

**HOSPITAL ADVISORY COUNCIL
Regular Quarterly Meeting
Thursday, August 21, 2014 at 3:30 p.m.**

Location: Oklahoma State Department of Health building
1000 NE 10th Street, Room 307
Oklahoma City, OK 73117
Telephone: 405-271-6576

Meeting Summary

The Hospital Advisory Council Regular Meeting Notices for the calendar year 2014 were filed with the Oklahoma Secretary of State's (SOS) website located at www.sos.state.ok.us/meetings.htm and the Oklahoma State Department of Health's (OSDH) website located at www.mfs.health.ok.gov on December 11, 2013.

The agenda for this regular meeting was posted on the OSDH website and at the OSDH building's front entrance on August 18, 2014 at 12:30 p.m.

1. Call to Order

Dr. Bratzler, Acting Chair called the meeting to order at approximately 3:38 p.m.

2. Roll Call

Devyn Tillman called roll. The following members were present when roll was called: Dale Bratzler and Dave Wallace. A quorum is not present.

The following members were absent: Heather Bell; Jeffrey Berrong; Darrel Morris and Darin Smith.

Identified OSDH staff members present were: Lee D. Martin, Jr., Chief-Medical Facilities Services, Devyn Tillman, AAll-Medical Facilities Service; Dr. Tim Cathey, MD – Medical Director for Protective Health Services; Don Maisch-OSDH General Counsel.

3. Presentation: Enrolled Senate Bill 1848

- Don Maisch, General Counsel

Mr. Maisch presented the group with a report on this enrolled legislation which affects abortion facilities, specialized hospitals in Oklahoma. A copy of this presentation and Enrolled Senate Bill 1848 is attached below.

4. Approval of the May 22, 2014 Regular Meeting Minutes

No official business could be conducted due to the lack of quorum.

5. Update: Hospital Advisory Council Membership

Mr. Martin reported the department has received two (2) applications for the one (1) hospital employee vacancy. These names will be submitted to the November Board of Health meeting for their consideration. There are now three (3) vacancies for public members. Nominations for these vacancies are needed as quickly as possible. The members briefly discussed the qualifying criteria for these as outlined in the statute at *Oklahoma Statute Title 63-1-707. (D.) (1.) (d.)*. "three members shall be citizens representing the public who: (1) are not hospital employees, (2) do not hold hospital staff appointments, and (3) are not members of hospital governing boards."

6. Update: Stroke Classification Workgroup meeting held on April 2, 2014

Mr. Martin presented the members (in Dr. Cathey's absence) with a copy of the recommended rule changes which resulted from the August 4, 2014 stroke workgroup meeting. There was discussion regarding some of the language presented in this draft. Mr. Martin stated the stroke workgroup will be meeting again on September 24, 2014 to further refine the language.

7. Report: Quality Initiatives

- Vonnie Meritt, Administrative Programs Manager

Mrs. Meritt reported she is currently preparing the 2013 Hospital Annual Report. It will be ready for presentation at the November 20, 2014 regular quarterly meeting. A link to the 2012 Hospital Annual report is included for your convenience.

http://www.ok.gov/health2/documents/MFS%20HospitalAnnualRpt_2012.pdf

8. CY 2014 Regular Quarterly Meeting Dates:

- 4th Quarter: Thursday, November 20, 2014 at 3:30 p.m. – Room 307

9. Adjourn

This meeting adjourned at approximately 4:27 p.m.

Respectfully submitted,

Devyn Tillman

Secretary to the Hospital Advisory Council

PRESENTATION ON SB 1848

Donald D. Maisch

General Counsel

Oklahoma State Department

Of Health

August 21, 2014



Oklahoma
State
Department
of Health

PRESENTATION ON SB 1848

SB 1848 is a bill that passed during the most recent legislative session. This bill deals with the issue of abortion. This presentation will cover the Hospital Advisory Committee's duties and responsibilities due to the passage of this bill.



