

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 37.104.601, 37.104.604,) PROPOSED AMENDMENT
37.104.606, 37.104.615, and)
37.104.616 pertaining to automated)
external defibrillators (AED))

TO: All Concerned Persons

1. On October 29, 2020, at 10:00 a.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed amendment of the above-stated rules. Because there currently exists a state of emergency in Montana due to the public health crisis caused by the coronavirus, there will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at <https://mt-gov.zoom.us/j/96400155640>, meeting ID: 964 0015 5640; or

(b) Dial by telephone +1 646 558 8656, meeting ID: 964 0015 5640. Find your local number: <https://mt-gov.zoom.us/u/aer65PeDoZ>.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on October 23, 2020, to advise us of the nature of the accommodation that you need. Please contact Heidi Clark, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.104.601 DEFINITIONS The following definitions apply to this chapter, in addition to the definitions contained in 50-6-501, MCA:

(1) "Automated external defibrillators (AED) training program" means a course of instruction approved by the department which provides the initial education in the use of the AED and which has requirements for continued assurance of the competency of individuals in using an AED and CPR.

(2) "CPR" means cardiopulmonary resuscitation.

~~(3) "Medical supervisor" means a physician, physician assistant, registered nurse, or nurse practitioner licensed in Montana who completes a training program provided by the department and who agrees to provide medical supervision to an approved AED program.~~

(3) "Entity manager" means the individual responsible for maintaining the automated external defibrillator (AED) according to manufacturer recommendations, registering the device with the state electronic registration site, recording all upkeep/maintenance and training information, and reporting all uses/incidents.

AUTH: 50-6-503, MCA

IMP: 50-6-501, MCA

37.104.604 WRITTEN PLAN (1) An entity wishing to use or allow the use of an AED shall develop, update as changes are made, and adhere to a written plan that register the AED with the department using the electronic registration site. Registration includes the following information:

- (a) for a stationary location, specifies the physical address where the AED will be located;
- (b) for a mobile location, specifies the geographic area in which the AED will be used and specifies how the AED will be transported to the scene of a cardiac arrest;
- (c) includes the names of the individuals currently authorized to use the AED;
- (d) describes how assurances the AED use will be coordinated with each licensed emergency medical service providing coverage in the area where the AED is located, including how emergency medical services will be activated every time that an AED is attached to a patient;
- (e) specifies the name, telephone number(s), and address of the Montana licensed medical supervisor who will be providing medical supervision to the AED program and how the medical supervisor, or the medical supervisor's designee, will supervise the AED program;
- (f) specifies the name, telephone number(s), and address of the medical supervisor's designee, if any, who will assist the medical supervisor in supervising the AED program;
- (g) (e) specifies the maintenance procedures for the AED, including how it will be maintained, tested, and operated according to the manufacturer's guidelines;
- (h) (f) requires assurances that written or electronic records of all maintenance and testing performed on the AED will be kept; and
- (i) describes the records that will be maintained by the program; and
- (j) (g) describes how assurances that the required electronic reports of AED use will be made to the medical supervisor of the AED program, or their designee, and to the department.

AUTH: 50-6-503, MCA

IMP: 50-6-501, 50-6-503, MCA

37.104.606 REPORTS (1) Every time an AED is attached to a patient, its use must be reported to the medical supervisor or the medical supervisor's designee and the report must include the information required by the medical supervisor.

(2) (1) Every time an AED is attached to a patient, the medical supervisor or the medical supervisor's designee entity manager shall provide to the department,

on a form provided by the department, the following information through the electronic portal:

- (a) the name of the entity responsible for the AED;
- ~~(b)~~ the name, address, and telephone number of the medical supervisor;
- ~~(c)~~ (b) the date of the call;
- ~~(d)~~ (c) the age of the patient;
- ~~(e)~~ (d) the gender of the patient;
- ~~(f)~~ (e) location of the cardiac arrest;
- ~~(g)~~ (f) estimated time of the cardiac arrest;
- ~~(h)~~ (g) whether or not CPR was initiated prior to the application of the AED;
- ~~(i)~~ (h) whether or not the cardiac arrest was witnessed;
- ~~(j)~~ (i) the time the first shock was delivered to the patient;
- ~~(k)~~ (j) the total number of shocks delivered;
- ~~(l)~~ (k) whether or not there was a pulse after the shocks and whether or not the pulse was sustained; and
- ~~(m)~~ (l) whether or not the patient was transported, and if so, the name of the transporting agency and the location to which the patient was transported.

