

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

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Chapter 667. Hospital Standards [AMENDED]

SUMMARY:

The proposed rule changes are: 310:667-1-2. Definitions; 310:667-1-3 Licensure; and 310-667-1-4 Enforcement as a result of new statutory language created through Senate Bill No. 1748. The proposed revision for the Definitions section is to align the "hospital" definition with 63 O.S. § 1-701(a). The proposed revision for the Licensure section provides additional clarity to the renewal application timeline, including the option for the licensee to file a notice with intent to renew application. The proposed revision for the Enforcement section states what an applicant needs to do if the license is revoked or surrendered. The rule change proposal for 310:667-19-2, Reports and records, is a response to the Governor's Executive Order 2020-03 to streamline content by removing unnecessary and duplicative wording. The proposed revision removes duplicative wording and now directs the reader to review certain provisions in the Department's infant hearing screening and newborn metabolic disorder screening rules.

AUTHORITY:

Commissioner of Health, Title 63 O.S. § 1-104; and 63 O.S. § 1-705.

COMMENT PERIOD:

January 15, 2021 through the close of the Department's normal business hours, 5 PM, on February 16, 2021. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on February 16, 2021, 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 February 16, 2021, via WebEx accessible from the site <https://oklahoma.gov/health/organization/public-hearings.html>, from 9AM to noon.

The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of extreme inclement weather or technical difficulties disrupting or preventing the meeting is February 23, 2021, via WebEx accessible from the site <https://oklahoma.gov/health/organization/public-hearings.html>, from 9AM to noon. Those wishing to present oral comments should be registered to speak by 9:15 a.m. Directions for comment registration will be provided on the website. The hearing will close at the conclusion of comments from those registered to speak. Interested persons may attend for the purpose of orally submitting data, views, or concerns 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 the close of the Department's normal business hours, 5 PM, on February 16, 2021, 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.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSON:

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

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

1. DESCRIPTION:

310:667-1-2. Definitions. Senate Bill No. 1748 amends the definition of hospital at 63 O.S. § 1-701(a). This section has been updated to reflect the new hospital definition which now includes facilities *primarily engaged* in the maintenance and operation of patients.

310:667-1-3. Licensure. As a result of Senate Bill No. 1748 amending 63 O. S § 1-706(D), the facility renewal application process has been updated to include the option for the licensee to file a notice with intent to renew the license which provides an additional 30 days. This section has also been updated to provide additional detail and clarity regarding the renewal timeline. This includes notice of renewal sent by the Department 60 days before expiration of a license, and notice of non-licensure if the licensee does not file a renewal application.

310:667-1-4. Enforcement. Senate Bill No. 1748 amends 63 O.S. § 1-706(E). It now states application for a new license after revocation creates a new license number, and that issuance of a license is based on compliance with applicable laws and rules for licensure; not correction upon which a revocation was based.

310:667-19-2. Reports and records. In compliance with the Governor's executive order 2020-03 to undertake a critical and comprehensive review of the agency's administrative rules, identify unnecessary regulatory restrictions, and simplify language. Chapter 667 now directs the reader to review Chapter 540 for infant hearing screening, and Chapter 550 for newborn metabolic disorder screening and removes duplicative language.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

Revisions as a result of Senate Bill No. 1748: Persons affected will include hospitals and recipients of care at the hospitals, in that Senate Bill No. 1748 provides guidance and timelines for clarification to the licensing requirement, and signage requirements.

There appears to be no cost to the patient. The cost to the hospital will include maintenance of signage and operational costs to meet minimal licensing requirements.

310:667-19-2: The proposed changes are being made to reduce regulatory restrictions in compliance with the governor's directive and executive order 2020-03, it is not expected that these changes will affect health outcomes or cost impact.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

Revisions as a result of Senate Bill No. 1748. The proposed benefits to patients include published notice that removes duplication of information and alleviates confusion.

Benefits to hospitals include alignment with current Centers for Medicare and Medicaid Services.

