APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number : 420-2-3
Rule Title: Alabama Statewide Health Systems for Stroke

X New ____ 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 P. Bentley Date 6/20/17

APA-2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-2-3 Alabama Statewide Health Systems for Stroke

INTENDED ACTION: To establish Alabama Statewide Health Systems for Stroke Rules.

SUBSTANCE OF PROPOSED ACTION: These rules establish a statewide stroke system as authorized by Act 2012-526.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on July 18, 2017 at 10:00 a.m., The RSA Tower, Suite 1544, 201 Monroe Street, Montgomery, AL 36104.

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 August 5, 2017. All comments and requests for copies of the proposed rule should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Stephen Wilson, Alabama Department of Public Health, Office of EMS , 201 Monroe Street, Suite 1100, Montgomery, Alabama 36104. Telephone number: 334-206-5383.

B. Brian Hale

Brian Hale, Agency Secretary

ALABAMA STATEWIDE HEALTH SYSTEMS FOR STROKE

TABLE OF CONTENTS

420-2-3-.01 General.

(1) Definitions.

(a) "Alabama Trauma Communications Center (ATCC)" - A central communication facility with the capability to constantly communicate with all pre-hospital providers and hospitals that have been designated by the Department as trauma/stroke/ST-Elevated Myocardial Infarction (STEMI) centers. The ATCC's capabilities include the ability to immediately and directly link the pre-hospital providers to these centers.

(b) "Board" - The Alabama State Board of Health.

(c) "Council" - The Statewide Trauma and Health Care Center Advisory Council.

(d) "Department" - The Alabama Department of Public Health.

(e) "Designated Health Care Center for Stroke" - A hospital that has met all the standards for stroke center designation as set out in these rules and that has been certified by the Department.

(f) "Designation" - A formal determination by the Department that a hospital is capable of providing designated stroke care.

(g) "Emergency Medical Service Personnel (EMSP)" - All recognized National Highway Traffic Safety Administration (NHTSA) levels of personnel licensed by the Board, who have met all primary and/or renewal educational requirements of the emergency medical services (EMS) rules, and are allowed to provide medical care within the level of their scope of practice granted by the Office of Emergency Medical Services (OEMS).

(h) "Hospital" - A health institution planned, organized, and maintained for offering to the public, facilities and beds for use in the diagnosis and treatment of patients requiring in-patient medical care, out-patient medical care, or other care performed by or under the supervision of physicians due to illness, disease, injury, deformity, abnormality, or pregnancy.

(i) "Hospital Stroke Patient" - A hospital patient who meets stroke system entry criteria and is entered into the

stroke system by calling the ATCC and obtaining a unique identification number.

(j) "Pre-Hospital Stroke Patient" - A pre-hospital patient who meets stroke system entry criteria and is entered into the stroke system by calling the ATCC and obtaining a unique identification number.

(k) "Quality Assurance/Quality Improvement (QA/QI)" - To document and foster continuous improvement in performances and the quality of patient care. In addition, it assists the Department in defining standards, evaluating methodologies, and utilizing evaluation results from continued system improvement. Materials prepared during the QA/QI process are confidential and privileged as provided in Sections 6-5-33, 22-21-8, and 34-24-58, Code of Ala. 1975.

(l) "Regional Agency" - A contractor located in a specific geographic area of the state that provides services specified in a contract. These agencies have no regulatory authority other than that conferred by the OEMS.

(m) "Regional Councils" - The regional advisory councils.

(n) "Regions" - The stroke care regions.

(o) "Registry" - The Statewide Stroke Registry.

(2) Stroke Care Regions. A map indicating the Stroke Care Regions is available at www.alabamapublichealth.gov. The Stroke Care Regions will be the same as the EMS Regions as approved by the Board.

(3) Quality Assurance/Quality Improvement. The Department shall develop guidelines for the state and regional level stroke staff regarding QA/QI activities.

Author:
Statutory Authority:
History:

420-2-3-.02 Health Care Center Designations for Stroke.

(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 stroke

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 stroke 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 stroke 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 stroke center's temporary loss of a component necessary to maintain a higher designation level.

2. A stroke center must submit a written corrective plan and interim operation plan for the provisional designation period including a timeline for corrective action to the Department within 30 days of receiving a provisional designation.

3. A provisional designation shall not extend beyond 15 months.

4. A stroke center may submit a written request to the Department 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 of the stroke center. A regular designation shall be granted in the event it is confirmed that all components of the corrective plan have been achieved.

(2) Levels of Designation. There shall be three levels of stroke center designation. The criteria of each level are set out in Appendix A.

(3) 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 Department shall set forth the name and location of the stroke center and the type and level of designation.

(b) Separate Designations. A separate designation certificate shall be required for each separately licensed hospital when more than one hospital is operated under the same management or owner.

