Agency Name: Department of Health and Environmental Control

Statutory Authority: 44-61-610 et seq.

Document Number: 4760

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- 01/09/2018 Received by Lt. Gov & Speaker 05/09/2018

H 01/09/2018 Referred to Committee

S 01/09/2018 Referred to Committee

S 02/16/2018 Committee Requested Withdrawal

 120 Day Period Tolled

- 02/16/2018 Withdrawn and Resubmitted 05/09/2018

S 03/01/2018 Resolution Introduced to Approve 1077

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 provided for in the Regulation

Document No. 4760

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-61-610 et seq.

**Synopsis:**

The Department of Health and Environmental Control (“Department”) has promulgated this new regulation to execute the requirements of the Stroke System of Care Act of 2011, S.C. Code Sections 44-61-610 et seq. (Supp. 2016). The regulation establishes a process of application and recognition of acute care hospitals wishing to be recognized as stroke centers within South Carolina. The regulation establishes a statewide stroke registry for the collection and analysis of stroke care by acute care hospitals within the state. Additionally, the regulation adopts a nationally recognized, standardized stroke-triage assessment tool, posted on the Department’s website and distributed to all Emergency Medical Services (“EMS”) agencies licensed by the Department.

The Department had a Notice of Drafting published in the *State Register* on April 28, 2017.

Changes made at the request of the Senate Medical Affairs

Committee by letter dated February 16, 2018:

**Section 202.E.** Requirements for additional information as part of the application process has been removed.

**Section 302.** Language allowing the Department to make exceptions to standards has been removed.

**Section 301.** Section 301 was re-codified to Section 300 to account for this section no longer having a Section 302.

**Section 600.** Severability language has been removed.

**Section 700.** Requirements for conditions not addressed in this regulation have been removed.

Table of Contents was adjusted in accordance with the above changes.

Section-by-Section Discussion of Final Regulation submitted

by the Department of Health and Environmental Control on

January 9, 2018, for legislative review:

TITLE: 61-118, South Carolina Stroke Care System

TABLE OF CONTENTS

The table of contents was added.

**Section 100. DEFINITIONS**

The definitions of 100.A Acute Care Hospital, 100.B Acute Stroke Ready Hospital, 100.C Certificate of Recognition, 100.D Certificate Holder, 100.E Comprehensive Stroke Center, 100.F Department, 100.G Emergency Medical Services, 100.H Primary Stroke Center, 100.I Recognition, 100.J State Stroke Registry Database, 100.K Stroke Advisory Council, 100.L Stroke Care System, 100.M Stroke Center, 100.N Stroke Patient, 100.O Telemedicine-Enabled Stroke Center, and 100.P Thrombectomy-Capable Stroke Center were added.

**Section 200. RECOGNITION PROCESS**

Section 200 delineates the process for recognition by the Department.

**Section 201. Eligibility for Recognition**

Section 201 allows for any acute care hospital certified or accredited as a Stroke Center by the Joint Commission or other nationally recognized organization to apply to the Department for recognition.

**Section 202. Application Process**

Section 202 outlines the process for application to the Department for recognition and delineates the required documentation therein.

**Section 203. Recognition Renewal**

Section 203 states that recognition expires upon expiration of current disease-specific certification or accreditation by the Joint Commission or other nationally recognized organization.

**Section 204. Recognition Levels**

Section 204 delineates the available levels of recognition and states that the Department may adopt and recognize any certification or accreditation by nationally recognized organizations that may become available at a later date.

**Section 205. Recognition**

Section 205 delineates the Department’s process for recognizing hospitals under the requirements of this regulation.

**Section 206. Process of Re-recognition**

Section 206 delineates the process for acute care hospitals seeking recognition after previously, but no longer, being a Certificate Holder.

**Section 300. CERTIFICATE OF RECOGNITION REQUIREMENTS**

Section 300 outlines the Certificate of Recognition requirements.

**Section 301. Issuance and Terms of the Certificate of Recognition**

Section 301 delineates the terms of certificates indicating Recognition and states that a Certificate of Recognition is not assignable or transferable.

**Section 302. Exceptions to the Standards**

Section 302 was added to grant the Department authority to make exceptions to these standards when the health and safety of patients will not be compromised and the standard is not specifically required by statute.

**Section 400. STATEWIDE SYSTEM OF STROKE CARE**

Section 400.A requires licensed EMS providers to utilize the South Carolina Stroke Assessment and Triage tool identified by the Department in the SC EMS Protocol “Suspected Stroke.” Section 400.B requires that after July 1, 2019, licensed EMS providers to utilize the SC EMS Protocol “Adult Stroke Patient Destination Determination by Stroke Center Capability” for transport of acute stroke patients to the closest stroke center within a specified timeframe of onset of symptoms unless one (1) or more exceptions listed therein applies.