310:667-19-2. The proposed changes are being made in an effort to align with the Governor's directive and executive order 2020-03 to identify unnecessary regulatory restrictions and simplify language. The rule sweep is intended to make rules easier to read for potential applicants and individuals involved in newborn screening process.

4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**

There are no anticipated costs associated with implementation.

5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**

There are no anticipated costs associated with implementation.

6. **IMPACT ON POLITICAL SUBDIVISIONS:**

There are no anticipated impacts on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. **ADVERSE EFFECT ON SMALL BUSINESS:**

There are no anticipated known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**

There have been no less costly means currently identified.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**

No effect on public health is expected as result of these rule changes.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

No detrimental effects on public health and safety would be experienced without adoption of this rule.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on November 24, 2020.

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

SUBCHAPTER 1. GENERAL PROVISIONS

310:667-1-2. Definitions

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise.

"Addition" means an extension or increase in floor area or height of a building structure.

"Administrator" means the chief executive officer for the hospital.

"Advanced practice nurse" means a licensed registered nurse recognized by the Oklahoma Board of Nursing as an advanced practice nurse. Advanced practice nurses shall include advanced registered nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists.

"Automatic" means providing a function without the necessity of human intervention.

"Building" means a structure used or intended for supporting or sheltering any use or occupancy. The term "building" shall be construed as if followed by the words "or portions thereof."

"Chemical restraint" means the use of a medication for the purpose of discipline, convenience, or in an emergency situation to control mood or behavior and not required to treat a patient's condition.

"Combustible" means capable of undergoing combustion.

"Critical Access Hospital" means *a hospital determined by the State Department of Health to be a necessary provider of health care services to residents of a rural community* [63 O.S. ~~Supp. 1999~~, § 1-701(a)(4)].

"Department" means the Oklahoma State Department of Health.

"Emergency hospital" means *a hospital that provides emergency treatment and stabilization services on a 24-hour basis that has the ability to admit and treat patients for short periods of time* [63 O.S., § 1-701(a)(5)].

"Existing facility" means licensed hospitals that are in existence or have had final drawings for construction approved by the Department at the date this Chapter become effective. A general medical surgical hospital that converts to a critical access hospital shall be considered an existing facility.

"General hospital" means *a hospital maintained for the purpose of providing hospital care in a broad category of illness and injury* ~~[63 O.S. 1991, § 1-701(a)(1)]~~.

"General medical surgical hospital" means a general hospital that provides medical and surgical procedures.

"Governing body" means the person(s) having ultimate responsibility, including fiscal and legal authority for the hospital.

"Hospital" means *any institution, place, building, or agency, public or private, whether organized for profit or not, devoted primarily to primarily engaged in the maintenance and operation of facilities for the diagnosis, treatment, or care of patients admitted for overnight stay or longer in order to obtain medical care, surgical care, obstetrical care, or nursing care for illness, disease, injury, infirmity, or deformity. All places where pregnant females are admitted and receive care incident to pregnancy or delivery shall be considered to be a "hospital" within the meaning of this publication regardless of the number of patients received or the duration of their stay. The term "hospital" includes general medical surgical hospitals, specialized hospitals, critical access and emergency hospitals, and birthing centers* [63 O.S. ~~Supp. 1999~~, § 1-701(a)].

"Hospital campus" means inpatient and/or outpatient facilities located at different addresses operated under a common hospital license issued by the Department.

"Licensed independent practitioner" means any individual permitted by law and by the licensed hospital to provide care and services, without direct supervision, within the scope of the individual's license and consistent with clinical privileges individually granted by the licensed hospital. Licensed

independent practitioners may include advanced practice nurses with prescriptive authority, physician assistants, dentists, podiatrists, optometrists, chiropractors, and psychologists.

"Licensed practical nurse" means a person currently licensed to practice practical nursing in Oklahoma.

"Licensed/registered dietitian" means a person who is registered as a dietitian by the American Dietetic Association and is currently licensed as a dietitian in Oklahoma.

