950 *et seq.*, the Administrative Procedure Act, notice is hereby given that the Louisiana Department of Health, Office of Public Health (LDH-OPH) intends to amend Chapter 61 (Automated External Defibrillators) of Subpart 3 (Licensing and Certification) of Part I (General Administration) of Title 48 (Public Health—General) of the Louisiana Administrative Code (LAC). The proposed amendments are necessary to update the LAC to match the amended R.S. 40:1137.3.

In 2016, R.S. 40:1137.3 was amended to no longer require any person or entity which possesses an Automated External Defibrillator (AED) to notify the Bureau of Emergency Medical Services in LDH-OPH. As of 2016, it is required that such notification be made only to a local provider of emergency medical services, such as 911 service, local ambulance service, or the fire department of the acquisition, location, and type of AED.

Title 48 Public Health—General Part I. General Administration Subpart 3. Licensing and Certification

Chapter 61. Automated External Defibrillators

§6101. Purpose and Definitions

A. Purpose. ~~These rules establish standards for the maintenance of automated external defibrillators for the owner of or the entity responsible for a physical fitness facility, any institution of higher education that competes in intercollegiate athletics, and any high school that possesses an automated external defibrillator.~~

AB. Definitions. ~~The Louisiana Department of Health and Hospitals, Office of Public Health (LDH-OPH), Bureau of Emergency Medical Services (BEMS), in the exercise of its regulatory authority, has adopted defines the following meaning for the following words and terms applicable to this Chapter.~~

~~*Athletic Department—high schools,* the division or department of an institution of higher education, including colleges, universitiesy, or community colleges, which schedules and compets in ~~interscholastic athletics and~~ intercollegiate athletics.~~

~~*Automated External Defibrillator (AED) (as defined under R.S. 40:1236.12)*—a medical device heart monitor and defibrillator that:~~

- ~~a. has received approval of its pre-market notification filed pursuant to 21 U.S.C. 360(k) from the United States Food and Drug Administration;~~
- ~~b. is capable of recognizing the presence or absence of ventricular fibrillation or rapid ventricular tachycardia and is capable of determining whether defibrillation should be performed;~~

- c. upon determining that defibrillation should be performed, the AED automatically charges and ~~requests~~ ~~delivers~~ delivery of an electrical impulse to an individual's heart;
- d. is capable of delivering the electrical impulse to an individual's heart; and
- e. pediatric AED capabilities are required.

Bureau—the ~~Department of Health and Hospitals, Office of Public Health, LDH-OPH, BEMS.~~

Cardiopulmonary Resuscitation (CPR)—the process of ~~ventilating and providing oxygen while~~ circulating blood ~~for~~to a patient in cardiopulmonary arrest usually, ~~but not exclusively,~~ in a combination of ~~mouth-to-mouth~~ breathes with external chest compressions.

Certification—adult and pediatric expected CPR providers and expected AED users ~~must be who have been~~ certified after successful completion of an adult and pediatric CPR and AED course recognized by a nationally recognized organization or association such as the American Heart Association (AHA), the American Red Cross (ARC), the National Safety Council and the Emergency Medical Physicians of America, or the equivalent cardiopulmonary resuscitation certification that has been approved by the Louisiana Department of Health, ~~which certification must be updated before the expiration listed on the certificate.~~

* * *

Health Club—~~a physical fitness facility emphasizing exercise to achieve physical fitness, or weight loss.~~

Physical Fitness Facility—~~any person or organization which, a facility for profit or nonprofit, with a membership of over 50 persons that offers physical fitness services. This includes but is not limited to clubs, studios, health spas, weight control centers, clinics, figure salons, tanning centers, athletic or sport clubs, and YWCA and YMCA organizations, whether at multiple outlets or single outlet. Any subsidiary of a center offering such services shall be deemed part of said center.~~

* * *

Sudden Cardiac Arrest—a medical emergency where ~~expected~~a person is unconscious, not breathing and has no pulse.

