

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 667. HOSPITAL STANDARDS**

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

Subchapter 59. Classification of Hospital Emergency Services
310:667-59-20 [AMENDED]

AUTHORITY:

Oklahoma State Board of Health, Title 63 O.S. Section 1-104; Title 63 O.S. Section 1-270; and Title 63 O.S. Section 1-705.

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SUPERSEDED EMERGENCY ACTIONS:

"n/a"

INCORPORATIONS BY REFERENCE:

"n/a"

ANALYSIS:

The amendments revise sections of rule within Subchapter 59, Classification of Hospital Emergency Services, to update classification standards for stroke centers. These standards are intended to stratify hospitals into those hospitals capable of providing comprehensive care for all stroke patients from those with limited or no capability to care for the acutely ill, time sensitive stroke patient. The amended rules allow the Oklahoma State Department of Health (OSDH) to recognize four levels of hospital based stroke care. The Level I stroke center is a comprehensive center capable of care for all stroke patients. The Level II stroke center is the most current standard required to be a primary stroke center. The Level III stroke center is mainly focused on the acute care of a patient presenting to the emergency room who is likely to benefit from stabilization and quick thrombolytic therapy prior to transfer to a higher level of care. The Level IV stroke center reflects a facility without the resources to provide acute care for the time sensitive needs of the stroke patient.

CONTACT PERSON:

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 11, 2015:

SUBCHAPTER 59. CLASSIFICATION OF HOSPITAL EMERGENCY SERVICES

310:667-59-20. Classification of emergency stroke services

(a) ~~**Secondary Stroke Facility.** A Secondary Stroke Facility shall provide services with at least a licensed independent practitioner, registered nurse, licensed practical nurse, or intermediate or paramedic level emergency medical technician on site twenty four (24) hours a day. A hospital shall be classified as a Secondary Stroke Facility if it meets the following requirements~~ **Level I Stroke Center.** A Level I Stroke Center shall be deemed to adhere to primary and secondary stroke recognition and prevention guidelines as required by state law and serve as a resource center for other hospitals in the region and be a comprehensive receiving facility staffed and equipped to provide total care for all major needs of the stroke patient as determined by:

(1) ~~**Clinical services and resources.** No diagnostic, surgical, or medical specialty services are required. An up-to-date certification as a Comprehensive Stroke Center from a Centers for Medicare and Medicaid Services deemed accrediting agency or a Department approved organization that uses a nationally recognized set of guidelines; and~~

(2) ~~**Personnel.** A physician, licensed independent practitioner, registered nurse, licensed practical nurse, or intermediate or paramedic level emergency medical technician shall be on site twenty four (24) hours a day. In the absence of a physician, licensed independent practitioner, registered nurse, or paramedic level emergency medical technician, at least one of the practitioners on duty shall have received training in advanced life support techniques and be deemed competent to initiate treatment of the emergency stroke patient~~ Providing quality assurance information, including benchmark tracking and other data to the department upon request.

~~(A) If the facility is licensed as a General Medical Surgical Hospital it shall also meet the personnel and staffing requirements at OAC 310:667-29-1 (relating to emergency service or department) and any other applicable parts of this Chapter.~~

~~(B) If the facility provides emergency medical services and is licensed as a Specialized Hospital: Psychiatric, it shall also meet the personnel and staffing requirements at OAC 310:667-33-2 (relating to services) and any other applicable parts of this Chapter.~~

~~(C) If the facility provides emergency medical services and is licensed as a Specialized Hospital: Rehabilitation, it shall also meet the personnel and staffing requirements at OAC 310:667-35-3 (relating to specialized requirements — policy and personnel) and any other applicable parts of this Chapter.~~

~~(D) If the facility provides emergency medical services and is licensed as a Critical Access Hospital, it shall also meet the personnel and staffing requirements at OAC 310:667-39-14 (relating to emergency services) and any other applicable parts of this Chapter.~~