"Licensure" means the process by which the Department grants to persons or entities the right to establish, operate, or maintain any facility.

"Occupancy" means the purpose for which a building or portion thereof is used or intended to be used.

"Pharmacist" means a person who is currently registered by the Oklahoma State Board of Pharmacy to engage in the practice of pharmacy.

"Physical restraint" means any manual method or physical or mechanical device, material or equipment attached or adjacent to a patient's body that the patient cannot remove easily, that is not used for the purpose of therapeutic intervention or body alignment as determined by the patient's physician or licensed independent practitioner, and which restricts the patient's desired freedom of movement and access to his or her body.

"Physician" means a doctor of medicine (M.D.) or osteopathy (D.O.) currently licensed to practice medicine and surgery in Oklahoma.

"Physician assistant" means an individual licensed as a physician assistant in Oklahoma.

"Practitioner" means a dentist, podiatrist, chiropractor, optometrist, physician assistant, psychologist, certified nurse mid-wife, advanced registered nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, physical therapist, occupational therapist, pharmacist, social worker or other individual currently licensed or authorized to practice as a medical professional in Oklahoma.

"Psychiatric hospital" means a specialized hospital maintained for the purpose of providing psychiatric care.

"Registered nurse" means a person currently licensed to practice registered nursing in Oklahoma.

"Rehabilitation hospital" means a specialized hospital maintained for the purpose of providing rehabilitation.

"Respiratory care practitioner" means a person licensed by this state and employed in the practice of respiratory care ~~{[59 O.S. Supp. 1995, § 2027]}~~.

"Specialized hospital" means a hospital maintained for the purpose of providing hospital care in a certain category, or categories, of illness and injury ~~{[63 O.S. 1994, § 1-701(a)(2)]}~~.

310:667-1-3. Licensure

(a) Application for licensure.

(1) No person or entity shall operate a hospital without first obtaining a license from the Department. The license is not transferable or assignable.

(2) The applicant shall file a licensure application in a timely manner. The application shall be on forms provided by the Department, with a check of \$10.00 for each census bed, crib and bassinet, payable to the Oklahoma State Department of Health.

(3) The entity responsible for operation of the hospital and appointment of the medical staff shall be considered the applicant for the license. This entity may be a lessee if the hospital is leased and the lessee is the operating entity. For the purposes of licensure, a company providing administrative management of a hospital, which functions by contract with the governing body of the hospital, shall not be considered the entity responsible for operation.

(4) An application is not considered to be filed unless it is accompanied by the application fee.

(b) Application filing. An initial license application or renewal application shall be filed as follows:

(1) The application for an initial license for a new hospital shall be filed prior to or at the time final drawings for construction are submitted to the Department for review which shall be at least thirty (30) days before a hospital begins operation.

(2) The application for an initial license for a change of ownership or operation, shall be filed at least thirty (30) days before the transfer. The sale of stock of a corporate licensee, where a majority of the governing body does not change, is not considered a change of ownership or operation. The sale or merger of a corporation that owns an operating corporation that is the licensed entity shall not be considered a change of ownership unless a majority of the governing body is replaced.

(3) The Department will mail a notice of renewal at least 60 days before the license expires.

~~(3)~~(4) The application for renewal of a license of an existing hospital shall should be filed at least thirty (30) days before the expiration date of the current license to ensure that it is approved before the license expires.

(5) If the license expires without the Department receiving a renewal application, then the Department will mail a notice of non-renewal to the facility. A notice of non-renewal provides the licensee 30 days to:

(A) file the renewal application; or

(B) file a notice with intent to renew the license

(6) If a licensee submits a notice with intent to renew the license, then the licensee receives an extra 30 additional days to file the renewal application. The 30 additional days begins from the date the Department receives the notice to renew the license.