PRESENTATION ON SB 1848

Background:

- State law defines a facility that performs an abortion as a hospital.
- The OSDH has the statutory authority to license and regulate hospitals.
- Therefore, the OSDH has regulatory authority over abortion facilities.
 - The physicians who perform abortions are regulated by their appropriate Licensure Board.



PRESENTATION ON SB 1848

Background:

- Currently the OSDH has issued licenses to three (3) abortion facilities in Oklahoma:
 - One in Tulsa – Reproductive Services;
 - One in Oklahoma City – Outpatient Services for Women; and
 - One in Norman – Abortion Surgery Center.



PRESENTATION ON SB 1848

SB 1848 is a bill to establish the requirements of and to regulate:

- the abortion procedure itself;
- the procedure in the recovery room after the abortion has been performed; and
- the post-abortion procedure after the patient has left the facility (including any follow-up visits with the physician).



PRESENTATION ON SB 1848

Pursuant to SB 1848, the Board of Health is required to adopt rules concerning the abortion procedure itself, the procedure in the recovery room after the abortion has been performed and the post-abortion procedure, which includes any follow-up visits with the physician.

Since abortion facilities are defined as hospitals by state law, the Hospital Advisory Council has the duty to recommend said proposed rules for adoption by the Board.



PRESENTATION ON SB 1848

SB 1848 will require the adoption of rules that cover:

- The required equipment, supplies and medications for the performance of an abortion;
- The training required for a physician's assistant of a physician that performs abortions;
- Training required for volunteers at facilities where abortions are performed;
- Requirements to medically screen and evaluate potential patients who wish to receive an abortion;



PRESENTATION ON SB 1848

(Continued Board of Health duties under HB 1848):

SB 1848 will require the adoption of rules that cover:

- The standards for abortion procedures (which include):
 - Adequate staff, equipment, supplies and medications are available;
 - Pain Management;
 - Intravenous Access;
 - Monitoring the patient through the process;
 - Use of Ultrasound equipment
 - Hospitalization, in the event an emergency occurs.



PRESENTATION ON SB 1848

(Continued Board of Health duties under HB 1848):

SB 1848 will require the adoption of rules that cover:

- The standards for recovery room procedure:
 - Monitor of patient's vital signs;
 - Monitor for possible reaction to sedation medication;
 - Supervision of the patient, which includes a person capable in providing cardiopulmonary resuscitation in the recovery room;
 - Physician to establish protocols for length of time to remain in recovery room;
 - Documentation of patient's health prior to discharge.



PRESENTATION ON SB 1848

(Continued Board of Health duties under HB 1848):

- SB 1848 will require the adoption of rules that cover:
 - After Discharge Standards:
 - Make available Rh-immunoglobulin;
 - Written instruction on post procedure sexual activity;
 - Written contact information in the event complications occur;
 - Contact with the patient within 24 hours of the procedure;
 - Schedule a follow-up visit;
 - During follow-up visit, testing to ensure pregnancy was terminated.



PRESENTATION ON SB 1848

(Continued Board of Health duties under HB 1848):

SB 1848 will require the adoption of rules that cover:

- Recordkeeping and reporting.

The proposed rules are scheduled to be considered by the Board during either the December, 2014 or the January, 2015, Board Meetings. The proposed rules should come before the Hospital Advisory Council during the November, 2014 meeting.



PRESENTATION ON SB 1848

Possibility of litigation due to the passage of SB 1848 is likely.

- One requirement of SB 1848 is for any physician who performs an abortion to have admitting privileges at a general medical surgical hospital which offers obstetrical or gynecological care in the state and the hospital must be within 30 miles of the location where the abortion is performed.
- The physicians at the abortion facilities in OKC and Norman have stated that they currently do not have admitting privileges and the physician in Norman does not believe it will be possible for him to obtain such privileges.

Effective date for SB 1848 is November 1, 2014.