- ~~(3) **Supplies and equipment.** The hospital shall also have the equipment and supplies required at OAC 310:667-59-9(a)(3) (relating to classification of trauma and emergency operative services at Level IV), on site, functional, and immediately available.~~
- ~~(4) **Agreements and policies on transfers.**~~
- ~~(A) The hospital shall have written policies defining the medical conditions and circumstances for those emergency patients which may be retained for treatment in-house, and for those who require stabilizing treatment and transfer to another facility.~~
- ~~(B) The facility shall have a written agreement with a hospital classified as a Primary Stroke Center, or with a board certified, board eligible, or residency trained neurologist, or group of neurologists to provide immediate consultative services for stroke patients twenty-four (24) hours a day. Such services shall include providing instructions for the initiation of appropriate therapy and/or patient transfer.~~
- ~~(b) **Primary Stroke Center.** A Primary Stroke Center shall provide emergency medical services with an organized emergency department. A physician shall be on call and immediately available to respond to the emergency department and nursing staff with special capability in emergent stroke care shall be on site twenty-four (24) hours a day. A hospital shall be classified as a Primary Stroke Center if it meets the following requirements **Level II Stroke Center.** A Level II Stroke Center shall be deemed to adhere to primary and secondary stroke recognition and prevention guidelines as required by state law and be a receiving center staffed by in-patient stroke services staff and be equipped to provide definitive care for a major proportion of stroke patients within the region as determined by:~~
- ~~(1) **Clinical services and resources.** An up-to-date certification as a Primary Stroke Center from a Centers for Medicare and Medicaid Services deemed accrediting agency or a Department approved organization that uses a nationally recognized set of guidelines; and~~
- ~~(A) **Emergency services.** A physician deemed competent in the care of the emergent stroke patient and credentialed by the hospital to provide emergency medical services shall be on call and immediately available to respond to the emergency department. Nursing personnel with special capability in emergent stroke care shall be on site twenty-four (24) hours a day.~~
- ~~(i) For a hospital licensed as a general medical surgical hospital or specialty hospital, emergency services shall also comply with the requirements of OAC 310:667-29-1 through OAC 310:667-29-2 (relating to emergency service or department and patient transfers.)~~
- ~~(ii) For a hospital licensed as a critical access hospital, emergency services shall also comply with OAC 310:667-39-14 (relating to emergency services.)~~
- ~~(B) **Stroke Team.** A stroke team shall be identified in writing and shall be on site or immediately available to respond to the emergency department:~~
- ~~(i) Stroke team members shall have at least annual training in the care of the stroke patient;~~
- ~~(ii) Response time standards for the stroke team shall be established and monitored;~~
- ~~(iii) Standard practice protocols for the care of the stroke patient shall be in place, including appropriate administration of an FDA approved thrombolytic agent within sixty (60) minutes of the arrival of the patient at the emergency department.~~
- ~~(C) **Diagnostic imaging.** The hospital shall have diagnostic x ray and computerized tomography services available twenty-four (24) hours a day. A radiologic technologist and computerized tomography technologist shall be on duty or on call and immediately available twenty-four (24) hours a day. A single technologist designated as qualified in both~~

diagnostic x ray and computerized tomography procedures by the radiologist may be used to meet this requirement if an on call schedule of additional diagnostic imaging personnel is maintained.

~~(i) For a hospital licensed as a general medical surgical hospital or specialty hospital, diagnostic imaging services shall also comply with the applicable requirements in Subchapter 23 of this Chapter (relating to diagnostic and treatment services.)~~

~~(ii) For a hospital licensed as a critical access hospital, diagnostic imaging services shall also comply with the applicable requirements in Subchapter 39 of this Chapter (relating to critical access hospitals.)~~

~~(D) **Clinical laboratory service.** The hospital shall have clinical laboratory services available twenty four (24) hours a day. All or part of these services may be provided by arrangements with certified reference laboratories provided these services are available on an emergency basis twenty four (24) hours a day. At least the following shall be available:~~

~~(i) Standard analysis of blood, urine, and other body fluids to include routine chemistry and hematology testing;~~

~~(ii) Coagulation studies;~~

~~(iii) Blood gas/pH analysis; and~~

~~(iv) Drug and alcohol screening.~~

~~(v) For a hospital licensed as a general medical surgical hospital or specialty hospital, clinical laboratory services shall also comply with the applicable requirements in Subchapter 23 of this Chapter (relating to diagnostic and treatment services.)~~

~~(vi) For a hospital licensed as a critical access hospital, clinical laboratory services shall also comply with the applicable requirements in Subchapter 39 of this Chapter (relating to critical access hospitals.)~~

(2) Personnel Providing quality assurance information, including benchmark tracking and other data to the department upon request.