(7) When a licensee fails to file the renewal application before the deadlines stated in this subsection the Department will mail a notice of non-licensure. The notice of non-licensure will inform the licensee:

(A) that the license is now considered surrendered; and

(B) identifies opportunities to show compliance.

(8) If the applicant files a renewal application before the deadlines provided in this subsection, then the license is considered renewed with no additional requirements.

(c) **Where to file.** The application and the license fee shall be delivered or sent to the Department. The effective date shall be the date the application and fee are received.

(d) **Forms.** The applicant for a license shall file application forms as follows:

(1) For an initial license of a new hospital, or for an existing hospital following a change in ownership or operation, the applicant shall file these forms: Application for License to Operate a Hospital or Related Institution; Board of Directors Information Sheet; and Designation of Licensed Beds Form.

(2) For renewal of a current license, the applicant shall file the Application for License to Operate a Hospital or Related Institution; Board of Directors Information Sheet; Designation of Licensed Beds Form; and a Fire Inspection Report For Hospitals.

(e) **Description of forms.** The forms used to apply for a hospital license are the following:

(1) The Application For License to Operate Hospital or Related Institution (Form 920) requests: identification of the type of license requested; the name and address of the hospital; the name and address of the operating entity; the number of beds and bassinets; the ownership of the building and grounds; the applicant's name; the chief executive officer/administrator's name; attachment for credentialed staff; and an affidavit attesting the signature of the applicant.

(2) The Board of Directors Information Form (Form 929) requests: The names and addresses of the Board of Directors for the hospital.

(3) The Designation of Licensed Beds Form (Form 929) requests: A listing of the types of beds operated by the hospital and a total of the beds.

(4) The Fire Inspection Report for Hospitals (Form 928) requests: a check list of the annual inspection conducted by the local fire marshal.

(f) **Eligibility for license.**

(1) Hospitals making appropriate application that have been determined to be compliant with these standards are eligible for a license.

(2) A hospital may operate inpatient and outpatient facilities under one (1) license as a hospital campus as long as the following requirements are met:

(A) The facilities shall be separated by no more than fifty (50) miles. This requirement may be waived if the services of the facilities are totally integrated through telecommunication or by other

means.

(B) The facilities are operated by the same governing body with one administrator.

(C) The medical staff for all facilities is totally integrated so that any practitioner's privileges extend to all facilities operated under the common license.

(3) An outpatient facility located at a different address from a hospital is eligible to be licensed as part of the hospital but is not required to be licensed.

(4) Each hospital shall participate in a functioning regional system of providing twenty-four (24) hour emergency hospital care approved by the Commissioner of Health in consultation with the Oklahoma Trauma Systems Improvement and Development Advisory Council. Participation in a regional system may include active participation of the hospital in the provision of emergency services based upon the system plan, participation of the hospital's medical staff in the provision of emergency services at other hospitals in the system based on the system plan, or payment into a fund to reimburse hospitals providing emergency services in the system.

(5) If an area of the state fails to develop a functioning regional system of providing twenty-four (24) hour emergency hospital care necessary to meet the state's needs for trauma and emergency care as established by the state-wide trauma and emergency services plan, the Commissioner of Health, in consultation with the Oklahoma Emergency Response Systems Development Advisory Council, shall develop a system for the area. Each hospital located in the area shall participate as specified by the system plan for that region.

(g) Regional system of emergency hospital care.

(1) In counties and their contiguous communities with populations of 300,000 or more, a functioning regional system of providing twenty-four (24) hour emergency hospital care shall include definitive emergency care for all clinical categories specified in OAC 310:667-59-7. In these regions, a functioning system shall only transfer emergent patients out of the system when treatment or diagnostic services are at capacity unless the patient has a special treatment need not normally provided by the system. Transfers out of the system may occur based upon the patient or the patient's legal representative's request or based upon a special circumstance for the transfer.