PRESENTATION ON SB 1848

The Federal Courts of Appeal have split on the issue whether the admitting privileges provision is constitutional:

- The 7th Circuit found such a provision to be Unconstitutional;
- The 4th and 8th Circuits have found such a provision to be constitutional;
- The 5th Circuit found the provision to be constitutional when the provision does not require all abortion facilities to close in a state; but found such a provision to be unconstitutional if the implementation of the provision would require that all abortion facilities within the state close.



PRESENTATION ON SB 1848

QUESTIONS



An Act

ENROLLED SENATE
BILL NO. 1848

By: Treat, Newberry, Allen,
Griffin and Echols of the
Senate

and

Grau, Christian, Ritze,
Kern, Reynolds, Turner,
Roberts (Sean), Fisher,
Derby, Johnson, Cockroft,
Biggs and Walker of the
House

An Act relating to public health; directing State Board of Health to establish certain standards; requiring physicians with certain privileges to remain at certain facilities for certain time period; requiring certain training for physicians, physician assistants, and volunteers; requiring medical screenings prior to performance of abortion; providing standards for screenings; requiring offer of examination after abortion; requiring certain facilities to keep certain records; requiring reporting of injuries and death to State Department of Health; requiring filing of incident reports to appropriate boards; providing penalties for performance of abortions without licensure; authorizing certain legal action against certain persons; providing for codification; and providing an effective date.

SUBJECT: Establishment of certain medical procedure standards

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-748 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Health shall establish abortion facility supplies and equipment standards, including equipment required to be immediately available for use in an emergency. Such standards shall, at a minimum:

1. Specify required equipment and supplies, including medications, required for the performance of abortion procedures and for monitoring the progress of each patient throughout the abortion procedure and post-procedure recovery period;

2. Require that the number or amount of equipment and supplies at the facility is adequate at all times to assure sufficient quantities of clean and sterilized durable equipment and supplies to meet the needs of each patient;

3. Specify the mandated equipment and supplies for required laboratory tests and the requirements for protocols to calibrate and maintain laboratory equipment at the abortion facility or operated by facility staff;

4. Require ultrasound equipment in all abortion facilities; and

5. Require that all equipment is safe for the patient and facility staff, meets applicable federal standards, and is checked annually to ensure safety and appropriate calibration.

B. On any day when any abortion is performed in a facility providing abortions, a physician with admitting privileges at a general medical surgical hospital which offers obstetrical or gynecological care in this state within thirty (30) miles of where the abortion is being performed must remain on the premises of the facility to facilitate the transfer of emergency cases if hospitalization of an abortion patient or a child born alive is necessary and until all abortion patients are stable and ready to leave the recovery room.

C. The State Board of Health shall adopt standards relating to the training physician assistants licensed pursuant to the provisions of Section 519.1 of Title 59 of the Oklahoma Statutes and employed by or providing services in a facility providing abortions shall receive in counseling, patient advocacy, and the specific medical and other services.

D. The State Board of Health shall adopt standards related to the training that volunteers at facilities providing abortions shall receive in the specific services that the volunteers provide, including counseling and patient advocacy.

E. The State Board of Health shall adopt standards related to the medical screening and evaluation of each abortion patient. At minimum these standards shall require:

1. A medical history, including the following:

- a. reported allergies to medications, antiseptic solutions, and latex,
- b. obstetric and gynecological history,
- c. past surgeries, and
- d. medication the patient is currently taking;

2. A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa; and

3. The appropriate preprocedure testing, including:

- a. urine or blood tests for pregnancy, if ordered by a physician,
- b. a test for anemia,
- c. Rh typing, unless reliable written documentation of blood type is available, and
- d. an ultrasound evaluation for all patients who elect to have an abortion. The physician performing the

abortion is responsible for estimating the gestational age of the unborn child based on the ultrasound examination and established standards of obstetrical care and shall write the estimate in the patient's medical record. An original print of each ultrasound examination of the patient shall be kept in the patient's medical record.