AUTHORITY NOTE: ~~Promulgated in accordance with R.S. 40:1236.11137.3(F).~~

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Bureau of Emergency Medical Services, LR 38:2928 (November 2012); amended by the Department of Health, Office of Public Health, Bureau of Emergency Medical Services, LR 47:

§6103. General Provisions

A. Possessor's Program

1. The Possessor's Responsibility and Requirements are as follows.
 - a. The AED ~~is~~must be maintained and tested according to the manufacturer's guidelines; in accordance with state and federal rules and polices, including review of product warranty expirations for AED machine, pads and batteries.
 - b. A licensed physician or advanced practice registered nurse in the state of Louisiana who is authorized to prescribe in the state of Louisiana must be ~~is~~ involved in the possessor's

program to ensure compliance with the requirements for training, emergency medical services (EMS) notification, and maintenance.

c. Expected AED users regularly, on the premises of a particular entity, such as a work site or users, who carry an AED in a private security patrol vehicle, must receive appropriate training in CPR and in the use of an AED by the American Heart Association, American Red Cross, or the equivalent cardiopulmonary resuscitation certification that has been approved by LDH, or by any other nationally recognized course in CPR and AED use.

~~i. For purposes of this Paragraph, "expected AED users" shall be any person designated by the possessor to render emergency care.~~

d. The local provider of emergency medical services (EMS) (such as a 911 service, local ambulance service, or fire department) system is must be activated by the individual rendering care as soon as possible when an individual renders emergency care to an individual in cardiac arrest by using CPR or an AED. It is the responsibility of the individual rendering the emergency care to activate the local EMS provider.

e. Any clinical use of the AED is reported to the licensed physician or advanced practice registered nurse involved in the possessor's program, ~~and BEMS, using the cardiac arrest profile/data collection form obtained from the BEMS office. A determination by the licensed physician or advanced practice registered nurse, whether or not the patient was treated in accordance with the pre-established protocol. A copy of the cardiac arrest profile/data collection form should be mailed~~

2. ~~Any-Every person or entity possessor which possesses an AED shall notify BEMS and a local provider of emergency medical services, such as a 911 service, local ambulance service, or the fire department of the acquisition, location and type of AED.~~

3. Any manufacturer, wholesale supplier, or retailer of an AED ~~shall~~must notify purchasers of AED's intended for use in the state of Louisiana of the requirements of R.S. 40:~~1236.131~~1237.3.

4. The owner of or the entity responsible for either a physical fitness facility or a physical fitness centers, ~~shall~~must keep an AED on its premises.

5. Any institution of higher education that competes in intercollegiate athletics ~~shall~~must have an AED on its premises in its athletic department, with posters approved by AHA/ARC on how to safely perform CPR and use the AED. The AED ~~is to~~must be placed in open view within ~~two~~2 feet of a telephone to ~~be able to readily enable a access~~call to 911 from within the athletic department. It must also and be placed in an area with easy access to coaches and athletic personnel where games-athletes are to training and/or be completed competing.

~~a.6. Each high school that participates in interscholastic athletics shall~~must have an AED on its premises, if funding is available, subject to appropriation. Per R.S. 40:1137.3(E)(2), each high school is authorized to accept donations of AEDs or funds to acquire AEDs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:~~1236.11~~1137.3(F).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Bureau of Emergency Medical Services, LR 38:2929 (November 2012), amended by the Department of Health, Office of Public Health, Bureau of Emergency Medical Services, LR 47:

§6105. ~~Regulations and Reports~~ Required Plan and Review of Use/Penalties

A. ~~Regulate/Self-Report~~ Plan and Usage Review

1. ~~Compliance of notification upon prescribing AED by completion, signing, and submission of BEMS automated external defibrillator acquisition notification form, to the BEMS office and notification to local provider of emergency services of BEMS notification information.~~

2. ~~— A written CPR/AED Pprotocol or Pplan must exist for use in a sudden cardiac arrest (SCA) occurring at a physical fitness facility or a physical fitness center and file a copy of this protocol/plan with BEMS.~~

3. ~~2. Every event in which an AED is used in a physical fitness facility is placed on a person, the use must be reported to BEMS on the cardiac arrest profile/data collection form and reviewed by the medical oversight of the possessor, in accordance with the CPR/AED protocol/plan and further determine if the CPR/AED protocol/plan protocol or plan should be modified. The review of use by medical oversight shall be privileged and confidential.~~