(2) In counties and communities with populations of less than 300,000, a functioning regional system of providing twenty-four (24) hour emergency hospital care shall include definitive care based upon the classification of hospital's emergency services in the region as specified in OAC 310:667-59-7. Transfers out of the regional system may be based upon lack of diagnostic or treatment capability or capacity. A functioning system shall not permit emergent patient transfers out of the system if the system has the capability and capacity to provide care unless the patient or patient's legal representative requests the transfer.

(3) A functioning regional system of providing twenty-four (24) hour emergency hospital care shall demonstrate compliance with OAC 310:667-1-3(g)(1) or (2) through system continuous quality improvement activities. Activities shall include monitoring of patient transfers and corrective actions when inappropriate transfers are identified. Special circumstance patient transfers shall be identified and reviewed through continuous quality improvement activities.

(h) Quality indicators. The Department, with the recommendation and approval of the Hospital Advisory Council, shall establish quality indicators to monitor and evaluate the quality of care provided by licensed hospitals in the state.

(1) The quality indicators shall focus on the following measurement areas:

(A) Acute myocardial infarction (including coronary artery disease);

(B) Heart failure;

(C) Community acquired pneumonia;

(D) Pregnancy and related conditions (including newborn and maternal care);

(E) Surgical procedures and complications;

(F) Patient perception measures such as satisfaction surveys; and

(G) Ventilator-associated pneumonia and device-related blood stream infections for certain intensive care unit patients in acute care hospital settings.

(2) The quality indicators in use shall be periodically evaluated and revised as health care quality issues are identified and others are resolved.

(i) **Data submission requirements.**

(1) The Department shall define the parameters and scope of each quality indicator, the beginning and ending dates of the period when each indicator will be in effect, how the indicator will be measured, any inclusionary or exclusionary criteria, and the frequency and format of how the data shall be reported.

(2) Each hospital shall report applicable data related to these indicators to the Department in the specified format and within required time frames.

310:667-1-4. Enforcement

(a) **Inspections.** All hospitals required to have a license are subject to inspection by Department staff. This includes hospitals under construction that have submitted final drawings and made application for a license. These inspections may be routine or conducted as a result of a complaint investigation.

(b) **Adverse actions.** The State Commissioner of Health may suspend or revoke any hospital license based on any of the following:

(1) Violation of any provisions of 63 O.S. 1991, § 1-701 et seq. or this Chapter.

(2) Permitting, aiding or abetting the commission of any illegal act in the licensed hospital.

(3) Conduct of practices deemed by the Commissioner to be detrimental to the welfare of patients of the hospital.

(c) **Hearings.** Hearings shall be conducted according to the Administrative Procedures Act and Chapter 2 of this Title 310:002.

(d) **Appeals.** A final order of the Commissioner of Health may be appealed to the District Court by any party affected or aggrieved by the order.

(e) **Revocation.** If a license is revoked, 63 O.S. Section 1-706(E) states what must occur to obtain a new license.

SUBCHAPTER 19. MEDICAL RECORDS DEPARTMENT

310:667-19-2. Reports and records

(a) Reports shall be made by each hospital to the appropriate agency, including but not limited to the following:

(1) Communicable disease.

(2) Births and deaths.

(3) Periodic reports to the Department on forms supplied for this purpose.

(4) Newborn hearing screening report. The hospital shall proceed pursuant to 310:540-1-3 (relating to newborn hearing screening).

(A) ~~All hospital nurseries shall complete a newborn hearing screening report form on all live newborns discharged from their facility. For facilities with a two-year average annual birth census of fifteen (15) or greater, physiologic hearing screening results as well as "at risk" indicators must be recorded on the report form; for facilities with a two-year average annual birth census of fewer than fifteen (15), "at risk" indicators must be recorded and if physiologic hearing screening is conducted, those results also must be recorded on the report form. It shall be the responsibility of the hospital administrator to assure that the Newborn Hearing Screening Report Form is correctly completed and subsequently submitted to the Department. The hospital administrator may designate one individual, who shall then be responsible for review of all newborn discharge summaries to insure that a report form has been completed for each infant and that the report form is a permanent part of that infant's record. A copy of the hearing screening report form must be given to the infant's caregiver at discharge.~~

(B) ~~If an infant is transferred from one hospital to another, the second hospital shall be responsible for providing physiologic hearing screening, "risk indicator" screening, and for completion of the~~

report form.