F. The State Board of Health shall adopt standards related to the performance of the abortion procedure and post-procedure follow-up care. At minimum these standards shall require:

1. That medical personnel are available to all abortion patients throughout the procedure;

2. The appropriate use of local anesthesia, analgesia, and sedation if ordered by the physician performing the procedure;

3. The use of appropriate precautions, such as the establishment of intravenous access;

4. That the physician performing the abortion procedure monitors the patient's vital signs and other defined signs and markers of the patient's status throughout the procedure and during the recovery period until the patient's condition is deemed to be stable in the recovery room;

5. Immediate post-procedure care and observation in a supervised recovery room for as long as the patient's condition warrants;

6. That the facility in which the abortion procedure is performed arranges for a patient's hospitalization if any complication beyond the management capability of the abortion facility's medical staff occurs or is suspected;

7. That a licensed health-care professional trained in the management of the recovery room and capable of providing cardiopulmonary resuscitation actively monitors patients in the recovery room;

8. That there is a specified minimum time that a patient remains in the recovery room by type of abortion procedure and duration of gestation;

9. That a physician discusses RhO(D) immune globulin with each patient for whom it is indicated and assures it is offered to the patient in the immediate post-operative period or that it will be available to her within seventy-two (72) hours after completion of the abortion procedure. If the patient refuses, a refusal form approved by the State Board of Health shall be signed by the patient and a witness and included in the medical record;

10. Written instructions with regard to post-abortion coitus, signs of possible complications, and general aftercare are given to each patient. Each patient shall have specific instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies;

11. That the physician ensures that a licensed health-care professional from the abortion facility makes a good faith effort to contact the patient by phone, with the patient's consent, within twenty-four (24) hours after procedure to assess the patient's recovery;

12. Equipment and services are located in the recovery room to provide appropriate emergency and resuscitative life-support procedures pending the transfer of the patient or a child born alive in the facility;

13. That a post-abortion medical visit shall be offered to each abortion patient and, if requested, scheduled for two (2) to three (3) weeks after the abortion procedure and shall include a medical examination and a review of the results of all laboratory tests; and

14. That a urine or blood test shall be obtained at the time of the follow-up visit to rule out continued pregnancy. If a continuing pregnancy is suspected, the patient shall be appropriately evaluated; and a physician who performs abortions shall be consulted.

G. Facilities performing abortions shall record each incident resulting in a patient's or a born-alive child's injury occurring at

the facility and shall report incidents in writing to the State Board of Health within ten (10) days of the incident. For the purposes of this subsection, "injury" shall mean an injury that occurs at the facility and creates a serious risk of substantial impairment of a major body organ or function.

H. If a patient's death occurs, other than the death of an unborn child properly reported pursuant to law, the facility performing abortions shall report the death to the State Board of Health no later than the next business day.

I. Incident reports shall be filed with the State Board of Health and all appropriate professional licensing and regulatory boards, including, but not limited to, the State Board of Medical Licensure and Supervision and the Oklahoma Board of Nursing.

J. Whoever operates a facility performing abortions without a valid license shall be guilty of a felony. Any person who intentionally, knowingly, or recklessly violates the provisions of this act or any standards adopted by the State Board of Health in accordance with this act shall be guilty of a felony.

K. Any violation of this act or any standards adopted under this act may be subject to a civil penalty or fine up to Twenty-five Thousand Dollars (\$25,000.00) imposed by the State Board of Health. Each day of violation constitutes a separate violation for purposes of assessing civil penalties or fines. In deciding whether and to what extent to impose civil penalties or fines, the State Board of Health shall consider the following factors:

1. Gravity of the violation, including the probability that death or serious physical harm to a patient or individual will result or has resulted;

2. Size of the population at risk as a consequence of the violation;

3. Severity and scope of the actual or potential harm;

4. Extent to which the provisions of the applicable statutes or regulations were violated;

5. Any indications of good faith exercised by facility;

6. The duration, frequency, and relevance of any previous violations committed by the facility; and

7. Financial benefit to the facility of committing or continuing the violation.

L. In addition to any other penalty provided by law, whenever in the judgment of the State Commissioner of Health any person has engaged, or is about to engage, in any acts or practices which constitute, or will constitute, a violation of this act, or any standard adopted in accordance with this act, the Commissioner shall make application to any court of competent jurisdiction for an order enjoining such acts and practices. Upon a showing by the Commissioner that such person has engaged, or is about to engage, in any such acts or practices, an injunction, restraining order, or such other order as may be appropriate shall be granted by such court without bond.

