

August 13, 2019

NOTICE OF PROPOSED RULEMAKING
Revisions to Chapter 511-9-2 "Emergency Medical Services"
Repeal of Chapter 511-9-2-.04
Adoption of Chapter 511-9-2-.05 "Designation of Specialty Care Centers"

The Department of Public Health proposes the attached revisions to DPH Regulations under Chapter 511-9-2, specifically related to Chapter 511-9-2-.04, entitled "Designation of Specialty Care Centers," pursuant to its authority under O.C.G.A. Sections 31-2A-6 and 31-11-110 et seq.

The purpose of the proposed rulemaking is to clarify language and make administrative changes to the current regulations by repealing Chapter 511-9-2-.04 and reposition the current language related to the designation of specialty care centers to Chapter 511-9-2-.05, currently "Reserved," and retitle Chapter 511-9-2-.05 as "Designation of Specialty Care Centers."

The proposed rulemaking will further make amendments to the regulation entitled "Designation of Specialty Care Centers" to add Thrombectomy-Capable Stroke Centers as an additional level of stroke centers designated by the Department as provided in O.C.G.A. § 31-11-112. This addition was made in consultation with the Georgia Coverdell Acute Stroke Registry and consistent with advancements in medicine and patient care. Further, the Joint Commission, in collaboration with the American Heart Association/American Stroke Association now recognizes hospitals with this advanced level of stroke certification for Thrombectomy-Capable Stroke Centers in response for the need to identify hospitals that meet rigorous standards for performing endovascular thrombectomy.

The proposed rulemaking will also clarify the requirements for hospitals to be designated by the Department as a trauma center, burn center, or as a remote treatment stroke center, clarify due process procedures when action is taken by the Department to suspend or revoke a hospital's designation as a specialty care center, as well provide for the Department to issue a provisional designation with specified terms and conditions.

The proposed amendments have been posted to the Department's website at <https://dph.georgia.gov/regulationsrule-making>. Interested persons may submit comments on these proposed revisions in writing addressed to:

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Written comments must be submitted on or before September 13, 2019. Comments may also be presented in person at a public meeting scheduled for 11:00 a.m. on September 4, 2019, in EOC Briefing Room, Room 3-240, at 2 Peachtree Street, NW, Atlanta, Georgia 30303. The Commissioner of Public Health will consider the proposed rules for adoption on or about September 16, 2019, to become effective on or about October 16, 2019.



M. Zain Farooqui
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RULES OF THE DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-9-2 Emergency Medical Services

~~511-9-2-.04 Designation of Specialty Care Centers. Repealed and Reserved.~~

~~511-9-2-.05 Reserved. Designation of Specialty Care Centers.~~

~~511-9-2-.04 Designation of Specialty Care Centers Repealed and Reserved.~~

~~(1) — Trauma Centers.~~

~~(a) — Applicability.~~

~~1. — This section is not intended to prevent any hospital or medical facility from providing medical care to any trauma patient.~~

~~2. — No hospital or medical facility shall hold itself out or advertise to be a designated trauma center without first meeting the requirements of these rules.~~

~~(b) — Designation.~~

~~1. — The department shall define the process for trauma center designation and re-designation.~~

~~2. — The department has the authority to review, enforce, and recommend removal of trauma center designation for trauma centers failing to comply with applicable statutes, Rules and Regulations, and department policy.~~

~~3. — Designation will be for a period of three years.~~

~~4. — Each designated trauma center will be subject to periodic review.~~

~~5. — Each designated trauma center shall submit data to the state trauma registry in a manner and frequency as prescribed by the department.~~

~~(2) — Stroke Centers~~

~~(a) — Applicability.~~

~~1. — This section is not intended to prevent any hospital or medical facility from providing medical care to any stroke patient.~~

~~2. — No hospital or medical facility shall hold itself out as or advertise to the public that it is designated by the department as a comprehensive, primary, remote treatment, or any other level of stroke center without first meeting the requirements of these rules.~~

~~3. — The department, in consultation with the Georgia Coverdell Acute Stroke Registry, may establish additional levels of stroke centers as necessary based on advancements in medicine and patient care.~~

~~(b) — Designation of Nationally Accredited Stroke Centers.~~

~~1. — Any hospital seeking designation and identification by the department as a comprehensive, primary, or remote treatment stroke center must submit a written application to the department.~~

~~2. — Hospitals seeking designation as either a comprehensive or primary stroke center must include adequate documentation of the hospital's valid certification as either a comprehensive or primary stroke center by a national healthcare accreditation body recognized by the department.~~

