ALABAMA STATEWIDE HEALTH SYSTEM FOR STROKE

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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/cardiac centers. The ATCC's capabilities include the ability to immediately and directly link the pre-hospital providers to these centers.

(b) "Board" - The Board of Health of the State of Alabama as defined by §22-2-1, Code of Ala. 1975, or the State Health Officer, or his or her designee, when acting for the Board.

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

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

(e) "Designated Stroke Center" - 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 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)" - The process 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 6-5-333, 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.

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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, except for 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 action 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 four 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, location, level of designation, and the expiration date.

(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) must be executed after the hospital has successfully completed the application and inspection process. The MOU shall be prepared 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. The Board shall deny a hospital application of stroke center designation for the following:

(a) If the application remains incomplete after an opportunity for correction has been made.

(b) If the applicant hospital has failed to meet the stroke center designation criteria as determined during an inspection.

(6) Suspension, Modification, or 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 or the executed MOU.

(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.

Authors: William Crawford, M.D., and Jamie Gray
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420-2-3-.03 Application Process.

(1) Application Provisions. To become a stroke center, a hospital must submit an application which can be downloaded from www.alabamapublichealth.gov/strokesystem/index.html and follow the application process provided in paragraph (2) below.

(2) The Application Process. The stroke center application must be submitted to the OEMS. 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 and whether it accepts or rejects the application.

1. If the application is accepted, the Department will coordinate a date for the inspection. If the application packet is not provided with the application, the Department will contact the hospital. The application packet can be downloaded at www.alabamapublichealth.gov/strokesystem/index.html. The required information must be returned to the Department 1 month prior to the scheduled inspection.

2. If rejected, the reason for rejection and a deadline for submission of a corrected application to the Department.

3. The Department accepts certifications (by The Joint Commission or equivalent) for all stroke center levels. The hospital needs only to provide a copy of its current certificate, with an application. The Department may still meet with the hospital, but a site inspection would not be required.

(b) The stroke center inspection process will be conducted as described in Section 420-2-3-.04 and will then proceed as follows:

1. The inspection report will be completed within 30 days after completion of the inspection.

2. The Council and Regional Council review of the 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.

Authors: William Crawford, M.D., and Jamie Gray
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420-2-3-.04 Inspection Process.

(1) Initial inspection.

(a) Each applicant hospital will have an opportunity to meet face to face with Department staff prior to designation as a stroke center.

(b) 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.

(c) 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.

(d) The Department's staff will coordinate the hospital inspection process with the inspection team and schedule a time for the inspection.

(e) The hospital will receive written notification of the onsite inspection results from the Department.

(2) Level designation change.

(a) If a state inspected and approved stroke center applies to upgrade its designation after being accredited by a nationally recognized stroke accreditation agency, a state site visit may be deferred.

(b) A state inspected and approved stroke center may request to downgrade its designation if coordinated with the OEMS and a site visit may be deferred.

(3) Stroke Center Reinspection. Each stroke center shall be re-evaluated no less than every 4 years to ensure designation criteria is maintained.

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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 14 members. Composition of the Stroke Workgroup will be as follows: the State EMS Medical Director, one EMSP appointed by OEMS, one EMS Regional staff member from each EMS Region, and one acute stroke neurologist or emergency medicine physician from each Region nominated by the Regional Council.

(4) Recommendations for Stroke Workgroup membership will be made to the Council by the Department after consultation with the Regional Council. Each Regional Council will nominate an acute stroke neurologist or an emergency medicine physician and a Regional EMS staff member. One EMSP will be appointed by the State EMS Medical Director. Stroke Workgroup members shall not be entitled to reimbursement for expenses incurred in the performance of their duties.

Authors: William Crawford, M.D., and Jamie Gray

Statutory Authority: Code of Ala. 1975, §22-11D-1, et seq.

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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 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 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 6-5-333, 22-21-8, and 34-24-58, Code of Ala. 1975.
Authors: William Crawford, M.D., and Jamie Gray
Statutory Authority: Code of Ala. 1975, §22-11D-1, et seq.
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420-2-3-.07 Patient Entry Criteria.

(1) Entry Criteria for Designated Stroke Centers. Stroke patients shall be entered into the Alabama Statewide Stroke System.

(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.

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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.

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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.

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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 6-5-333, 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.