**Section 500. STATE STROKE REGISTRY DATABASE**

Section 500 outlines the requirements of submission to the State Stroke Registry Database.

**Section 501. Data Submission**

Section 501 requires Certificate Holders to participate in the State Stroke Registry Database and outlines the required schedule for submission.

**Section 502. Inclusion and Exclusion Criteria**

Section 502 states that patient inclusion and exclusion criteria will be established by the Department under the guidance of the Stroke Advisory Council and maintained in the State Stroke Registry Guidelines.

**Section 503. Confidentiality Protection of Data and Reports**

Section 503 requires that reports show only general information and shall not identify any protected information or hospital information.

**Section 600. SEVERABILITY**

Section 600 was added to allow the regulation to remain valid should it be determined that a portion of the regulation be invalid or unenforceable.

**Section 700. GENERAL**

Section 700 was added to allow the Department to utilize best practices to manage any conditions not covered by these regulations.

**Instructions:**

Add new Regulation 61-118, South Carolina Stroke Care System, to Chapter 61 regulations in the South Carolina Code of Regulations.

**Text**:

61-118. South Carolina Stroke Care System.

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SECTION 300 – ISSUANCE AND TERMS OF THE CERTIFICATE OF RECOGNITION

SECTION 400 – STATEWIDE SYSTEM OF STROKE CARE

SECTION 500 – STATE STROKE REGISTRY DATABASE

501. Data Submission

502. Inclusion and Exclusion Criteria

503. Confidentiality Protection of Data and Reports

SOUTH CAROLINA STROKE CARE SYSTEM

SECTION 100

DEFINITIONS

 A. Acute Care Hospital. A hospital licensed by the Department that has facilities, medical staff and all necessary personnel to provide diagnosis, care, and treatment of a wide range of acute conditions, including injuries.

 B. Acute Stroke Ready Hospital (“ASRH”). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Acute Stroke Ready Hospital and recognized by the Department.

 C. Certificate of Recognition. A document issued by the Department to an Acute Care Hospital indicating the Department has recognized the Acute Care Hospital as a Stroke Center at a stroke Recognition level appearing in Section 204 of this regulation.

 D. Certificate Holder. An Acute Care Hospital with a current Certificate of Recognition from the Department and with whom rests the ultimate responsibility for compliance with this regulation.

 E. Comprehensive Stroke Center (“CSC”). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Comprehensive Stroke Center, and recognized by the Department.

 F. Department. The South Carolina Department of Health and Environmental Control (“DHEC”).

 G. Emergency Medical Services (“EMS”). The treatment and transport of patients in crisis health situations occurring from a medical emergency or from an accident, natural disaster, or similar life-threatening situation, through a system of coordinated response and emergency medical care.

 H. Primary Stroke Center (“PSC”). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Primary Stroke Center, and recognized by the Department.

 I. Recognition. The formal determination by the Department that an Acute Care Hospital is certified or accredited to provide a particular level of stroke care services.

 J. State Stroke Registry Database. The stroke data collection and evaluation system, also known as “Get With The Guidelines-Stroke,” designed to include, but not be limited to, stroke studies, patient care and outcomes, and severity of illness in the State. The data elements collected in the State Stroke Registry Database are determined by the Department with collaboration from the Stroke Advisory Council.

 K. Stroke Advisory Council (“SAC”). Stroke System of Care Advisory Council created pursuant to S.C. Code Section 44-61-650(A).

 L. Stroke Care System. An organized statewide system of care for the Stroke Patient, including the Department, EMS providers, hospitals, inpatient rehabilitation providers, and other providers who have agreed to participate in coordinating stroke care services and who have been recognized by the Department in an organized statewide system.

 M. Stroke Center. A hospital recognized by the Department as certified or accredited by the Joint Commission or another nationally recognized organization that provides disease-specific certification or accreditation for stroke care.

 N. Stroke Patient. An individual being treated for a sudden brain dysfunction due to a disturbance of cerebral circulation. The resulting impairments include, but are not limited to, paralysis, slurred speech, and/or vision loss. Strokes can be classified as either ischemic or hemorrhagic.