(4) Memorandum of Understanding.

(a) A memorandum of understanding (MOU) will be completed after the hospital has successfully completed the application and inspection process. The designation contract shall be issued by the Department. It shall set forth the name and location of the stroke center and the type and level of designation.

(b) Separate MOUs. A separate MOU shall be required for each separately licensed hospital when more than one hospital is operated under the same management or owner.

(5) Basis for Denial of a Designation. The Board shall deny a hospital application of stroke 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 stroke center designation criteria as determined during an inspection.

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

(a) A stroke 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 stroke center designation shall be governed by the Alabama Administrative Procedure Act, §41-22- 1, et seq., Ala. Admin. Code.

(c) 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.

Author:
Statutory Authority:
History:

420-2-3-.03 Application Process.

(1) Application Provisions. In order to become a stroke center, a hospital must submit an application which can be

downloaded from www.alabamapublichealth.gov and follow the application process provided in paragraph (2) below.

(2) The Application Process. To become designated as a stroke center, an applicant hospital and its medical staff shall submit a completed "Application for Stroke Center Designation." An application may be submitted online, or by 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) Application has been received by the Department.

(b) Whether the Department accepts or rejects the application.

(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 to the Department.

(e) Upon receipt of an application deemed to be complete 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 1 month prior to the scheduled inspection.

(f) The stroke center post-inspection process will proceed as listed below:

1. The inspection report will be completed 2 weeks after completion of the inspection.

2. A Statewide Trauma and Health Care Center Advisory Council and Regional Advisory Council review of the inspection report and a recommendation for or against designation will be made within 120 days after completion of the inspection.

3. A final decision will be made known to the applicant hospital within 30 days of the completion of the inspection and the Council's recommendation.

4. Focus visits may be conducted by the Department as needed.

Author:
Statutory Authority:
History:

420-2-3-.04 Inspection Process.

(1) Each applicant hospital will have an opportunity to meet face to face with Department staff prior to designation as a stroke center. Each applicant hospital will be asked to provide information to the Department for inspection to ensure the hospital meets the minimum standards for the desired stroke center designation. The hospital shall also receive an onsite inspection to ensure the hospital meets the minimum standards for the desired stroke center designation level as required by these rules. The Department's staff will coordinate the hospital inspection process with the inspection team and schedule a time for the inspection. The hospital will receive written notification of the onsite inspection results from the Department.

Author:
Statutory Authority:
History:

420-2-3-.05 Statewide Trauma and Health Care Center Advisory Council.

(1) There is established a Statewide Trauma and Health Care Center Advisory Council. The Council assists in the development of these rules and serves as a consultant to the Board on matters related to the statewide trauma system and other statewide coordinated health care systems that may be implemented, such as the statewide stroke system. The Council shall be appointed as provided in Section 22-11D-5, Code of Ala. 1975.

(2) Subcommittees and Workgroups.

(a) The Council may appoint subcommittees and workgroups to serve as consultants to the Council on matters related to the implementation of other statewide coordinated health care systems, such as stroke, and the development of regulations and standards for such systems. When appointed, the Council shall consult with and rely upon the advice of subcommittees and workgroups prior to making decisions or recommendations to the Board.

(b) Subcommittees shall consist of Council members and workgroups may consist of non-Council members.

(3) Stroke Workgroup. The Stroke Workgroup appointed by the Council will consist of a minimum of 24 members. Recommendations for Stroke Workgroup membership will be made to the Council by the Department after consultation with the Regional Agency. A minimum of four members from each Regional Agency will be included. Each Regional Agency will nominate an acute stroke neurologist, an emergency medicine physician, a stroke hospital coordinator, and a regional EMS staff member who is responsible for stroke program QA issues. Stroke Workgroup members shall not be entitled to reimbursement for expenses incurred in the performance of their duties.

Author:
Statutory Authority:
History:

420-2-3-.06 Regional Advisory Councils.

(1) Creation. Regional Councils are established to advise, consult with, and accommodate specific regional needs. Each Regional Council shall provide data required by the Department or the Council to assess the effectiveness of the statewide stroke system.

(2) Membership. Each Regional Council shall have a minimum of ten members. The membership of the Regional Councils shall be appointed in the same manner as the Statewide Trauma and Health Care Center Advisory Council is appointed and shall be composed of representatives of the same groups, in accordance with Section 22-11D-5, Code of Ala. 1975. The chair of each Regional Council shall be elected by its members to serve for a 4-year term. The members shall represent the demographic composition of the region served, as far as practicable. Regional Council members shall be entitled to reimbursement for expenses incurred in the performance of their duties at the same rate as state employees.