~~3. — Hospitals seeking designation as a remote treatment stroke center must include adequate documentation of the hospital's valid certification as an acute stroke ready hospital by a national healthcare accreditation body recognized by the department.~~

~~(c) — Designation of Non-Nationally Accredited Remote Treatment Stroke Centers.~~

~~1. — Hospitals that are not nationally accredited as an acute stroke ready hospital may seek designation and identification as a remote treatment stroke center through an application process as determined by the department.~~

~~(i) — Upon receipt of a completed application, the department shall schedule and conduct an inspection of the applicant's facility no later than ninety days after receipt of the application.~~

~~(ii) — Hospitals will be evaluated on the standards and clinical practice guidelines established by the American Heart Association and American Stroke Association and must utilize current and acceptable telemedicine protocols relative to acute stroke treatment.~~

~~2. — Each hospital seeking designation as a remote treatment stroke center under subsection (2)(c) must establish cooperating stroke care agreements with designated comprehensive or primary stroke centers.~~

~~(d) — In order to assure that patients are receiving the appropriate level of care and treatment at each level of stroke center in the state, each hospital designated and identified by the department as a stroke center must participate in the Georgia Coverdell Acute Stroke Registry, and shall submit data to the Registry as required by the department including, but not limited to, the following information:~~

~~(i) — Date of admission and discharge;~~

~~(ii) — Patient disposition at discharge;~~

~~(iii) — Patient identifier, currently known as "Georgia LONGID," that consists of elements as defined by the department;~~

~~(iv) — Patient age, gender, and race;~~

~~(v) — Location where stroke occurred;~~

~~(vi) — Patient arrival mode;~~

- (vii) — Patient's past medical and medication history;
 - (viii) — Clinical diagnosis of type of stroke or transient ischemic attack;
 - (ix) — The National Institutes of Health stroke scale score;
 - (x) — Serum low density lipoprotein level;
 - (xi) — Whether stroke symptoms were resolved at time of presentation;
 - (xii) — Earliest time patient placed on comfort measure only;
 - (xiii) — Whether patient was admitted for elective carotid intervention;
 - (xiv) — Whether patient was participating in a stroke related clinical trial;
 - (xv) — Whether in hospital treatment with intravenous or intra-arterial thrombotic or mechanical clot removal, antithrombotic, or venous thromboembolism prophylaxis was provided, or reason for not providing each treatment;
 - (xvi) — Date and time of last known well visit, hospital arrival, imaging, and treatment administration;
 - (xvii) — Whether dysphagia screen had been completed;
 - (xviii) — Whether treatment at discharge with antithrombotic, anticoagulant, or statin (lipid lowering medication) was provided, or reason for not providing each treatment;
 - (xix) — Whether smoking cessation advice or counseling was provided;
 - (xx) — Whether stroke education was provided;
 - (xxi) — Whether rehabilitation services was provided; and
 - (xxii) — Modified Rankin Scale score at discharge.
- (e) — The department may suspend or revoke a hospital's designation as a stroke center, after notice and hearing, if the department determines that the hospital is not in compliance with the requirements of these rules or applicable statutes.
- (3) — Emergency Cardiac Care Centers.
- (a) — Applicability.
1. — This section is not intended to prevent any hospital or medical facility from providing medical care to any cardiac patient.
 2. — No hospital or medical facility shall hold itself out as or advertise to the public that it is designated by the department as a Level I, Level II, or Level III emergency cardiac care center without first meeting the requirements of these rules and obtaining approval from the department.
 3. — The department may establish additional levels of emergency cardiac care centers as necessary based on advancements in medicine and patient care.
- (b) — Designation of Emergency Cardiac Care Centers

1. ~~Any hospital seeking designation or re-designation by the department as an emergency cardiac care center must submit a written application to the department in a manner and on forms as determined by the department.~~

2. ~~The department's review of applications for designation and re-designation as an emergency cardiac care center may include an on-site inspection of the hospital.~~

(c) ~~Designation Criteria~~

1. ~~Applicants for designation as an emergency cardiac care center shall meet, at a minimum, the following criteria:~~

(i) ~~Level I:~~

(a) ~~Cardiac catheterization and angioplasty facilities available 24 hours, seven days per week, 365 days per year;~~

(b) ~~On-site cardiothoracic surgery capability available 24 hours, seven days per week, 365 days per year;~~

(c) ~~Established protocols for therapeutic hypothermia for out-of-hospital cardiac arrest patients;~~

(d) ~~The ability to implant percutaneous left ventricular assist devices for support of hemodynamically unstable patients experiencing out-of-hospital cardiac arrest for heart attack;~~

