

APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number : 420-2-2-.03

Rule Title: Trauma Center Designation

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? YES

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer  Date 7/25/12



APA-2
11/96

**STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION**

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-2-2-.03 Trauma Center Designation

INTENDED ACTION: To establish Alabama Statewide Trauma System Rules.

SUBSTANCE OF PROPOSED ACTION: To amend current rule to allow automatic acceptance of an American College of Surgeon certified trauma center, as long as the facility can provide proof that they can fulfill the Alabama Trauma System requirement for an in-house anesthesiologist.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on August 14, 2012, at 9:00 a.m. in Montgomery at the RSA Tower, 201 Monroe Street, Room 1586.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on September 4, 2012. All comments and requests for copies of the proposed rule should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Choona Lang, Alabama Department of Public Health, Office of EMS and Trauma, 201 Monroe Street, Suite 750, Montgomery, Alabama 36104. Telephone number: 334-206-5383.



Patricia E. Ivie, Agency Secretary

420-2-2-.03 Trauma Center Designation.

(1) Types of Designation.

- (a) Regular Designation. A regular designation may be issued by the Board after it has determined that an applicant hospital has met all requirements to be designated as a trauma center at the level applied for and is otherwise in substantial compliance with these rules.
- (b) Provisional Designation. At its discretion, the Board may issue a provisional designation to an applicant hospital that has met all requirements to be designated as a trauma center at the level applied for, with exception to minor deviations from those requirements that do not impact patient care or the operation of a trauma region.
 - 1. The provisional designation may be used for an initial designation or for an interim change in designation status to a lower level due to a trauma center's temporary loss of a component necessary to maintain a higher designation level.
 - 2. A trauma center must submit a written corrective plan and interim operation plan for the provisional designation period including a timeline for corrective action to the Office of EMS and Trauma within 30 days of receiving a provisional designation.
 - 3. A provisional designation shall not extend beyond 15 months.
 - 4. A trauma center may submit a written request to the Office of EMS and Trauma that a provisional designation be removed once all components of its corrective plan have been achieved. Following its receipt of such a request, the Department will conduct a focused survey on the trauma center. A regular designation shall be granted in the event it is confirmed that all components of the corrective plan have been achieved.

(c) Automatic Designation.

- 1. Trauma centers designated at Levels I-III by the American College of Surgeons (ACS) will be issued a regular designation by the Board, at that same level, after submitting an application and providing proof that the trauma center can meet ATS anesthesiologist requirements. The ATS will determine if an on-site survey revisit, to confirm resources, will be needed based upon the recommendation of the RTAC and/or the STAC. A final decision as provided in Rule 420-2-2-.03(4)(f)2, will not be required.

2. Trauma centers designated as a Level IV by ACS must meet state Level III designation criteria as set out in Appendix A in order to be issued a regular designation by the Board.

- (2) **Levels of Designation.** There shall be three levels of trauma center designation. The criteria of each level is set out in Appendix A.
- (3) **Application Provision.** In order to become a trauma center, a hospital must submit an application (attached to these rules as Appendix B) and follow the application process provided in paragraph (4) below.
- (4) **The Application Process.** To become designated as a trauma center, an applicant hospital and its medical staff shall complete the Department's "Application for Trauma Center Designation." An applicant hospital shall submit the completed application via mail or hand delivery to the address listed on the application. Within 30 days of receipt of the application, the Department shall provide written notification to the applicant hospital of the following:
- (a) That the application has been received by the Department;
 - (b) Whether the Department accepts or rejects the application for incomplete information;
 - (c) If accepted, the date scheduled for hospital inspection;
 - (d) If rejected, the reason for rejection and a deadline for submission of a corrected "Application for Trauma Center Designation" to the Department;
 - (e) Upon receipt of a completed application by the Department, an application packet containing a pre-inspection questionnaire will be provided to the applicant hospital. The pre-inspection questionnaire must be returned to the Department one month prior to the scheduled inspection.
 - (f) The trauma center post-inspection process will proceed as listed below:
 - 1. The inspection report will be completed two weeks after completion of the inspection.
 - 2. A State and Regional review of the inspection report and a recommendation for or against designation will be made thirty days after completion of the inspection.
 - 3. A final decision will be made known to the applicant hospital within 120 days of the completion of the inspection.
 - 4. Focus visits may be conducted by the Department as needed.
- (5) **The Inspection Process.** Each applicant hospital will receive an onsite inspection to ensure the hospital meets the minimum standards for the desired trauma center designation level as required by these rules. The Department's Office of EMS and

Trauma staff will coordinate the hospital inspection process to include the inspection team and a scheduled time for the inspection. The hospital will receive written notification of the onsite inspection results from the Office of EMS and Trauma.

(6) Designation Certificates.

- (a) A designation certificate will be issued after an applicant hospital has successfully completed the application and inspection process. The designation certificate issued by the Office of EMS and Trauma shall set forth the name and location of the trauma center, and the type and level of designation. The form of the designation certificate is attached to these rules as Appendix C.
- (b) Separate Designations. A separate designation certificate shall be required for each hospital when more than one hospital is operated under the same management.

(7) Designation for Contract.

- (a) A designation contract will be completed after the hospital has successfully completed the application and inspection process. The designation contract shall be issued by the Office EMS and Trauma. It shall set forth the name and location of the trauma center and the type and level of designation.
- (b) Separate Designation Contracts. A separate designation contract shall be required for each hospital when more than one hospital is operated under the same management.
- (c) The form of the designation contract is attached to these rules as Appendix D.

(8) Basis for Denial of a Designation.

The Department shall deny a hospital application for trauma center designation if the application remains incomplete after an opportunity for correction has been made, or if the applicant hospital has failed to meet the trauma center designation criteria as determined during the inspection.

(9) Suspension, Modification, and Revocation of a Designation.

- (a) A trauma center's designation may be suspended, modified, or revoked by the Board for an inability or refusal to comply with these rules.
- (b) The Board's denial, suspension, modification or revocation of a trauma center designation shall be governed by the Alabama Administrative Procedure Act, §41-22-1, et seq., *Ala. Admin. Code*.

- (c) Hearings. Contested case hearings shall be provided in accordance with the Alabama Administrative Procedure Act, §41-22-1, et seq., and the Board's Contested Case Hearing Rules, Chapter 420-1-3, *Ala Admin. Code*.
- (d) Informal settlement conferences may be conducted as provided by the Board's Contested Case Hearing Rules, Chapter 420-1-3, *Ala. Admin. Code*.

Authors: John Campbell, M.D., and Choona Lang

Statutory Authority: Alabama Legislature, Act 299, Regular Session, 2007 (Code of Alabama 1975, §22-11D-1, et seq.)

History: Filed February 18, 2009, Effective March 25, 2009.