 O. Telemedicine-Enabled Stroke Center. A center utilizing interactive audio, video, and other electronic media for the purpose of diagnosis, consultation, or treatment of acute stroke. Telemedicine-Enabled Stroke Centers offer telemedicine services for stroke on a twenty-four (24) hour, seven (7) day per week basis, have a transfer plan in place with at least one (1) PSC or CSC, and report a minimum of four (4) performance measures of their choosing, at least two (2) of which are clinical measures related to clinical practice guidelines, quarterly to the State Stroke Registry Database.

 P. Thrombectomy-Capable Stroke Center (“TSC”). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Thrombectomy-Capable Stroke Center, and recognized by the Department.

SECTION 200

RECOGNITION PROCESS

**201. Eligibility for Recognition**

 A. Any Acute Care Hospital certified or accredited as a stroke center by the Joint Commission or other nationally recognized organization that provides disease-specific certification or accreditation for stroke care may apply to the Department for Recognition.

 B. In order to maintain Department Recognition, an Acute Care Hospital shall maintain certification or accreditation as a stroke center by the Joint Commission or from an equivalent process by another nationally recognized organization that provides disease-specific certification or accreditation for stroke care.

 C. Any facility that no longer meets nationally recognized, evidence-based standards as a stroke center, or no longer possesses disease-specific certification or accreditation for stroke care, shall notify the Department within thirty (30) business days as required by S.C. Code Section 44-61-640(D), and surrender the Certificate of Recognition to the Department.

**202. Application Process**

 A. An Acute Care Hospital seeking Recognition shall submit to the Department a completed application. The application shall include the applicant’s attestation assuring that the contents of the application and other requested documents are accurate and true. The application shall be authenticated as follows:

 1. If the applicant is an individual or a partnership, the application shall be signed by the owner(s);

 2. If the applicant is a corporation, nonprofit organization, or limited liability company, the application shall be signed by two (2) of its officers;

 3. If the applicant is a governmental unit, the application shall be signed by the head of the governmental unit having jurisdiction.

 B. The application shall set forth the full name and address of the Acute Care Hospital for which the Recognition is sought, and the name and address of the owner of the facility in the event that his or her address is different from that of the facility. In the event of a change in ownership of the Acute Care Hospital, the Department shall be notified in writing within forty-eight (48) hours of the change.

 C. The application shall include a copy of the full accreditation report by the Joint Commission or other nationally recognized organization at the level of Recognition requested.

 D. The application shall include signed copies of agreements to allow the Department to access data submitted to the State Stroke Registry Database.

**203. Recognition Renewal**

 A. Recognition shall expire upon expiration of current disease-specific certification or accreditation for stroke care by the Joint Commission or other nationally recognized organization.

 B. To maintain Recognition, an Acute Care Hospital shall renew its recognition upon renewal of current disease-specific certification or accreditation for stroke care as required by the Joint Commission or other nationally recognized organization.

 C. The application process for renewal shall follow the same process outlined in Section 202.

**204. Recognition Levels**

 A. Recognition Levels by the Department for Stroke Centers include Acute Stroke Ready Hospital (“ASRH”), Primary Stroke Center (“PSC”), Thrombectomy-Capable Stroke Center (“TSC”), and Comprehensive Stroke Center (“CSC”).

 B. As nationally recognized, disease-specific certification or accreditation programs become available at more comprehensive and less comprehensive levels, the Department may adopt and recognize those hospitals that have achieved the certification or accreditation.

**205. Recognition**

 A. Recognition is based upon Department review and verification of the application and its supporting documents, as indicated in Section 202. Failure to meet recognition requirements, misrepresentation, and/or false information provided by the hospital is grounds for denial.

 B. Upon approval, the Department will issue a Certificate of Recognition to the hospital denoting the Recognition level. The Department will also place the name of the hospital and its corresponding Recognition level on the Department’s website.

**206. Process of Re-recognition**

An Acute Care Hospital seeking Recognition after previously, but no longer, being a Certificate Holder shall follow the Recognition procedures outlined in Section 202.

SECTION 300

ISSUANCE AND TERMS OF THE CERTIFICATE OF RECOGNITION

 A. The issuance of a Certificate of Recognition does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety, or the well-being of any patient.

 B. A Certificate of Recognition is not assignable or transferable.

 C. A Certificate of Recognition shall be effective for a specific Stroke Center at a specific physical location. A Certificate of Recognition shall remain in effect until expiration of current disease-specific certification or accreditation.

SECTION 400

STATEWIDE SYSTEM OF STROKE CARE

 A. Licensed EMS providers shall establish a stroke assessment and triage system that incorporates the South Carolina Stroke Assessment and Triage tool identified by the Department and located in the SC EMS Protocol “Suspected Stroke.”

