RULEMAKING ACTION:
Notice of proposed PERMANENT rulemaking

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

SUMMARY:
The amendments to OAC 310:667 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 proposed rules would allow the Oklahoma State Department of Health (OSDH) to recognize four levels of hospital based stroke care. Level I would be a comprehensive center capable of care for all stroke patients. The Level II would represent the most current standard required to be a primary stroke center. OSDH will recognize certification from a Center for Medicare and Medicaid Services deemed accrediting agency or an OSDH approved organization using nationally recognized guidelines for Level I and II facilities.

The Level III stroke facility will be mainly focused on the acute care of a patient presenting to the emergency room who is likely to benefit from stabilization and expeditious thrombolytic therapy prior to transfer to a higher level of care. The Level IV hospital reflects a facility without the resources to provide acute care for the time sensitive needs of the stroke patient. They would be organized to quickly evaluate, stabilize and arrange transfer of the acute stroke patient. OSDH would recognize a Level III facility by way of a current certification as an Acute Stroke Ready Hospital from a deemed accrediting agency, a department approved nationally recognized guidelines based organization or through OSDH. The Level IV facility would be certified only by OSDH.

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.

COMMENT PERIOD:
October 1, 2014, through November 5, 2014. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through November 5, 2014, submit written comment to the contact person identified below; or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:
Pursuant to 75 O.S. § 303 (A), the public hearing for the proposed rulemaking in this chapter shall be on November 5, 2014, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 beginning at 10:00 a.m. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:
Business entities affected by these proposed rules are requested to provide the agency with
information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through November 5, 2014, to the contact person identified below.

**COPIES OF PROPOSED RULES:**

The proposed rules may be obtained for review from the contact person identified below or via the agency website at [www.health.ok.gov](http://www.health.ok.gov).

**RULE IMPACT STATEMENT:**

Pursuant to 75 O.S., §303(D), a rule impact statement is available at the location listed above for obtaining copies of the rule.

**CONTACT PERSON:**

Timothy Cathey, M.D., Medical Director, Protective Health Services, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, or by e-mail to TimC@health.ok.gov.
1. DESCRIPTION: The amendments to OAC 310:667 revise sections of rule within SUBCHAPTER 59. CLASSIFICATION OF HOSPITAL EMERGENCY SERVICES to establish classification standards for 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 proposed rules would allow OSDH to recognize four levels of hospital based stroke care. Level I would be a comprehensive Center capable of care for all stroke patients. The Level II would represent the most current standard required to be a Primary Stroke Center. OSDH will recognize certification from a CMS deemed accrediting agency or a department approved nationally recognized guidelines based organization for level I and II facilities.

The level III stroke facility will be mainly focused on the acute care of a patient presenting to the emergency room who is likely to benefit from stabilization and expeditious thrombolytic therapy prior to transfer to a higher level of care. The level IV hospital reflects a facility without the resources to provide acute care for the time sensitive needs of the stroke patient. They would be organized to quickly evaluate, stabilize and arrange transfer of the acute stroke patient. OSDH would recognize a level III facility by way of a current certification as an Acute Stroke Ready Hospital from a deemed accrediting agency, a department approved nationally recognized guidelines based organization or through OSDH. The level IV facility would be certified only by OSDH.

2. CLASSES OF PERSONS AFFECTED: Affected persons are operators of licensed hospitals in the State of Oklahoma.

3. CLASSES OF PERSONS BENEFITED: Current and emerging technologies and treatments now allow a much higher likelihood of benefit over a longer window of time than the current system we use. The benefit is time sensitive and linearly deteriorates with delays in definitive care. These delays often result in death, permanent disability and an enormous financial burden to families of surviving stroke patients. A four level system that classifies all licensed hospitals will simplify the identification and triage of these patients not only by hospitals but also by the EMS out-of-hospital providers as well as the public at large. Once
this system is established it could be used to implement a state level referral network similar to what is currently used for severely injured trauma patients.

The current system has almost exclusively focused on the patient with an ischemic stroke. This new system would also provide a framework from which we could launch a more timely and useful triage of patients with the most severe presentations including hemorrhagic stroke. We are in the early stages of advanced medical teletechnology applications and this system will allow providers to better focus their efforts to the greatest benefit for acutely ill Oklahomans.

Most important, to the time critical ischemic stroke patient is this new system will result in more thrombolytic agent being provided in more areas of the state, and in a more timely fashion than currently exists.

4. **ECONOMIC IMPACT:** This rule involves no additional fees. There will be no economic impact on any political subdivision by the proposed rule changes. Several hospitals already pay for national accreditation to be “Primary Stroke Centers” and a few have become Comprehensive Stroke Centers. The cost at this time is approximately $8k to $10k per year depending on which national accrediting body is used. Hospitals that are currently state designated as “Primary Stroke Centers” could easily transition to be designated as level III facilities and function much as they do now for no added cost.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY** The cost to the Department to implement the amendments will be approximately $1500.00 to distribute the amended rules. The proposed rules will be implemented and enforced by existing Department personnel. In order to offset, the increased number of hospitals requiring state certification, EMS administrators will also be cross-trained to perform level III and IV visits. The time required for each visit will be significantly reduced compared to the current rules due to a much shorter checklist and use of an internal quality assurance approach method.