Authors: William Crawford, M.D., and Jamie Gray
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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.
Authors: William Crawford, M.D., and Jamie Gray
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Appendix A

Statewide Trauma and Health Systems – Stroke Center Designation Criteria

These items have been deemed Essential per the Statewide Stroke System Plan	Level IIa	Level II	Level III
	TSC	PSC	ASRH
HOSPITAL ORGANIZATION			
Stroke Service or Equivalent	E	E	
Stroke Program Director: Physician with neurology background, extensive expertise, and ability to provide clinical and administrative guidance to program	E		
Stroke Service Director: Physician with training and expertise in cerebrovascular disease		E	
Physician Medical Director for stroke services: Physician with sufficient knowledge of cerebrovascular disease			E
Stroke Coordinator	E	E	E
Hospital Departments/Sections			
Neurology	E	E	
Neurosurgery			
Neurointerventional	E		
Neurocritical Care			
Critical Care	E		
Emergency Medicine	E	E	E
CLINICAL CAPABILITIES			
Specialty availability upon notification of patient need			
Emergency Medicine – Physician Staffed (10 minutes)	E	E	E
Neurologist 24/7	E		
24/7 on-call neurology OR a neurologist by telemedicine		E	
24/7 on-call neurology OR a physician with expertise and experience in diagnosing and treating stroke OR a neurologist by telemedicine			E
Physician or nurse with ability to evaluate patient for tPA use			E
Neurosurgeon within 2 hours	E	E	
Neurosurgery Transfer Plan - timely transfer (may use ATCC) *			E
Neurointerventionalist** availability at least 70% of time	E		
Intensivist coverage 24/7	E		
Consultants availability			
Internal Medicine	E	E	
Critical Care	E	E	
Cardiology	E	E	
Neuroimaging	E	E	
FACILITIES AND RESOURCES			
Emergency Department (ED)			
Physician staffed ED (must be in hospital)	E	E	E
Nursing Personnel (continuous monitoring until admission or transfer)	E	E	E
Emergency Department available 24/7	E	E	E
Stroke Treatment Protocols in place that define tPA administration	E	E	E
Pharmacy with tPA in stock 24/7	E	E	E
Written plan for higher level of care for patients who require it	E	E	E
Equipment			
Airway control and ventilation equipment	E	E	E
Pulse oximetry	E	E	E
End-tidal CO2 determination	E	E	E
Suction devices	E	E	E
Electrocardiograph	E	E	E

Standard intravenous fluid administration equipment	E	E	E
Sterile sets for percutaneous vascular access (venous and arterial)	E	E	E
Gastric decompression	E	E	E
Drugs necessary for emergency care	E	E	E
X-ray availability	E	E	E
CT availability and interpretation in 45 minutes	E	E	E
Catheter Angiographic suite available 24/7	E		
Two-way communication with emergency vehicles	E	E	E
Sterile ventriculostomy tray readily available if NS coverage	E	E	
Operating suites adequately staffed (within 30 minutes of stroke alert)	E	E	
Post anesthetic recovery room available	E	E	
Dedicated neurointensive care beds for stroke patients	E		
Intensive Care Unit or dedicated beds for stroke patients (stroke unit)	E	E	
Personnel of intensive care unit or stroke unit			
Designated Medical Director	E	E	
Dedicated neurointensivists/proxy in-house			
Dedicated intensivists/proxy in-house	E		
Specialists with privileges in critical care in-house or on-call		E	
Monitoring equipment			
Telemetry	E	E	E
Pulse Oximetry	E	E	E
Neuroimaging special capabilities			
In-house radiology technical personnel capable of brain CT	E	E	E
Catheter angiography	E		
CTA and MRA	E	E	
Carotid duplex ultrasound and transcranial Doppler	E		
Carotid duplex ultrasound		E	
Computed tomography (emergent and routine)	E	E	E
Magnetic Resonance Imaging (MRI)	E	E	
Rehabilitation			
Rehabilitation services protocol for stroke patients	E	E	
Clinical laboratory services			
Standard analyses of blood, urine, etc	E	E	E
Blood typing and cross-matching	E	E	
Comprehensive blood bank or access to equivalent facility	E	E	
Blood gases and pH determination	E	E	
CSF examination capabilities	E	E	
Comprehensive coagulation testing	E	E	E
CONTINUING EDUCATION			
At least 8 hours annual program education are provided for:			
Stroke Program Director/ Stroke Service Director	E	E	
At least 4 hours annual program education are provided for:			
Physician Medical Director for stroke services			E
At least 2 hours annual program education are provided for:			
Staff Physicians who care for stroke patients	E	E	E
At least twice a year stroke program education is provided for:			
All other staff members who care for stroke patients	E	E	E
Stroke Prevention Program Coordinator	E	E	D
Annual Acute Health Systems Training:			
Physicians	E	E	E
Emergency Department staff	E	E	E
PERFORMANCE IMPROVEMENT			
Does hospital track patient outcomes?	E	E	E
Perform on-going evaluations?	E	E	E

Strive for improvement?	E	E	E
Community outreach/public education?	E	E	E
RESEARCH AND REGISTRIES			
Participate in a stroke registry	E	E	D
PROCEDURAL VOLUME REQUIREMENTS			
Organization performs 15 mechanical thrombectomies over 1 year (or 30 over 2 years)	E		
Neurointerventionalist** performs 15 mechanical thrombectomies over 1 year (or 30 over 2 years)	E		

*ATCC can be used to coordinate transfers within the stroke system.
**Physician with neurology, neurosurgery, or radiology background with 1 year formal training or experience in performing intracranial cerebrovascular procedures, including minimum 15 mechanical thrombectomy during this period.

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.

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