B. ~~Non-Complying Provisions/Failure to Report Possess Required AED~~

1. ~~The BEMS shall inspect the premises in response to a complaint which specifies the name, address and telephone number of the alleged violator filed with the BEMS alleging a violation of R.S. 40:12361137.3(D) or (E). The BEMS may inspect facilities or premises at other times to ensure compliance with this Rule.~~

a. ~~Penalties for violations: If a physical fitness facility, physical fitness center, collegiate athletic department or high school violates this rule by failing to have on the premises an accessible and operational AED or to adopt or implement a plan for responding to medical emergencies as required by this Chapter, then the following actions, inclusive of the issuance of assessing monetary penalties on a per violation basis, is hereby authorized.~~

i. ~~Voluntary Compliance Effort.~~

(a). ~~The BEMS or its designee may issue to a physical fitness facility, athletic department or high school a written administrative warning without monetary penalty upon determining that an initial violation of either of the requirements in this Subparagraph exists. The written notification of violation shall state that the physical fitness facility, athletic department or high school will be provided with a 30-day grace period from the date of the violation determination to voluntarily comply.~~

ii. ~~Mandatory Compliance Penalties.~~

(a). ~~at least \$100 but less than \$150 per violation upon determination that one or more violations continues to exist after the 30-day voluntary compliance grace period has expired;~~

(b). ~~at least \$150 but less than \$200 per violation upon determination that one or more violations continues to exist for the third or subsequent times; and~~

(c). ~~upon determination that a fourth violation exists, the BEMS or its designee may report said violations to the Louisiana attorney general's office or other governing authorities requesting issuance of further warning and/or the institution of judicial enforcement procedures.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:~~1236.11~~1137.3(F).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, Bureau of Emergency Medical Services, LR 38:2930 (November 2012) ~~), amended by the Department of Health, Office of Public Health, Bureau of Emergency Medical Services, LR 47:~~

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;
2. the authority and rights of persons regarding the education and supervision of their children;
3. the functioning of the family;
4. family earnings and family budget;
5. the behavior and personal responsibility of children;
6. the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;
2. the effect on early childhood development and preschool through postsecondary education development;
3. the effect on employment and workforce development;
4. the effect on taxes and tax credits;
5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The proposed Rule should have no adverse impact on small businesses as defined in the Small Business Protection Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Thursday, April 8, 2021 at COB, 4:30 pm, and should be addressed to Allen Enger, LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Thursday, April 8, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9 am on Tuesday, April 27, 2021, in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-

1342 after Thursday, April 8, 2021. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to the Bienville Building's front security desk.

Dr. Courtney N. Phillips
LDH Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Stacy Barbay Dept.: Louisiana Department of Health
Phone: 225-925-3840 Office: Office of Public Health
Return Address: 7273 Florida Blvd,
Baton Rouge, LA 70806

Rule Title: Chapter 61. Automated External Defibrillators

Date Rule Takes Effect: June 20, 2021

SUMMARY

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS:

In FY 21, this rule change is anticipated to increase the expenses of the Office of Public Health (OPH) by \$365.14 SGF for publication costs. There are no other anticipated impacts on state or local government expenditures.

The proposed rule amends Chapter 61, Automated External Defibrillators (AED), Sections 6101, 6103, and 6105. Specifically, the proposed rule updates definitions, removes the requirement that OPH must be notified when care is rendered using an AED, clarifies that a high school may accept donations of AEDs or funds to acquire AEDs, and clarifies penalties for failure to possess a required AED. There is no change in the amount of the penalty.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS


There is no anticipated impact on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES OR NON-GOVERNMENTAL GROUPS (Summary)

The owner of or the entity responsible for a physical fitness facility, any institution of higher education that competes in intercollegiate athletics, and any high school that participates in interscholastic athletics and possesses an automated external defibrillator may have a reduced workload as a result of no longer having to report AED use to OPH.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT

The proposed rule has no anticipated impact on competition and employment.



Signature of Agency Head or Designee

Kimberly L. Hood, JD, MPH
Assistant Secretary, Office of Public Health
Typed Name & Title of Agency Head or Designee
3-8-2021

Date of Signature



Legislative Fiscal Officer or Designee

3/9/21

Date of Signature