AUTH: 50-6-503, MCA
IMP: 50-6-502, 50-6-503, MCA

37.104.615 MEDICAL PROTOCOL (1) A medical protocol for defibrillation use must be consistent with the requirements for defibrillation set out in the ~~"2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care"~~ published in "Circulation", a journal of the American Heart Association, November 29, 2005, Volume 112, Issue 22 Supplement, and in the ~~2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care.~~ "2015 AHA Guidelines Update for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC) Science" published in "Circulation," a journal of the American Heart Association, November 3, 2015, Volume 132, Issue 18 Supplement 2 and in the 2015 American Heart Association Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC).

(2) The department adopts and incorporates by reference the guidelines for defibrillation referred to in (1), which set guidelines for proper defibrillation. A copy of the documents referred to in (1) may be obtained from the American Heart Association at http://circ.ahajournals.org/content/vol112/24_suppl/ https://www.ahajournals.org/toc/circ/132/18_suppl_2.

AUTH: 50-6-503, MCA
IMP: 50-6-502, MCA

37.104.616 REQUIREMENTS OF AUTOMATED EXTERNAL DEFIBRILLATORS (AED) (1) An AED used by an AED program must be a unit approved by the U.S. Food and Drug Administration in accordance with its Final Order established Feb 2015.

(2) A copy of the Final Order referred to in (1) may be obtained from the U.S. Food and Drug Administration:
<https://www.federalregister.gov/documents/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems>.

AUTH: 50-6-503, MCA

IMP: 50-6-503, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) is proposing to amend ARM 37.104.601, 37.104.604, 37.104.606, 37.104.615, and 37.104.616 pertaining to automated external defibrillator (AED) devices.

The department is proposing to revise these rules for two primary reasons. First, the department has recently procured software that enables entities providing public AED access to meet registration requirements through an online process. The proposed rule revisions will allow for implementation and use of this new software system. Second, American Heart Association Guidelines and Food and Drug Administration (FDA) requirements reflecting AED device best practices have changed since the rules were last revised. The proposed rule revisions update references to the current version of these guidelines and requirements.

ARM 37.104.601 Definitions

This rule defines terms related to a public access defibrillation program. The department is proposing to revise the definitions within this rule for clarity and to align with updates being proposed to the other rules. A new definition is proposed to define the term "entity manager." Additionally, the department is proposing to remove the definition of "medical supervisor" since the term is no longer used under the proposed rules. Finding an appropriate medical supervisor has been a significant barrier for entities wishing to begin an AED program. Due to the improved transmission ability of the devices, the event recordings can be transmitted to the department for review and feedback, rather than requiring an "on-site" medical supervisor.

ARM 37.104.604 Written Plan

This rule specifies the requirements for a written AED plan. The department has recently procured software that allows an entity to submit its plan online in lieu of using a paper form. The department is proposing to revise this rule to take into account use of the new software system. By completing the online registration, the entity assures the device will be used and maintained appropriately and be integrated into the 911 emergency system. Since the requirement for an on-site medical supervisor is no longer required, the department is proposing to remove the current language in (1)(e). Each entity must continue to maintain records of device

maintenance and individual training. Notification of a device deployment through the web-based portal is still required.

ARM 37.104.606 Reports

This rule outlines the requirements for a report if an AED device is attached to a patient. The department is proposing to revise this rule to align with the revisions made to ARM 37.104.604 by requiring that reports be sent only to the department and the entity manager using the online reporting site. The proposed rule change is necessary to ensure consistency between the rules.

37.104.615 Medical Protocol

This rule establishes the medical basis for the use of an AED. The department is proposing to revise this rule to reference updated guidance from the American Heart Association that aligns with best practices relating to AED use.

37.104.616 Requirements of Automated External Defibrillators (AED)

This rule establishes the requirements for approved AED devices. The department is proposing to revise the rule to reference the most current FDA requirements governing approved AED devices.

Fiscal Impact

This proposed rule amendment is anticipated to have no fiscal impact to the state.

The proposed rulemaking is estimated to affect approximately 1,000 registered entities and approximately 1,000 non-registered entities. The department does not anticipate the proposed rulemaking will have a significant fiscal impact on these entities.

The department intends for these proposed rule amendments to be effective upon the date of adoption.

5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Heidi Clark, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphslegal@mt.gov, and must be received no later than 5:00 p.m., November 6, 2020.

6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have

their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 5 above or may be made by completing a request form at any rules hearing held by the department.

8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

9. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Robert Lishman
Robert Lishman
Rule Reviewer

/s/ Laura Smith for Sheila Hogan
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State September 29, 2020.