~~(A) **Emergency services director.** The medical staff shall designate a physician credentialed to provide emergency medical care as emergency services director.~~

~~(B) **Neurologist.** A physician board certified, board eligible, or residency trained, in neurology shall be available for consultation on site or immediately available by telephone or other electronic means twenty four (24) hours a day.~~

(3) Supplies and equipment. In addition to the requirements at OAC 310:667-59-9(a)(3) (relating to classification of trauma and emergency operative services at Level IV), the hospital shall have an FDA approved thrombolytic agent on site and immediately available for treatment of acute nonhemorrhagic stroke.

(4) Agreements and policies on transfers.

~~(A) The hospital shall have written policies defining the medical conditions and circumstances for those emergency patients, which may be retained for treatment in-house, and for those who require stabilizing treatment and transfer to another facility.~~

~~(B) If the facility does not have a neurologist, either board certified, board eligible, or residency trained, or group of neurologists similarly qualified, on staff to provide immediate consultative services for emergent stroke patients twenty four (24) hours a day, the facility shall have a written agreement with a hospital, or a neurologist, either board certified, board eligible, or residency trained, or group of neurologists similarly qualified, to provide such services for emergent stroke patients on a twenty four (24) hour basis. Such services shall include providing instructions for the initiation of appropriate therapy and/or patient transfer.~~

~~(5) **Quality Improvement.** The hospital shall ensure an appropriate quality improvement process is in place to monitor and evaluate the care provided to the critically ill stroke patient, and to provide regular feedback to emergency medical service agencies and referring hospitals on the optimal care of the critically ill stroke patient.~~

(c) **Level III Stroke Center.** A Level III Stroke Center shall be deemed to adhere to secondary stroke recognition and prevention guidelines as required by state law and be staffed and equipped to provide initial diagnostic services, stabilization, thrombolytic therapy, emergency care to patients who have suffered an acute stroke (which is a stroke wherein symptoms have on-set within the immediately preceding twelve (12) hours). They shall have an up-to-date certification as an Acute Stroke Ready Hospital from a Centers for Medicare and Medicaid Services deemed accrediting agency or from a department approved organization that uses a nationally recognized set of guidelines or from the department for a period not to exceed three years and meet the following requirements:

(1) **Stroke Team:**

- (A) Having a stroke team available twenty-four (24) hours a day, seven (7) days a week;
- (B) Having a licensed physician trained in the care of the emergent stroke patient and credentialed by the hospital to provide emergency medical service for stroke patients, including the ability to administer thrombolytic agents;
- (C) Having designated stroke team(s) that are identified in writing, which is either on-site or each member is able to respond to the hospital within twenty (20) minutes to the emergency department of the Stroke Center;
- (D) Having members trained in the care of a stroke patient, with said training updated annually;
- (E) Having response times of the stroke team established and tracked in writing;
- (F) Adoption of standard practice protocols for the care of a stroke patient in writing, which shall include the appropriate administration of an FDA-approved thrombolytic agent within sixty (60) minutes following the arrival of a patient who has suffered a stroke at the emergency department at least fifty percent (50%) of the time;
- (G) Written emergency stroke care protocols adopted; and
- (H) A licensed nurse or other health professional designated as the stroke coordinator.