(e) ~~Neurologic protocols to measure functional status at hospital discharge; and~~

(f) ~~The ability to implant automatic implantable cardioverter defibrillators.~~

(ii) ~~Level II:~~

(a) ~~Cardiac catheterization and angioplasty facilities available 24 hours, seven days per week, 365 days per year, but no on-site cardiothoracic surgery capability;~~

(b) ~~Established protocols for therapeutic hypothermia for out-of-hospital cardiac arrest patients;~~

(c) ~~Neurologic protocols to measure functional status at hospital discharge; and~~

(d) ~~A written transfer plan with one or more Level I emergency cardiac care centers for patients who need left ventricular assist devices or cardiothoracic surgery.~~

(iii) ~~Level III:~~

(a) ~~Established protocols for therapeutic hypothermia for out-of-hospital cardiac arrest patients; and~~

(b) ~~A written plan for systematic transfer of patients to a Level I or Level II facility.~~

2. ~~Coordinating agreements established between cardiac care centers shall be in writing and shall include at a minimum:~~

(a) ~~Transfer agreements for the transport and acceptance of:~~

i. ~~Cardiac patients seen by a Level I emergency cardiac care center for care which a Level II or III emergency cardiac care center does not provide; or~~

~~ii. — Cardiac patients seen by a Level II emergency cardiac care center for care which a Level III emergency cardiac care center does not provide; and~~

~~(b) — Communications criteria and protocols between the emergency cardiac care centers.~~

~~(d) — Data Reporting~~

~~1. — Each hospital designated and identified by the department as an emergency cardiac care center must report the following to designated registries as determined by the department in accordance with time frame requirements established by the department:~~

~~(i) — Required data elements on all out of hospital cardiac arrest patients as determined by the department; and~~

~~(ii) — Required data elements on all heart attack patients as determined by the department.~~

~~2. — Each emergency cardiac care center shall have a written system describing the timely submission of all data described in subsection (i) and (ii) of this section.~~

~~(e) — The department may suspend or revoke a hospital's designation as an emergency cardiac care center, after notice and hearing, if the department determines that the hospital is not in compliance with the requirements or criteria of these rules or applicable statutes. In lieu of suspending or revoking a hospital's designation, the department may re-designate a hospital at another level of emergency cardiac care if it is determined that a hospital does not meet the criteria for a hospital's current level of designation.~~

~~(4) — Confidentiality. All information reported to any registry as described by this Rule shall be deemed confidential, except that the Department may in its discretion release such reports or data in de-identified form or for research purposes determined by the Department to have scientific merit. Under no circumstances may information reported to any registry as described by this Rule be released in such a manner as to lead to the identification of any hospital, institution, or clinic.~~

Rule 511-9-2-.05 Reserved Designation of Specialty Care Centers.

(1) Trauma and Burn Centers.

(a) Applicability.

1. No hospital shall hold itself out as or advertise to the public that it is designated by the Department as a trauma or burn center without first meeting the requirements of these rules and obtaining approval from the Department.
2. This section is not intended to prevent any hospital from providing medical care to any trauma or burn patient.

(b) Designation of Trauma and Burn Centers.

1. Any hospital seeking designation or re-designation by the Department as a Level I, Level II, Level III, or Level IV trauma center must submit a written application to the Department in a manner and on forms as determined by the Department, and shall meet, at a minimum, the requirements defined by the American College of Surgeons Committee on Trauma.
2. Any hospital seeking designation or re-designation by the Department as a burn center must submit a written application to the Department in a manner and on forms as determined by the Department, and must hold and maintain current verification as a burn center by the American Burn Association.
3. The Department may establish additional levels and types of trauma and burn centers as necessary based on advancements in medicine and patient care.
4. Each designated trauma center shall submit data to the state trauma registry in a manner and frequency as prescribed by the Department.

(c) The Department may suspend or revoke a hospital's designation as a trauma or burn center, after providing written notice to the hospital, if the Department determines that the hospital is not in compliance with the requirements or criteria of these rules or applicable statutes. The Department shall provide an administrative hearing on the action to suspend or revoke a hospital's designation if the hospital makes a written request for a hearing. Such written request must be delivered to and received by the Department no later than twenty days after the hospital receives notice of the action. If a timely request for a hearing is not received, the action will become effective twenty days after the hospital's receipt of the notice. In lieu of suspending or revoking a hospital's trauma or burn center designation, the Department may re-designate the hospital at another level and/or type of trauma or burn center if it is determined that the hospital does not meet the criteria for its current level of designation.