(C) It shall be the responsibility of the hospital administrator to insure that all completed report forms are mailed to the Department within seven (7) days of an infant's birth.

(D) It shall be the responsibility of the attending physician or licensed independent practitioner to inform parents if their infant passed or was referred on the physiologic hearing screening and/or if the infant is to be considered "at risk" for hearing impairment. Prior to discharge, the attending physician or licensed independent practitioner shall review the completed report form and shall inform the parents of their infant's status. Infants who do not pass the physiologic screening shall be referred for a diagnostic audiological evaluation as soon as possible.

(E) It shall be the responsibility of the coordinator of the Newborn Hearing Screening Program at the Department to arrange for hospital in-service training for all hospital personnel involved in the process of completion of report forms. A manual of procedures shall be available in regard to processing of screening forms. The literature for distribution to parents shall be available from the Department.

(5) Newborn metabolic disorder screening.

(A) **Testing of newborns.** All newborns in Oklahoma shall be tested for phenylketonuria, hypothyroidism, galactosemia and sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium chain acyl coenzyme A dehydrogenase deficiency (MCAD), biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, organic acid disorders, severe combined immunodeficiency (SCID), spinal muscular atrophy (SMA), x linked adrenoleukodystrophy (X-ALD), mucopolysaccharidosis type I (MPS I) and Pompe disease upon completion of laboratory validation studies, establishment of short term follow up services, and approval by the Commissioner of Health as defined in Chapter 550 of this Title. All infants born at a birthing facility in Oklahoma shall be screened for Critical Congenital Heart Disease (CCHD) utilizing pulse oximetry. A parent or guardian may refuse newborn screening and/or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and/or practices. A parent or guardian who refuses newborn screening or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and/or practices shall also indicate in writing this refusal in the newborn's medical record with a copy sent to the Newborn Screening Program, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299. The hospital shall proceed pursuant to 310:550-3-1 (relating to newborn metabolic disorder screening).

(B) **Specimen Blood specimen collection for hospital births.** For all live hospital births, the physician or licensed independent practitioner shall order the collection of a newborn screening specimen prior to transfusion, as early as possible after twenty-four (24) hours of age or immediately prior to discharge, whichever comes first. Specimens shall be collected on the Newborn Screening Form Kit using capillary or venous blood. Cord blood is unacceptable. The hospital is responsible for collecting specimens on all infants.

(i) If the initial specimen for any infant is collected at or prior to twenty-four (24) hours of age, the hospital and the physician or licensed independent practitioner are responsible for notifying the infant's parents that a repeat specimen is necessary at three to five days of age. The infant's physician or licensed independent practitioner is responsible for ensuring that the repeat specimen is collected.

(ii) The hospital is responsible for submitting a satisfactory specimen and for documenting all requested information on the form kit including the parent/guardian's name, address, phone or contact phone number and the planned health care provider who will be providing well care for the infant after discharge. Or if the infant is to be hospitalized for an extended period of time, the name of the infant's physician or licensed independent practitioner.

(iii) The hospital is responsible for documenting specimen collection and results in the infant's hospital record.

(iv) Infants transferred from one hospital to another during the newborn period shall have

specimen collection documented in the infant's hospital record. It is the responsibility of the physician or licensed independent practitioner and the receiving hospital to insure a specimen is collected.

(v) It is the responsibility of the hospital and physician or licensed independent practitioner to ensure that all infants are screened prior to discharge. If an infant is discharged prior to specimen collection, the Newborn Screening Program Coordinator shall be notified by contacting Newborn Screening Program, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299, (405) 271-6617, FAX (405) 271-4892, 1-800-766-2223, ext. 6617. The physician or licensed independent practitioner is responsible for ensuring the specimen is collected as early as possible after twenty four (24) hours of age. The hospital shall proceed pursuant to 310:550-5-1 (relating to newborn metabolic disorder screening).