SECTION 2. This act shall become effective November 1, 2014.

Passed the Senate the 22nd day of May, 2014.

Presiding Officer of the Senate

Passed the House of Representatives the 23rd day of May, 2014.

Presiding Officer of the House
of Representatives

OFFICE OF THE GOVERNOR

Received by the Office of the Governor this _____

day of _____, 20_____, at _____ o'clock _____ M.

By: _____

Approved by the Governor of the State of Oklahoma this _____

day of _____, 20_____, at _____ o'clock _____ M.

Governor of the State of Oklahoma

OFFICE OF THE SECRETARY OF STATE

Received by the Office of the Secretary of State this _____

day of _____, 20 _____, at _____ o'clock _____ M.

By: _____

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

(a) **Secondary Level I Stroke Facility Center.** A Secondary Level I Stroke Facility Center 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: 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 Systems 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. by 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 Level II Stroke Center.** A Primary Level II 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:~~ 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 large number of stroke patients within the region as determined by:

~~(1) **Clinical services and resources.** 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~~

~~(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.** by 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) and initiate timely transfer of the patient to a Level I or Level II Stroke Center as determined by obtaining certification as an Acute Stroke Ready Hospital by the Centers for Medicare and Medicaid Systems deemed accrediting agency, by a Department approved organization that uses a nationally recognized set of guidelines, or a Stroke Center that is not certified as a Level I or a Level II Stroke Center, which meets the following requirements and is approved by the Department:

(1) **Stroke Team:**

(A) Having a stroke team available twenty-four (24) hours a day, seven (7) days a week;

(B) 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;

(C) Having members trained in the care of a stroke patient, with said training updated annually;

(D) Having response times of the stroke team established and tracked in writing;

(E) 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

(F) Written emergency stroke care protocols adopted;

(2) Emergency Department:

(A) Having a licensed physician in the care of emergent stroke patient and credentialed by the Stroke Center to provide emergency medical service for stroke patients, including the ability to administer thrombolytic agents, shall be on-call and be available to immediately respond to the emergency department;

(B) 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;

(C) 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;

(D) For a hospital, licensed as critical access hospital, all emergency services shall meet the requirements of OAC 310:667-39-14;

(E) 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
 - (F) Collaborate with emergency management agencies to develop inter-facility transfer protocols for stroke patients and will only use those emergency management agencies that have a Department approved protocols 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; and
 - (E) Have available on-site, twenty-four (24) hours a day, seven (7) days a week, sterile procedure trays for lumbar puncture;
 - (4) Medical staff organization:
 - (A) A physician designated as the stroke center director;
 - (B) A physician credentialed to provide emergency medical care designated as the emergency services director; and
 - (C) A licensed nurse or other health profession designated as the stroke coordinator;
 - (5) 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;

(6) 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;
- (iv) Pregnancy testing;
- (v) Troponin I; and
- (vi) Spinal fluid cell count;

(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;

(7) 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) A facility that admits to inpatient over half of their acute stroke patients during any 12 month period will be required to obtain certification as a level I or II Stroke Center;

(B) 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;

(C) 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;

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

(E) 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;

(F) provide no less than quarterly feedback to:

(i) Hospital physicians and other health professionals;

(ii) Emergency medical service agencies; and

(iii) Referring hospitals;

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

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

(I) Door-to-computer link time for cases where a tele-technology is used; and

(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) For possible stroke patients, utilize at least one standardized stroke scale;

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

(F) 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;

(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 for treatment in-house;

(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

(C) If a stroke telemedicine program is utilized, development and implementation of a written, contractual agreement addressing, at a minimum, performance standards, legal issues and reimbursement.