(3) Responsibilities. The Regional Council is responsible for direct oversight and management of its specific regional stroke system. The Regional Council shall review regional stroke program activities for appropriateness, quality, and quantity, including pre-hospital and hospital care. The Regional Councils shall decide the appropriate secondary patient care triage criteria for their specific region to ensure patients are routed to the closest and most appropriate hospital.

(4) In addition, the Regional Council shall fulfill the responsibilities as listed below:

(a) Maintain guidelines for hospitals.

(b) Collect data.

(c) Evaluate data-determined audit filters.

(d) Re-evaluate to determine effectiveness of corrective action.

(e) Participate on Regional Stroke QI Committee.

(f) Devise plan of corrective action for QI issues.

(5) QA/QI Committees. The Regional Councils shall document the effectiveness of hospital and emergency medical services QA/QI evaluations through routine reports of these QA/QI activities provided by each stroke system entity in their specific region. The Regional Council will routinely perform focused review of specific QA/QI items of pre-hospital and hospital stroke care activities as determined appropriate by the Regional Council. Recommendations for action will be developed by the committee based on analysis of data/information evaluated during committee function. The Regional Council will submit quarterly compliance reports to the Department for review to ensure system processes are followed. Materials prepared during the QA/QI process are confidential and privileged as provided in Sections 6-5-33, 22-21-8, and 34-24-58, Code of Ala. 1975.

Author:
Statutory Authority:
History:

420-2-3-.07 Patient Entry Criteria.

(1) Entry Criteria for Hospitals. Patients shall be entered into the Alabama Statewide Stroke System according to the criteria set out in the Alabama EMS Patient Care Protocols.

(2) Entry Criteria for Pre-hospital Providers. Patients shall be entered into the Alabama Statewide Stroke System according to the Alabama EMS Patient Care Protocols.

Author:
Statutory Authority:
History:

420-2-3-.08 Statewide Stroke Registry.

(1) Creation. The Statewide Stroke Registry shall become operational within 12 months after the Department has received sufficient funds to finance its development, implementation, and operation. At this time, the Statewide Stroke Registry shall collect data on the incidence, severity, and outcomes of stroke. The registry shall be used to improve the availability and delivery of pre-hospital or out-of-hospital care and hospital stroke care services.

(2) Data and Reporting. Data elements and reporting requirements will be established by the Council.

(3) Confidentiality. All registry data shall be held confidential pursuant to state and federal laws, rules, and policies. No patient name or other identifying data shall be made public.

Author:
Statutory Authority:
History:

420-2-3-.09 Centralized Dispatch and Communications System.

(1) The ATCC will be staffed 24-hours a day by personnel with specific in-depth knowledge of stroke system design, function, and protocols.

(2) It will be a primary responsibility of the ATCC to coordinate stroke system activities by maintaining and providing information and recommendations whenever needed to the field staff and hospital personnel in providing care to patients meeting the stroke system entry criteria.

Author:
Statutory Authority:
History:

420-2-3-.10 Confidentiality.

(1) State and Regional Stroke QA/QI Committees shall be provided access to all information, reports, statements, or memoranda reviewed by or furnished to the State and Regional Stroke QA/QI Workgroups members; and any discussion, findings, conclusions, or recommendations resulting from the review of the records by the State and Regional Stroke QA/QI Workgroups are declared to be privileged and confidential. All information, reports, statements, or memoranda reviewed by or furnished to the State and Regional Stroke QA/QI Workgroups shall be used

only in the exercise of proper functions and duties of the State and Regional Stroke QA/QI Workgroups. Materials prepared during the QA/QI process are confidential and privileged as provided in Sections 6-5-33, 22-21-8, and 34-24-58, Code of Ala. 1975.

(2) All information furnished to the State and Regional Stroke QA/QI Workgroups shall include pertinent safety and health information associated with each case summary. All identifying patient information will be removed before preparing case summary.

(3) All information and records acquired or developed by the State and Regional Stroke QA/QI Workgroups shall be secured and have restricted access and shall be destroyed when no longer of use.

(4) Statistical information and data may be released by the State and Regional Stroke QA/QI Workgroups as long as no identifying protected health information, as defined by the Health Insurance Portability and Accountability Act, is provided.

Author:
Statutory Authority:
History:

420-2-3-.11 Statewide Health System Fund.

(1) The Department shall distribute funding allocated to the Department for the purpose of creating, administering, maintaining, or enhancing the statewide health system for stroke. The Department may apply for, receive, and accept gifts and other payments, including property and services, for the fund from any governmental or other public or private entity or person and may utilize the fund for activities related to the design, administration, operation, maintenance, or enhancement of the statewide health system.

(2) Distribution of Funds. The methodology of distribution of funds and allocation of funds shall be established by the Council and subsequently adopted by the Board pursuant to the Administrative Procedure Act. Fund allocation to health care centers shall be based upon the designated level of health care and the number of qualified patients directed through the health care centers, as defined by the rules of the Board.