(C) Pulse oximetry screening for birthing hospitals. For all live hospital births, the physician or licensed independent practitioner shall order the pulse oximetry screening for newborns to be performed after twenty four (24) hours of age or prior to discharge from a facility.

(i) If unable to perform the screening after twenty four (24) hours of age or prior to discharge, schedule the infant to be screened at the hospital between twenty four (24) hours and forty eight (48) hours of life; or notify the infant's physician if screening was not performed.

(ii) If the newborn infant is discharged from a facility after twelve (12) hours of life but before twenty four (24) hours of life, the birthing facility shall perform screening as late as is practical before the newborn infant is discharged from the birthing facility.

(iii) If the infant is discharged before twelve (12) hours of life, the birthing facility shall perform the screening between twenty four (24) hours and forty eight (48) hours of life.

(iv) For newborn infants in special care or intensive care, birthing facilities shall perform pulse oximetry screen on infants prior to discharge utilizing recommended protocol, unless the infant has an identified congenital heart defect or has an echocardiogram performed. Continuous pulse oximetry monitoring may not be substituted for CCHD screening.

(v) There may be instances where screening for CCHD is not indicated, including but not limited to instances where:

(I) The newborn infant's clinical evaluation to date has included an echocardiogram which ruled out CCHD; or

(II) The newborn infant has confirmed CCHD based on prenatal or postnatal testing.

(III) Indicate on NBS filter paper that screening was not performed. The hospital shall proceed pursuant to 310:550-5-2 (relating to pulse oximetry screening).

(D) Screening for premature/sick infants. For all premature/sick infants, the physician or licensed independent practitioner shall order the collection of a newborn screening specimen prior to red blood cell transfusion, as early as possible after 24 hours of age but no later than three to seven days of age, or immediately prior to discharge, whichever comes first. Due to the need to identify infants at risk for the disorders quickly, the specimen should be collected as early as possible after twenty-four (24) hours of age. It is recommended that a repeat newborn screening specimen be collected at fourteen (14) days of age. Specimens shall be collected on the Newborn Screening Form Kit using capillary or venous blood. The hospital is responsible for collecting specimens on all premature/sick infants.

(i) Premature/sick infants screened prior to twenty four (24) hours of age must be re-screened between seven to fourteen (7-14) days of age.

(ii) Premature/sick infants who could not be screened prior to a red blood cell transfusion should be re-screened by the seventh (7th) day of life and a repeat specimen collected when plasma and/or red cells will again reflect the infant's own metabolic processes or phenotype. The accepted time period to determine hemoglobin type is ninety to one hundred and twenty (90 to 120) days after transfusion.

(iii) The recommended follow up study for an abnormal thyroid screen in a premature infant is a serum free T4 (measured by direct dialysis or an equivalent method) and TSH at seven to

~~fourteen (7-14) days of age. The hospital shall proceed to 310:550-5-1 (relating to newborn metabolic disorder screening).~~

(E) Newborn Screening screening Hospital hospital recording. ~~The hospital shall implement a procedure to assure that a newborn screening specimen has been collected on every newborn and mailed to the Newborn Screening Laboratory within twenty four to forty eight (24—48) hours of collection.~~

~~(i) The hospital shall immediately notify the infant's physician or licensed independent practitioner, and parents or guardians if an infant is discharged without a sample having been collected. This notification shall be documented in the infant's hospital record.~~

~~(ii) If no test results are received within fifteen (15) days after the date of collection, the hospital shall contact the Newborn Screening Laboratory to verify that a specimen had been received. If no specimen has been received, the hospital shall notify the physician or licensed independent practitioner.~~