(2) Stroke Centers

(a) Applicability.

1. No hospital shall hold itself out as or advertise to the public that it is designated by the Department as a comprehensive, thrombectomy-capable, primary, remote

treatment, or any other level of stroke center without first meeting the requirements of these rules and obtaining approval from the Department.

2. This section is not intended to prevent any hospital from providing medical care to any stroke patient.
3. The Department, in consultation with the Georgia Coverdell Acute Stroke Registry, may establish additional levels of stroke centers as necessary based on advancements in medicine and patient care.

(b) Designation of Comprehensive, Thrombectomy-Capable, and Primary Stroke Centers.

1. Any hospital seeking designation or re-designation by the Department as a comprehensive, thrombectomy-capable, or primary stroke center must submit a written application to the Department in a manner and on forms as determined by the Department.
2. An applicant for designation or re-designation as a comprehensive, thrombectomy-capable, or primary stroke center must hold and maintain a current certification as a comprehensive, thrombectomy-capable, or primary stroke center by a national healthcare accreditation body recognized by the Department.

(c) Designation of Remote Treatment Stroke Centers.

1. Any hospital seeking designation or re-designation by the Department as a remote treatment stroke center must submit a written application to the Department in a manner and on forms as determined by the Department.
2. Designation Through National Accreditation. An applicant must hold and maintain a current certification as an acute stroke-ready hospital by a national healthcare accreditation body recognized by the Department to be eligible for designation as a remote treatment stroke center.
3. Designation Through Evaluation by Department.
 - (i) An applicant that does not hold a current certification as an acute stroke-ready hospital by a national healthcare accreditation body recognized by the Department shall undergo an evaluation by the Department. The Department will schedule and conduct an inspection of the applicant's facility within ninety days of receipt of a complete application.
 - (ii) The applicant will be evaluated on the standards and clinical practice guidelines established by the American Heart Association and American Stroke Association. In addition, the applicant must establish cooperating stroke care agreements with designated comprehensive, thrombectomy-capable, or primary stroke center and must utilize current and acceptable telemedicine protocols relative to acute stroke treatment.

(d) In order to assure that patients are receiving the appropriate level of care and treatment at each level of stroke center in the state, each hospital designated and identified by the Department as a stroke center must participate in the Georgia Coverdell Acute Stroke Registry, and shall submit data to the Registry as required by the Department in accordance with time frame requirements as established by the Department, including, but not limited to, the following information:

1. Date of admission and discharge;
2. Patient disposition at discharge;
3. Patient identifier, currently known as "Georgia LONGID," that consists of elements as defined by the Department;
4. Patient age, gender, and race;
5. Location where stroke occurred;
6. Patient arrival mode;
7. Patient's past medical and medication history;
8. Clinical diagnosis of type of stroke or transient ischemic attack;
9. The National Institutes of Health stroke scale score;
10. Serum low density lipoprotein level;
11. Whether stroke symptoms were resolved at time of presentation;
12. Earliest time patient placed on comfort measure only;
13. Whether patient was admitted for elective carotid intervention;
14. Whether patient was participating in a stroke related clinical trial;
15. Whether in-hospital treatment with intravenous or intra-arterial thrombotic or mechanical clot removal, antithrombotic, or venous thromboembolism prophylaxis was provided, or reason for not providing each treatment;
16. Date and time of last known well visit, hospital arrival, imaging, and treatment administration;
17. Whether dysphagia screen had been completed;
18. Whether treatment at discharge with antithrombotic, anticoagulant, or statin (lipid-lowering medication) was provided, or reason for not providing each treatment;
19. Whether smoking cessation advice or counseling was provided;
20. Whether stroke education was provided;
21. Whether rehabilitation services were provided; and
22. Modified Rankin Scale score at discharge.

(e) The Department may suspend or revoke a hospital's designation as a stroke center, after providing written notice to the hospital, if the Department determines that the hospital is not in compliance with the requirements or criteria of these rules or applicable statutes. The Department shall provide an administrative hearing on the action to suspend or revoke a hospital's designation if the hospital makes a written request for a hearing. Such written request must be delivered to and received by the Department no later than twenty days after the hospital receives notice of the action. If a timely request for a hearing is not received, the action will become effective twenty days after the hospital's receipt of the notice. In lieu of suspending or revoking a hospital's stroke center designation, the Department may re-designate the hospital at another level of stroke center if it is determined that the hospital does not meet the criteria for its current level of designation.

(3) Emergency Cardiac Care Centers.

(a) Applicability.