6. **IMPACT ON POLITICAL SUBDIVISIONS:** This rule will have no economic impact on any governmental entity, and it will not require their cooperation in implementing or enforcing the rule.

7. **ADVERSE EFFECT ON SMALL BUSINESS:** Very few hospitals can be classified as small businesses; these amendments are not expected to have any adverse impact on any licensed hospital.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:** OSDH could take on the responsibility of on-site certification of all hospitals which may result in less cost to the hospitals but would require a significant infusion in
resources and infrastructure by OSDH to meet this requirement. We expect to require 1 FTE to cover the hospital survey process. In order to save money and yet maintain a high quality of care we chose the tiered accreditation system mentioned previously.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
In 2010, Oklahoma had the 4th highest death rate from stroke in the country. Stroke is a leading cause of major disability. Approximately, 150,000 Oklahomans are currently stroke survivors. This year over 2,000 Oklahomans will die from stroke and over 10,000 will be diagnosed and admitted to the hospital. Hospital costs alone range from $70,000 to $90,000 for each event. Half of survivors will be forced to live with moderate to severe disability.
Seven out of eight patients will present with an ischemic stroke which can often be treated with thrombolytic therapy leading to reperfusion and drastically improved outcomes. Even so, within the current dysfunctional system <5% of stroke patients get thrombolytics.
Since our previous rules were passed in 2008, significant improvements in care have been realized. For example, the window of time for thrombolytic use has expanded by 50%. Instead of 3 hours which is in our current rules the new standard is 4.5 hours.
An integrated system would mean pre-hospital identification of stroke patients and earlier activation of the hospital team resulting in a significant time savings and shortened time to reperfusion therapy (Each minute delay in reperfusion results in the death of 2 million neurons).
The overall benefit of an integrated system of care will be to ensure all stroke patients are rapidly identified, stabilized and if necessary, expeditiously transferred to the hospital providing the most appropriate level of care for their needs. A fully functioning system that reduces deaths by just 2%-3% could save another 50-100 lives in our state each year.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**
Over the past decade, there has been a 53% increase in the incidence of stroke in the 15-44yo age group. Now 1 in 5 strokes occur in someone aged 20-55. Failure to implement an improved, integrated system of care will negatively impact our ability to implement earlier intervention and definitive treatment.
Pre-hospital providers (EMS) will remain confused about how best to triage and where to transport patients resulting in delays. Each added 15 minute delay will mean a 4% decrease in survival, walking independently and going home and living independently.
Not adopting these new rules will also mean we are unable to
strategically develop a system of care where patients receive reperfusion within 90 minutes which would have resulted in a 51% improvement in independent movement and a 33% increased likelihood of living independently. But these long-term goals would never be achieved. Where you live should not determine if you live but that will be the impact of not creating the framework for an integrated system of acute stroke care. The group most negatively impacted will be rural Oklahomans living furthest away from our urban centers. The large hospital health systems will continue to develop islands of excellence but with no global strategic focus or collaborative effort large rural geographic areas will continue to be neglected.

11. This rule impact statement was prepared on August 7, 2014
310:667-59-20. Classification of emergency stroke services
(a) 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) An up-to-date certification as a Comprehensive Stroke Center from a Centers for Medicare and Medicaid Systems deemed accrediting agency or a Department approved organization that uses a nationally recognized set of guidelines; and
   (2) Providing quality assurance information, including benchmark tracking and other data to the department upon request.
(b) 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 receive 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) An up-to-date certification as a Primary Stroke Center from a Centers for Medicare and Medicaid Systems deemed accrediting agency or a Department approved organization that uses a nationally recognized set of guidelines; and
   (2) Providing quality assurance information, including benchmark tracking and other data to the department upon request.
(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 onset 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 Systems 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; and
(G) Written emergency stroke care protocols adopted;
(H) A licensed emergency stroke care protocols adopted;

(2) Emergency Department:
(A) A licensed independent practitioner able to recognize, assess and if indicated administer thrombolytic therapy to stroke patients and
(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; 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;

(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;
(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;
Laboratory services:

(A) Laboratory services shall be provided on-site and available twenty-four (24) hours a day, seven (7) days a week, and 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;

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;

(8) 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; and
(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 Center.** A level IV stroke 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 Center shall provide prompt assessment, indicated resuscitation and appropriate emergency intervention. The Level IV Stroke Center shall arrange and expedite transfer to a higher level stroke center as appropriate. A hospital shall receive a Level IV Stroke 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; and

(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

(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 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 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; and

(5) Agreements and policies:
(A) A Level IV Stroke 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; and