

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 37.104.3001, 37.40.3012,) PROPOSED AMENDMENT
37.104.3020, and 37.104.3022)
pertaining to trauma facility)
designation.

TO: All Concerned Persons

1. On September 28, at 11:00 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. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at: <https://mt-gov.zoom.us/j/89229080338?pwd=Mm84SDZKUkFHUkpDZCtJUzNCVm9EUT09>, meeting ID: 892 2908 0338, and password: 320256; or

(b) Dial by telephone: +1 646 558 8656, meeting ID: 892 2908 0338, and password: 320256. Find your local number: <https://mt-gov.zoom.us/u/kbm2RUtrym>.

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 September 14, 2023, to advise us of the nature of the accommodation that you need. Please contact Bailey Yuhas, 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 hhsadminrules@mt.gov.

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

37.104.3001 DEFINITIONS In addition to the definitions in 50-6-401, MCA, the following definitions apply to this subchapter:

(1) "Application" means the submission of written information by a health care facility, on forms required by the department, requesting designation as a specific level of trauma facility and providing information regarding its compliance with the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~ concerning the resources a facility must have to qualify as that level of trauma facility.

(2) "Area trauma hospital" means a health care facility that is designated by the department as having met the essential standards for area trauma hospitals as specified in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~.

(3) "Community trauma facility" means a health care facility that is designated by the department as having met the standards for a community trauma facility as described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~.

(4) "Comprehensive Trauma Center" means a health care facility that is designated by the department as having met the standards for a comprehensive trauma center as described in the Montana Trauma Facility Designation Criteria.

(4) remains the same but renumbered (5)

~~(5)(6)~~ "Designated facility" refers to a health care facility that has been determined by the department to satisfy the requirements of one of the four categories of trauma facilities as described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~.

~~(6)(7)~~ "Designation" means a formal determination by the department that a health care facility has met the requirements for a level of trauma facility as described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~.

(7) remains the same but renumbered (8)

(8) remains the same but renumbered (9)

~~(9)(10)~~ "Focused review" means a method established by the department to assess a health care facility's compliance with a corrective action plan to meet the resource criteria in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~.

~~(10)(11)~~ "Montana Trauma Facility Designation Criteria ~~(2019)~~" means the document within the Montana Trauma System Plan that contains the requirements for a facility to meet in order to be designated as a particular type of trauma care facility. The department adopts and incorporates by reference the department's Montana Trauma Facility Designation Criteria ~~(2019)~~ (2024). A copy of the Montana Trauma Facility Designation Criteria ~~(2019)~~ (2024) may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Emergency Medical Services and Trauma Systems Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951 or electronically at: <https://dphhs.mt.gov/publichealth/emsts/Trauma/Regulation>

(11) remains the same but renumbered (12)

(12) remains the same but renumbered (13)

(13) remains the same but renumbered (14)

(14) remains the same but renumbered (15)

(15) remains the same but renumbered (16)

(16) remains the same but renumbered (17)

~~(17)(18)~~ "Regional trauma center" means a health care facility that is designated by the department as having met the criteria for a regional trauma center as described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~.

(18) remains the same but renumbered (19)

(19) remains the same but renumbered (20)

(20) remains the same but renumbered (21)

(21) remains the same but renumbered (22)

(22) remains the same but renumbered (23)

~~(23)~~(24) "Trauma receiving facility" means a health care facility that is designated by the department as having met the criteria for a trauma receiving facility as described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan.~~

AUTH: 50-6-402, MCA
IMP: 50-6-401, 50-6-402, MCA

37.104.3012 LEVELS OF TRAUMA FACILITIES (1) The department may designate a health care facility as belonging to one of the following ~~four~~ levels of trauma facilities:

(a) comprehensive trauma center,

(a) remains the same but renumbered (b)

(b) remains the same but renumbered (c)

(c) remains the same but renumbered (d)

(d) remains the same but renumbered (e)

(2) Requirements for each level are contained in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan.~~

AUTH: 50-6-402, MCA
IMP: 50-6-402, MCA

37.104.3020 COMPOSITION OF SITE REVIEW TEAMS ~~(4) The site review team for regional trauma centers must be composed of out-of-state surveyors, including two general surgeons and department staff or any other members determined to be necessary by the department or requested by the health care facility being reviewed.~~

~~(2)~~(1) The site review team for comprehensive trauma centers, regional trauma centers, area trauma hospitals, and community trauma facilities must be composed of either out-of-state or in-state surveyors from a trauma center that is not owned or operated by the same entity as the applicant ~~Montana trauma region other than the one in which the facility is located~~ and must include a general surgeon, a trauma nurse coordinator, department staff, and other members determined to be necessary by the department or requested by the health care facility being reviewed.

~~(3)~~(2) The site review team for a trauma receiving facility must be composed of either out-of-state or in-state surveyors from a trauma center that is not owned or operated by the same entity as the applicant and must include a physician, a trauma nurse coordinator, department staff, and other members determined to be necessary by the department or requested by the health care facility being reviewed.