 B. After July 1, 2019, licensed EMS providers shall utilize SC EMS Protocol “Adult Stroke Patient Destination Determination by Stroke Center Capability” for transport of acute Stroke Patients to the closest Stroke Center within a specified timeframe of onset of symptoms unless one (1) or more of the following exceptions apply:

 1. It is medically necessary to transport the patient to another hospital;

 2. It is unsafe or medically inappropriate to transport the patient directly to a Stroke Center due to adverse weather or ground conditions;

 3. Transporting the patient to a Stroke Center would cause a shortage of local EMS resources (defined as no resources available for longer than thirty (30) minutes in a reasonable response area) and air transport is unavailable;

 4. No appropriate Stroke Center is able to receive and provide stroke care to the Stroke Patient without undue delay; or

 5. Before transport of a patient begins, the patient requests to be taken to a particular hospital that is not a Stroke Center or, if the patient is less than eighteen (18) years of age or is not able to communicate, such request is made by an adult member of the patient’s family or a legal representative of the patient.

SECTION 500

STATE STROKE REGISTRY DATABASE

**501. Data Submission**

 A. All Certificate Holders shall participate in the State Stroke Registry Database by:

 1. Submitting data identified by the Department to the State Stroke Registry Database; and

 2. Signing and completing agreements to allow the Department to access data submitted to the State Stroke Registry Database.

 B. The Certificate Holder shall ensure that all data is submitted to the State Stroke Registry Database quarterly, as outline below. The Certificate Holder shall ensure that the data entered in the State Stroke Registry Database is accurate and complete.

|  |  |
| --- | --- |
| **Admission Period** | **Due Date** |
| January – March | July 1 |
| April – June  | October 1 |
| July – September  | January 1 |
| October – December  | April 1 |

**502. Inclusion and Exclusion Criteria**

Patient inclusion and exclusion criteria shall be established by the Department under the guidance of the Stroke Advisory Council and maintained in the State Stroke Registry Guidelines.

**503. Confidentiality Protection of Data and Reports**

Information that identifies individual patients shall not be disclosed. Reports that do not contain protected health information or any identifiable information may be generated and distributed. Such reports shall not identify any protected information or hospital information.

**Fiscal Impact Statement**:

There is no anticipated additional cost by the Department or State government due to any requirements of this regulation. There are no external costs anticipated.

**Statement of Need and Reasonableness**:

The following is based on an analysis of the factors listed in 1976 Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: R.61-118, South Carolina Stroke Care System.

Purpose: The purpose of this new regulation is to establish a process of application and recognition of acute care hospitals wishing to be recognized as Stroke Centers within the State, encourage Stroke Centers to submit data to the State Stroke Registry Database, and establish a statewide stroke assessment and triage tool for EMS. This regulation seeks to direct EMS agencies to transport stroke patients to appropriate facilities to treat stroke patients in a timely manner.

Legal Authority: 1976 Code Sections 44-61-610 et seq.

Plan for Implementation: The DHEC Regulation Development Update (accessible at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>) provides a summary of and link to this new regulation. Additionally, printed copies are available for a fee from the Department’s Freedom of Information Office. Department personnel will take appropriate steps to inform the regulated community of the regulation and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Pursuant to S.C. Code Section 44-61-640(B) (Supp. 2016), the Department must establish a process to recognize acute care hospitals as Stroke Centers within the State, given an applicant is certified as a Stroke Center by the Joint Commission or another nationally recognized organization that provides disease-specific certification or accreditation for stroke care. Furthermore, the Department must supply a list of these recognized Stroke Centers to EMS agencies and create and provide a statewide stroke assessment-triage tool. This regulation establishes the process of recognition of Stroke Centers, requires the use of a statewide stroke assessment-triage tool and transport plan, and outlines the process to participate in the State Stroke Registry Database.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost to the Department, State government, or the regulated community due to any inherent requirements of this regulation.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The regulation seeks to support the Department’s goals relating to protection of public health through the anticipated benefits highlighted above. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the regulation is not implemented, transport of stroke patients within the State by EMS agencies will be up to the determination and agreements between EMS agencies and the local hospitals regardless of their certification as Stroke Centers.

**Statement of Rationale:**

This new regulation addresses the requirements of the Stroke System of Care Act of 2011. This regulation is necessary to establish a process of application and recognition of acute care hospitals wishing to be recognized as Stroke Centers within South Carolina. The regulation establishes a State Stroke Registry Database for the collection and analysis of stroke care by acute care hospitals within the State. Finally, the regulation adopts a nationally recognized, standardized stroke-triage assessment tool to be posted on the Department’s website and distributed to all EMS agencies licensed by the Department.