(2) **Emergency Department:**

- (A) A licensed independent practitioner able to recognize, assess and if indicated administer thrombolytic therapy to stroke patients;
- (B) A licensed independent practitioner will assess potential stroke patients within 15 minutes of arrival;
- (C) Having nursing personnel available on-site twenty-four (24) hours a day, seven (7) days a week who are trained in emergent stroke care, which is demonstrated at least every two (2) years through evidence of competency;
- (D) For a hospital, licensed as a general medical surgical hospital or a specialty hospital, all emergency services shall meet the requirements of Oklahoma Administrative Code (OAC) 310:667-29-1 and 310:667-29-2;
- (E) For a hospital, licensed as critical access hospital, all emergency services shall meet the requirements of OAC 310:667-39-14;
- (F) Adopt written comprehensive stroke protocols for the treatment and stabilization of a stroke patient, which shall include, but not be limited to:
 - (i) Detailed instructions on IV thrombolytic use;

- (ii) Reversal of anticoagulation in patients with hemorrhagic stroke;
- (iii) A standardized stroke assessment scale;
- (iv) Protocols for the control of seizures;
- (v) Blood pressure management; and
- (vi) Care for patients, who have suffered a stroke, but are not eligible to receive thrombolytic agents.

(G) Collaborate with emergency medical service agencies to develop inter-facility transfer protocols for stroke patients and will only use those emergency medical service agencies that have a Department approved protocol for the inter-facility transfer of stroke patients.

(3) Supplies and equipment:

- (A) All equipment and supplies shall meet the requirements of OAC 310:667-59-9 (a);
- (B) Have available on-site, twenty-four (24) hours a day, seven (7) days a week, thrombolytic agents, which are FDA approved for the treatment of acute non-hemorrhagic stroke;
- (C) Have available on-site, twenty-four (24) hours a day, seven (7) days a week, seizure control agents; and
- (D) Have available on-site, twenty-four (24) hours a day, seven (7) days a week, thiamine and glucose for intravenous administration.

(4) Neuroimaging services:

- (A) Have available on-site, twenty-four (24) hours a day, seven (7) days a week diagnostic x-ray and computerized tomography (CT) services;
- (B) Have on duty or on call with a twenty (20) minute response time, twenty-four (24) hours a day, seven (7) days a week radiologic technologist and CT technologist. A single technologist designated as qualified in both diagnostic x-ray and CT procedures by the radiologist may be used to meet this requirement if an on-call schedule of additional diagnostic imaging personnel is maintained;
- (C) For a hospital licensed as a general medical surgical hospital or specialty hospital, diagnostic imaging services shall also comply with the applicable requirements in OAC 310:667-23 of this Chapter; and
- (D) For a hospital licensed as a critical access hospital, diagnostic imaging services shall also comply with the applicable requirements in OAC 310:667-39.

(5) Laboratory services:

- (A) Laboratory services shall be provided on-site and available twenty-four (24) hours a day, seven (7) days a week, and at a minimum provide the following:
 - (i) A complete blood count;
 - (ii) Metabolic profile;
 - (iii) Coagulation studies (prothrombin time, international normalized ratio);
 - (iv) Pregnancy testing; and
 - (v) Troponin I.
- (B) For a hospital licensed as a general medical surgical hospital or specialty hospital, clinical laboratory services shall also comply with the applicable requirements in OAC 310:667-23; and
- (C) For a hospital licensed as a critical access hospital, clinical laboratory services shall also comply with the applicable requirements in OAC 301:667-39.

(6) Outcome and quality improvement:

Outcome and quality improvement activities shall include the tracking of all stroke patients, appropriate use of thrombolytic therapy, performance measures and at a minimum the following steps shall be accomplished, which shall be verifiable and made available upon request by the Department:

(A) The facility will track the number of stroke and acute stroke patients, the number treated with thrombolytic therapy, including how soon after hospital presentation (arrival to needle time), the number of acute stroke patients not treated and indications for why they were not treated;

(B) There will be an official policy to review the care of all acute stroke patients that were eligible for thrombolytics and did not receive them;

(C) There will be a policy for and review of all patients who received thrombolytics more than 60 minutes after hospital presentation;

(D) If a facility fails to provide thrombolytics within 60 minutes to at least 50% of eligible patients for two consecutive quarters, they will develop and implement an internal plan of corrections;

(E) Provide no less than quarterly feedback to:

(i) Hospital physicians and other health professionals;

(ii) Emergency medical service agencies; and

(iii) Referring hospitals;

(F) There will be a review of all acute stroke patients who require more than 2 hours to be transferred (arrival-to-departure time);

(G) The time from ordering to interpretation of a head CT or MRI will be tracked; and

(H) Door-to-computer link time for cases where a tele-technology is used.