Author:
Statutory Authority:
History:

Alabama Department of Public Health
Office of Emergency Medical Services

Statewide Trauma and Health Systems-Stroke Designation Criteria

Master Checklist

MASTER CHECKLIST

Statewide Trauma and Health Systems-Stroke Designation Criteria

These items have been deemed essential per the State Stroke System plan.	Level II	Level III
HOSPITAL ORGANIZATION		
Stroke Service or Equivalent	E	-
Stroke Service Director	E	-
Stroke Coordinator	E	E
Physician Medical Director for stroke services	-	E
Hospital Departments/Sections		
Neurology[1]	E	-
Vascular Neurosurgery (or transfer plan)	E	-
Emergency Medicine	E	-
CLINICAL CAPABILITIES		
Specialty availability upon notification of patient need		
Emergency Medicine (10 minutes)	E	E
Neurology[1]	E	-
Vascular Neurosurgery	E	-
Physician or nurse with ability to evaluate patient for tPA use	-	E
24/7 on-call neurology or, a physician with expertise and experience in diagnosing and treating stroke, or a neurologist by telemedicine[1]	-	E
Consultants availability		
Internal Medicine	E	-
Critical Care	E	-
Cardiology	E	-
Neuroimaging	E	-
FACILITIES AND RESOURCES		
Emergency Department		
Designated Physician Director (with 8 hours stroke related CME)	E	-
Emergency Medicine Specialists	E	-
Nursing Personnel (continuous monitoring until admission)	E	-
Emergency Department available 24/7	E	E

MASTER CHECKLIST

Statewide Trauma and Health Systems-Stroke Designation Criteria

	Level II	Level III
Stroke Treatment Protocols in place that define tPA administration	E	E
Pharmacy with tPA in stock 24/7	E	E
Written plan for higher level of care for patients who require it	E	E
Equipment		
Airway control and ventilation equipment	E	E
Pulse oximetry	E	E
End-tidal CO2 determination	E	E
Suction devices	E	E
Electrocardiograph	E	E
Standard intravenous fluid administration equipment	E	E
Sterile sets for percutaneous vascular access (venous and arterial)	E	E
Gastric decompression	E	E
Drugs necessary for emergency care	E	E
X-ray availability	E	E
CT availability and interpretation in 45 minutes	E	E
Angiographic suite available	E	E
Two-way communication with emergency vehicles	E	E
Sterile ventriculostomy try readily available if NS coverage	E	-
Operating suites adequately staffed (within 30 minutes of stroke alert)	E	-
Post anesthetic recovery room available	E	-
Intensive Care Unit or dedicated bed for stroke patients	E	-
Personnel		
Designated Medical Director	E	-
Specialists with privileges in critical care in-house or on-call	E	-
Monitoring equipment		
Telemetry	E	-
Pulse Oximetry	E	-
Neuroimaging special capabilities		

Statewide Trauma and Health Systems-Stroke Designation Criteria

	Level II	Level III
In-house radiology technical personnel capable of brain CT	E	-
Angiography (CTA and MRA)	E	-
Neurovascular sonography	E	-
Computed tomography (emergent and routine)	E	-
Magnetic Resonance Imaging (MRI)	E	-
Rehabilitation		
Rehabilitation services protocol for stroke patients	E	-
Clinical laboratory services		
Standard analyses of blood, urine, etc.	E	-
Blood typing and cross-matching	E	-
Comprehensive blood bank or access to equivalent facility	E	-
Blood gases and pH determination	E	-
CSF examination capabilities	E	-
Comprehensive coagulation testing	E	-
CONTINUING EDUCATION		
At least 8 hours annual program education are provided for:		
Staff Physicians who care for stroke patients	E	E
At least twice a year stroke program education is provided for:		
All other staff members who care for stroke patients	E	E
Stroke Prevention Program Coordinator	E	-
PERFORMANCE IMPROVEMENT (PI)		
Does hospital track patient outcomes?	E	E
Perform on-going evaluations?	E	E
Strive for improvement?	E	E
Community outreach/public education	E	E

APPENDIX

[1]Neurology: A physician with experience in diagnosing and treating stroke is defined as a licensed physician who is board-certified or board-eligible (BC/BE) in emergency medicine or neurology through the American Board of Medical Specialties, or who is BC/BE in another specialty, but has a minimum of 8 hours of stroke related continuing medical education (CME) annually.

Level I Comprehensive Stroke Center Guidelines

To be recognized as a Level I Comprehensive Stroke Center, a hospital must be certified by the Joint Commission as a Comprehensive Stroke Center or equivalent and maintain status with the ATCC.

NOTES