Regulation 61-118
South Carolina Stroke Care System

Disclaimer

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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.


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.

<table>
<thead>
<tr>
<th>Admission Period</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>January – March</td>
<td>July 1</td>
</tr>
<tr>
<td>April – June</td>
<td>October 1</td>
</tr>
<tr>
<td>July – September</td>
<td>January 1</td>
</tr>
<tr>
<td>October – December</td>
<td>April 1</td>
</tr>
</tbody>
</table>

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.