AUTH: 50-6-402, MCA
IMP: 50-6-402, MCA

37.104.3022 DESIGNATION PROCEDURES FOR FACILITIES VERIFIED AS A TRAUMA FACILITY BY AMERICAN COLLEGE OF SURGEONS (1) A health care facility with a current certificate of verification from the American College of Surgeons as a trauma facility qualifies as one of the following types of Montana

trauma facility as set out in (2), providing it submits an application, department staff attend the on-site or virtual review conducted by the American College of Surgeons, and the facility demonstrates compliance with any all requirements described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~ that may differ from ~~exceed~~ the American College of Surgeons' standards in the college's document entitled "Resources for Optimal Care of the Injured Patient: ~~2014~~ 2022 standards" A copy of this document may be obtained as set forth in (8).

(2) A current certificate of verification for the following levels established by the American College of Surgeons ~~qualified~~ qualifies a health care facility as the following type of Montana trauma facility:

(a) a level I trauma center qualifies as a comprehensive trauma center;

(a) remains the same but renumbered (b)

(b) remains the same but renumbered (c)

(c) remains the same but renumbered (d)

(3) through (3)(a) remains the same.

(b) any additional information required by the department to verify compliance with any requirements described in the Montana Trauma Facility Designation Criteria ~~of the State Trauma Plan~~ that ~~exceed~~ differs from the American College of Surgeons' standards;

(c) through (d) remains the same.

(4) remains the same.

(5) When the application and the site review are complete, and the American College of Surgeons' letter is received that indicates whether the facility is ~~successfully~~ verified as a trauma facility, the department will provide a copy of the application and the letter to the designation subcommittee at the next quarterly State Trauma Care Committee meeting.

(6) through (7)(a) remain the same.

(b) issue a provisional designation to the applicant provided that:

(i) through (ii) remain the same.

(c) through (d) remain the same.

(8) The department adopts and incorporates by reference "Resources for Optimal Care of the Injured Patient: ~~2014~~, 2022 standards" published by the American College of Surgeons. The document contains the trauma facility criteria used by the American College of Surgeons in its process for verification of trauma facilities. A copy may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Emergency Medical Services and Trauma Systems Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: 50-6-402, MCA

IMP: 50-6-402, 50-6-410, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) proposes to amend the above-stated rules pertaining to trauma facility designation. The proposed rule amendments are necessary to add a new trauma care designation

level for trauma care centers seeking to serve as comprehensive trauma centers. The proposed rule amendments also update trauma facility designation criteria to reflect the continued advancement of medical practice and conform with best practices. The department is also proposing amendments to update vague and outdated language to improve clarity and readability of the rules.

ARM 37.104.3001

The department is proposing to amend this rule to update the Montana Trauma Facility Designation Criteria adopted and incorporated by reference under ARM 37.104.3001(10). Two primary changes to the criteria are proposed. First, the Department proposes to add a new comprehensive trauma center designation level. This new designation level will enable trauma facilities meeting the criteria to be designated as comprehensive trauma centers. The establishment of comprehensive trauma centers in Montana will enable patients in need of the highest level of trauma care to have the option of receiving care within Montana rather than having to be transferred out-of-state. Second, the Department is proposing to update trauma designation criteria based upon the continued advancement of medical practice and to conform with nationally recognized best practices.

A copy of the proposed changes to the Montana Trauma Facility Designation Criteria is electronically accessible at:

<https://dphhs.mt.gov/publichealth/emsts/Trauma/Regulation>

ARM 37.104.3012

The department is proposing to amend this rule to add comprehensive trauma centers to the list of trauma center designation levels available in Montana. This proposed rule change aligns with the changes being proposed to the Montana Trauma Facility Designation Criteria.

ARM 37.104.3020

The department is proposing to amend this rule to make comprehensive trauma centers part of the site review team process. This proposed rule change aligns with the changes being proposed to the Montana Trauma Facility Designation Criteria. The department is also proposing to update the rule to align with nationally recognized best practices and to remove vague and outdated language.

ARM 37.40.3022

The department is proposing to amend this rule to add a comprehensive trauma center designation level to the acceptable list of verification allowed by the American College of Surgeons. This proposed rule change aligns with the changes being proposed to the Montana Trauma Facility Designation Criteria. The department is also proposing to update the rule to align with nationally recognized best practices and to remove vague and outdated language.

The department intends for these proposed rule amendments to be effective January 1, 2024.

Fiscal Impact

There is no anticipated fiscal impact associated with this rulemaking.

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: Bailey Yuhas, 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 hhsadminrules@mt.gov, and must be received no later than 5:00 p.m., October 6, 2023.

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.

8. An electronic copy of this notice is available on the department's web site at <https://dphhs.mt.gov/LegalResources/administrativerules>, or through the Secretary of State's web site at <http://sos.mt.gov/ARM/register>.

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

10. 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/ David Gerard

David Gerard, Deputy Director
Department of Public Health and Human
Services

Certified to the Secretary of State August 29, 2023.