1. No hospital shall hold itself out as or advertise to the public that it is designated by the Department as a Level I, Level II, or Level III emergency cardiac care center without first meeting the requirements of these rules and obtaining approval from the Department.
2. This section is not intended to prevent any hospital from providing medical care to any cardiac patient.
3. The Department may establish additional levels of emergency cardiac care centers as necessary based on advancements in medicine and patient care.

(b) Designation of Emergency Cardiac Care Centers

1. Any hospital seeking designation or re-designation by the Department as an emergency cardiac care center must submit a written application to the Department in a manner and on forms as determined by the Department.
2. The Department's review of applications for designation and re-designation as an emergency cardiac care center may include an on-site inspection of the hospital.

(c) Designation Criteria

1. Applicants for designation as an emergency cardiac care center shall meet, at a minimum, the following criteria:

(i) Level I:

- (I) Cardiac catheterization and angioplasty facilities available 24 hours per day, seven days per week, 365 days per year;
- (II) On-site cardiothoracic surgery capability available 24 hours per day, seven days per week, 365 days per year;
- (III) Established protocols for therapeutic hypothermia for out-of-hospital cardiac arrest patients;

(IV) The ability to implant percutaneous left ventricular assist devices for support of hemodynamically unstable patients experiencing out-of-hospital cardiac arrest or heart attack;

(V) Neurologic protocols to measure functional status at hospital discharge; and

(VI) The ability to implant automatic implantable cardioverter defibrillators.

(ii) Level II:

(I) Cardiac catheterization and angioplasty facilities available 24 hours per day, seven days per week, 365 days per year, but no on-site cardiothoracic surgery capability;

(II) Established protocols for therapeutic hypothermia for out-of-hospital cardiac arrest patients;

(III) Neurologic protocols to measure functional status at hospital discharge; and

(IV) A written transfer plan with one or more Level I emergency cardiac care centers for patients who need left ventricular assist devices or cardiothoracic surgery.

(iii) Level III:

(I) Established protocols for therapeutic hypothermia for out-of-hospital cardiac arrest patients; and

(II) A written plan for systematic transfer of patients to a Level I or Level II facility.

2. Coordinating agreements established between cardiac care centers shall be in writing and shall include at a minimum:

(i) Transfer agreements for the transport and acceptance of cardiac patients seen by:

i. A Level I emergency cardiac care center for care which a Level II or III emergency cardiac care center does not provide; or

ii. A Level II emergency cardiac care center for care which a Level III emergency cardiac care center does not provide; and

(ii) Communications criteria and protocols between the emergency cardiac care centers.

(d) Data Reporting

1. Each hospital designated and identified by the Department as an emergency cardiac care center must report the following to designated registries as

determined by the Department in accordance with time frame requirements established by the Department:

(i) Required data elements on all out-of-hospital cardiac arrest patients as determined by the Department; and

(ii) Required data elements on all heart attack patients as determined by the Department.

2. Each emergency cardiac care center shall have a written system describing the timely submission of all data described in subsection (i) and (ii) of this section.

(e) The Department may suspend or revoke a hospital's designation as an emergency cardiac care center, after providing written notice to the hospital, if the Department determines that the hospital is not in compliance with the requirements or criteria of these rules or applicable statutes. The Department shall provide an administrative hearing on the action to suspend or revoke a hospital's designation if the hospital makes a written request for a hearing. Such written request must be delivered to and received by the Department no later than twenty days after the hospital receives notice of the action. If a timely request for a hearing is not received, the action will become effective twenty days after the hospital's receipt of the notice. In lieu of suspending or revoking a hospital's designation, the Department may re-designate a hospital at another level of emergency cardiac care if it is determined that a hospital does not meet the criteria for a hospital's current level of designation.

(4) Confidentiality. All information reported to any registry as described by this Rule shall be deemed confidential, except that the Department may in its discretion release such reports or data in de-identified form or for research purposes determined by the Department to have scientific merit. Under no circumstances may information reported to any registry as described by this Rule be released in such a manner as to lead to the identification of any hospital, institution, or clinic.

(5) Provisional designation. A hospital seeking initial designation as a specialty care center may be designated on a provisional basis, in the Department's sole discretion, to afford the hospital additional time to demonstrate that its facilities and operations are able to maintain full compliance with the requirements of this rule. Provisional designation shall be granted for a specified time period, not to exceed one year, and shall be subject to the terms and conditions established by the Department.

Authority: O.C.G.A. §§ 31-5-5, 31-2A-6, 31-11-110 through 31-11-119, 31-11-130 through 31-11-139.