

**Fiscal Impact Analysis of  
Permanent Rule Adoption without Substantial Economic Impact**

**Agency Proposing Rule Change**

North Carolina Department of Health and Human Services (Secretary)/ Division of Health Service Regulation (Director)

**Contact Persons**

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**Impact Summary**

Federal Government: No Impact  
State Government: Negligible Impact (\$461.17: see table page 3)  
Local Government: No Impact  
Small Business: No Impact  
Substantial Impact: Negligible

**Titles of Rule Changes and Statutory Citations**

*\*See proposed text of these rules in the Appendix*

**10A NCAC 14L**

Section .0100 – Definitions

- Definitions 10A NCAC 14L .0101 (Adopt)

Section .0200 – Stroke Center Designation

- Stroke Center Designation Criteria 10A NCAC 14L .0201 (Adopt)

**Authorizing Statutes**

S.L. 2013-44  
Gen. Stat. 131E-78.5  
Gen. Stat. 143B-10

**Background**

Under authority of Gen. Stat. § 143B-10, the Department of Health and Human Services (Department) has delegated the promulgation of these rules to the Division of Health Service Regulation (DHSR). 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 DHSR 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. Once designation is granted, the OEMS will reflect the hospital's information on the Department's Internet Web site and update this list of designated hospitals in June of each calendar year.

The Department has recognized national accreditation organizations that will be used to qualify the hospital(s) for stroke center designation, although confirmation of additional accrediting organizations may be deemed acceptable if the certification standards are determined by the Department to meet those identified in these rules. These organizations are the Joint Commission (JC); the American Heart Association (AHA) Primary Stroke Center Designation or the JC and AHA Comprehensive Stroke Center, Disease Specific Certification Program: “Healthcare Facilities Accreditation Program,” or the Det Norske Veritas (DNV) accreditation program.

### **Rules Summary and Anticipated Fiscal Impact**

Rule “.0101 – **Definitions**” has been created to provide clarity on terminology used in support of the designation criteria utilized in Rule .0201 – Stroke Center Designation Criteria.

#### Fiscal Impact

No fiscal impact associated with the adoption of this rule.

Rule “.0201 – **Stroke Center Designation Criteria**” is being adopted to establish the criteria associated with receiving Stroke Center Designation by the Department for all hospitals that have meet the certification standards by a nationally recognized accrediting organization. This rule includes the requirement of maintaining certification of the accrediting body to qualify for continued designation by the Department. There is also provided notice that upon receipt of certification, the OEMS will post a list of all qualified hospitals designated as stroke centers by the Department on the Department’s Internet Web site.

#### Fiscal Impact

##### Federal

No fiscal impact associated with the adoption of this rule.

##### State

The OEMS has identified one FTE to receive and process the notice of certification by hospitals and estimate it will take a total of 4 hours annually at \$19.44 (including salary and fringe) per hour for an annual total cost of \$77.76, to collect and sort these documents and provide written response to these hospitals indicating designation.

The OEMS has identified one additional FTE to review and verify the notices of certification received for designation and estimate it will take a total of 8 hours annually at \$43.18 (including salary and fringe) per hour for an annual total cost of \$345.44, to process these documents and confirm designation.

The DHSR has identified one FTE to post the list of designated stroke centers on the Department’s Internet Web site and estimate it will take a total of 1 hour annually at \$37.97 (including salary and fringe) per hour for an annual total cost of \$37.97, to update this list.

##### Local Government

No fiscal impact associated with the adoption of this rule.

Small Business

No fiscal impact associated with the adoption of this rule.

Substantial Impact

Negligible (see table below)

Staff FTE	Number Hours per Year	Cost per Hour	Total Cost per Year
OEMS Processing Ass't	4	19.44	77.76
OEMS Technical	8	43.18	345.44
DHSR Technical	1	37.97	37.97
TOTAL ANNUAL COST			461.17

**Summary**

The only fiscal affect identified in adopting these rules involve the receipt of the hospitals notice of certification to the OEMS and the posting of the list of designated hospitals in June of each year on the Department's Internet Web site. The cost of this action can easily be absorbed within the OEMS and Department's operating budget without any increase in necessary state funds. The total estimated annual cost is \$461.17.

## APPENDIX

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. January 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.

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