



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

October 1, 2014
*Amended October 6, 2014

MEMORANDUM

TO: Interested Parties

FROM: Megan Lamphere, Rule-making Coordinator *ML*
N.C. Medical Care Commission

RE: Proposed Adoption of Designation of Primary Stroke Center Rules
*10A NCAC 14L

GS 150B-21.2 requires a rule-making body to notify certain individuals of its intent to amend a permanent rule and adopt new rules. It also requires notification of the date, time and location of the public hearing on the rule and any fiscal note that has been prepared in connection with the proposed rule.

This set of rules reflects the requirement of S.L. 2013-44, Gen. Stat. 131E-78.5, to create a process by which hospitals licensed by the Division of Health Service Regulation can submit documentation of stroke center certification by a national accrediting authority to the Office of Emergency Medical Services (OEMS) to qualify for stroke center designation by the Department. Accordingly, the Department has submitted form OAH 0300 to the Codifier of Rules, Office of Administrative Hearings, indicating its intent to proceed with adoption of *Subchapter 10A NCAC 14L.

In accordance with G.S. 150B-19.1, the Department obtained certification of these rules from the Office of State Budget and Management on August 28, 2014.

The proposed rule text will be published in the October 1, 2014 edition of the N.C. Register which can be found at the Office of Administrative Hearings web site at <http://www.ncoah.com/rules/register>.

A public hearing is scheduled for November 18, 2014 at 10:00 a.m. in Room 131, Wright Building, 1201 Umstead Drive, Raleigh, NC 27603. The building is located on the Dorothea Dix Hospital campus. The Department is accepting public comments on these rules and fiscal note from October 1, 2014 – December 1, 2014. Comments will also be accepted in person at the public hearing. The proposed effective date of these rules is February 1, 2015.

A copy of the proposed rules, draft fiscal note, and instructions for submitting comment can be found at the Division of Health Service Regulation web site at www.ncdhhs.gov/dhsr/ruleactions.html. If you have questions related to the proposed rules and fiscal note please contact the Office of Emergency Medical Services Section at (919) 855-4620.



<http://www.ncdhhs.gov/dhsr/>

Phone: 919-855-3750 / Fax: 919-733-2757

Location: 809 Ruggles Drive v Dorothea Dix Hospital Campus v Raleigh, N.C. 27603

Mailing Address: 2701 Mail Service Center • Raleigh, North Carolina 27699-2701

An Equal Opportunity / Affirmative Action Employer



cc:

Drexdal Pratt, Director, Division of Health Service Regulation
Emery Milliken, General Counsel, N.C. Department of Health & Human Services
Regina Godette-Crawford, Chief, OEMS Section

10A NCAC 14L .0101 is proposed for adoption as follows:

SUBCHAPTER 14L – STROKE CENTER DESIGNATION

SECTION .0100 – DEFINITIONS

10A NCAC 14L .0101 DEFINITIONS

The following definitions apply throughout this Subchapter:

- (1) “Acute Stroke Care” means the process for the rapid assessment and treatment of patients experiencing an acute cerebrovascular accident.
- (2) “Catchment Area” means the geographical area from which a hospital’s patients are drawn.
- (3) “Comprehensive Stroke Care” means state-of-the-art infrastructure, staff and training to receive and treat patients with the most complex stroke cases, including advanced imaging capabilities, 24 hours per day, seven days per week availability of specialized treatments, and staff with the unique education and competencies to care for complex stroke patients.
- (4) “Comprehensive Stroke Center” means a hospital that has satisfied all requirements for certification from a nationally recognized hospital certifying organization for the provision of comprehensive stroke care.
- (5) “Conditional Designation” means a hospital that is pursuing certification but has not satisfied all certification requirements of the national accrediting body to qualify for Primary Stroke Center or Comprehensive Stroke Center designation.
- (6) “Department” means the Department of Health and Human Services.
- (7) “Designated Stroke Center” means a hospital that has presented evidence to the Department of current certification by a national accrediting organization as a Comprehensive or Primary Stroke Center.
- (8) “Designation” means the recognition by the Department of a hospital’s certification by a nationally recognized hospital certifying organization for the provision of comprehensive or acute stroke care.
- (9) “EMS System” means a coordinated arrangement of local resources under the authority of the county government (including all agencies, personnel, equipment, and facilities) organized to respond to medical emergencies and integrated with other health care providers and networks including public health, community health monitoring activities, and special needs populations, that are approved by the Department in accordance with the EMS and Trauma Rules of the North Carolina Medical Care Commission 10A NCAC 13P .0201.
- (10) “EMS Provider” means those entities defined in G.S. 131E-155(13a) that hold a current license issued by the Department pursuant to G.S. 131E-155.1.
- (11) “Office of Emergency Medical Services (OEMS)” means a section of the Division of Health Service Regulation of the North Carolina Department of Health and Human Services located at 1201 Umstead Drive, Raleigh, North Carolina 27603.
- (12) “Primary Stroke Center” means a hospital that has satisfied all requirements for certification from a nationally recognized hospital accrediting organization for the provision of acute stroke care.

*History Note: Authority G.S. 143B-10; 131E-78.5;
Eff. February 1, 2015.*

10A NCAC 14L .0201 is proposed for adoption as follows:

SECTION .0200 –STROKE CENTER DESIGNATION

10A NCAC 14L .0201 STROKE CENTER DESIGNATION REQUIREMENTS

(a) The Department shall designate hospitals licensed by the Division of Health Service Regulation pursuant to G.S. 131E-78.5 as certified “Designated Stroke Centers,” as defined in Rule .0101(7) of this Section, upon receipt of evidence provided by the hospital as defined in Paragraph (b) of this Rule that the hospital has received Primary or Comprehensive Stroke Center certification by any of the following:

- (1) the “Joint Commission,” “American Heart Association,” and “American Stroke Association” Comprehensive Stroke Center, Disease Specific Certification Program; “Healthcare Facilities Accreditation Program” (HFAP);
- (2) “Det Norske Veritas” (DNV); or
- (3) other nationally recognized hospital certifying body as determined by the Department.

(b) Hospitals designated as a Primary or Comprehensive Stroke Center shall notify the Office of Emergency Medical Services within 90 days of certification of the following information:

- (1) the name of the accrediting organization issuing certification to the hospital;
- (2) the date of certification;
- (3) the level of certification (Primary or Comprehensive);
- (4) the date of renewal of the certification; and
- (5) the name and phone number of the primary contact person at the hospital who is responsible for obtaining the certification.

(c) The Department shall maintain a list of all Primary and Comprehensive Stroke Centers on its Internet website at <http://www.ncdhhs.nc.gov>.

(d) Each designated Primary or Comprehensive Stroke Center shall coordinate the provision of acute stroke care with other hospitals in their catchment area through written agreements that address the following minimum requirements:

- (1) transportation of acute stroke patients to the designated Primary or Comprehensive Stroke Center; and
- (2) acceptance of patients initially treated at hospitals incapable of providing appropriate management of the acute stroke patient.

(e) The Office of Emergency Medical Services shall provide written notification annually through email to the medical directors of each EMS system and EMS provider a list of all Primary and Comprehensive Stroke Centers contained on the Department’s Internet website.

(f) Hospitals shall notify the Office of Emergency Medical Services within 30 days of any change to the hospital’s Primary or Comprehensive Stroke Center certification.

(g) Hospitals that have received a conditional certification are ineligible for designation by the Department as a Primary or Comprehensive Stroke Center until the hospital receives Primary or Comprehensive Stroke Center certification by the accrediting body issuing the certification.

(h) Hospitals that fail to maintain certification shall be removed from the Department’s Internet website by the Office of Emergency Medical Services within 30 days following receipt of written notification from the affected hospital.

(i) Non-certified hospitals shall not advertise or utilize signage representing the hospital as a Primary or Comprehensive Stroke Center if the hospital has not received that designation by the Department.

Eff. February 1, 2015.