(7) Agreements and policies:

(A) The stroke center shall develop and implement a written plan for transfer of patients to a Level I or Level II stroke facility as appropriate, defining medical conditions and circumstances for those emergency patients who:

(i) May be retained for treatment in-house;

(ii) Require stabilizing treatment; and

(iii) Require transfer to another facility.

(B) If a stroke telemedicine program is utilized, there will be a written, contractual agreement addressing, at a minimum, performance standards, legal issues and reimbursement.

(d) Level IV Stroke Referral Center. A Level IV Stroke referral center shall be deemed to adhere to secondary stroke recognition and prevention guidelines as required by state law and is a referral center lacking sufficient resources to provide definitive care for stroke patients. A Level IV Stroke referral Center shall provide prompt assessment, indicated resuscitation and appropriate emergency intervention. The Level IV Stroke referral Center shall arrange and expedite transfer to a higher level stroke center as appropriate. A hospital shall receive a Level IV Stroke referral Center designation by the Department, which shall be renewed in three (3) year intervals, providing the hospital is not certified as a level I, II or III stroke center and meets the following requirements:

(1) Emergency Department:

(A) For a hospital licensed as a general medical surgical hospital or specialty hospital, emergency services shall comply with the requirements of OAC 310:667-29-1 and OAC 310:667-29-2;

(B) For a hospital licensed as a critical access hospital, emergency services shall comply with OAC 310:667-39-14;

(C) For acute stroke patients requiring transfer by emergency medical services, said services will be contacted and emergently requested no more than 20 minutes after patient arrival;

(D) Enter into transfer agreements for expeditious transfer of acute stroke patients to stroke centers able to provide a higher level of care;

(E) Have a comprehensive plan for the prompt transfer of acute stroke patients to higher level stroke centers which includes an expected arrival-to-departure time of < 60 minutes, with the ability to provide documentation demonstrating the ability to meet this requirement at least 65% of the time on a quarterly basis;

(F) A health care professional able to recognize stroke patients will assess the patient within 15 minutes of arrival; and

(G) Collaborate with emergency medical service agencies to develop inter-facility transfer protocols for stroke patients and will only use those emergency medical service agencies that have a Department approved protocol for the inter-facility transfer of stroke patients.

(2) Supplies and equipment:

All Level IV Stroke referral Centers shall meet the requirements of OAC 310:667-59-9(a)(3).

(3) Laboratory services:

(A) For a hospital licensed as a general medical surgical hospital or specialty hospital, clinical laboratory services shall also comply with the applicable requirements in OAC 310:667-23; and

(B) For a hospital licensed as a critical access hospital, clinical laboratory services shall also comply with the applicable requirements in OAC 310:667-39.

(4) Outcome and quality improvement:

The following outcome and quality improvement requirements are applicable to Level IV Stroke referral Centers, which include tracking of all patients seen with acute stroke:

(A) A facility will meet the applicable outcome and quality measures listed in section 310:667-59-20(G); and

(B) Track and review all acute stroke transfer cases requiring longer than an arrival-to-departure time of > 60 minutes. If over two consecutive quarters inter-facility transfers (arrival-to-departure) exceeds > 60 minutes more than 35% of the time the facility will create and implement an internal plan of correction.

(5) Agreements and policies:

(A) A Level IV Stroke referral Center shall develop and implement a written plan for transfer of patients to a Level I, II or III Stroke Center. The written plan shall establish medical conditions and circumstances to determine:

(i) Which patients may be retained or referred for palliative or end-of-life care;

(ii) Which patients shall require stabilizing treatment; and

(iii) Which patients shall require transfer to a Level I, II or III Stroke Center;

(B) Development and implementation of policy and transfer agreements directing transfer of acute stroke patients to the closest appropriate higher level facility. Patient preference may be taken into consideration when making this decision.