~~(iii) Any hospital or any other laboratory which collects, handles or forwards newborn screening samples shall keep a log containing name and date of birth of the infant, name of the attending physician or licensed independent practitioner, name of the health care provider who will be providing well care for the infant after discharge, medical record number, serial number of the form kit used, date the specimen was drawn, date the specimen was forwarded, date the test results were received and the test results, and pulse oximetry screening results. The hospital shall proceed pursuant to 310:550-7-1 (relating to newborn metabolic disorder screening).~~

(F) Pulse oximetry screening hospital recording. ~~The hospital shall implement a procedure to assure that pulse oximetry screening has been performed on every newborn prior to discharge.~~

~~(i) All pulse oximetry screening results shall be recorded in the newborn infant's medical record and results reported to a parent or guardian prior to discharge from the hospital.~~

~~(ii) All pulse oximetry screening results shall be recorded on the Newborn Screening Form Kit, or faxed to the Oklahoma State Department of Health Newborn Screening Program. The hospital shall proceed pursuant to 310:550-7-1 (relating to newborn pulse oximetry screening).~~

(G) Parent, guardian and health care provider education. ~~The hospital will be responsible or designate a responsible party to distribute the Newborn Screening Program's written educational materials on newborn screening and pulse oximetry screening provided by the Department to at least one of each newborn's parent or legal guardian. The hospital shall proceed pursuant to 310:550-13-1 (relating to newborn disorder screening).~~

(H) Training. ~~Hospitals shall provide ongoing training programs for their employees involved with newborn screening procedures. These training programs shall include methods of collecting a satisfactory newborn screening specimen and proper pulse oximetry screening methods. The hospital is responsible for ensuring that employees who collect, handle or perform newborn screening tests; or perform pulse oximetry screening are informed of their responsibilities with respect to screening procedures. The hospital shall proceed pursuant to 310:550-13-1 (relating to newborn disorder screening).~~

(6) Birth defects. Each hospital shall ~~maintain~~ have the capability of producing a list of patients up to six (6) years of age who have been diagnosed with a birth defects-defect(s), and all women discharged with a diagnosis of stillbirth, ~~or miscarriage, or poor reproductive outcome.~~ On request, each hospital shall make the medical records of these individuals available to the State Department of Health.

(7) Abortions. Attending physicians shall complete and submit to the Department a report form for each abortion performed or induced as required by 63 O.S. 1999, Section 1-738.

(b) Record of patient admission.

(1) All persons admitted to any institution covered by these standards shall be under the care of a doctor of medicine (M.D.) or osteopathy (D.O.) duly licensed to practice medicine and surgery in the State of Oklahoma or a licensed independent practitioner, whose name shall be shown on the admitting record.

(2) The hospital admitting record also shall show the following for each patient.

(A) Full name of patient with age, sex, address, marital status, birth date, home phone number, date

of admission, and admitting diagnosis.

(B) Next of kin, with address, phone number, and relationship.

(C) Date and time of admission, the admission and final diagnoses, and the name of physician or licensed independent practitioner.

(D) Any advanced directive for health care as defined in the Oklahoma Rights of the Terminally Ill or Persistently Unconscious Act.

(3) Special clinical reports shall be kept, including the following:

(A) Obstetrical patients throughout labor, delivery, and post-partum.

(B) Newborn, giving the infant's weight, length, and other notes relative to physical examination.

(C) Surgical and operative procedures, including pathological reports.

(D) Record of anesthesia administration.

(c) Orders for medications, treatments, and tests.

(1) All medication orders shall be written in ink and signed by the ordering physician or practitioner authorized by law to order the medication, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician- approved hospital policy after an assessment for contraindications. The order shall be preserved on the patient's chart.

(2) All orders shall be written in ink and signed by the ordering physician or practitioner. Orders received by resident physicians shall be co-signed if required by medical staff bylaws. The order shall be preserved on the patient's chart.

(3) All orders taken from the physician or practitioner, for entry by persons other than the physician or practitioner, shall be countersigned.

(4) Telephone or verbal orders may be authenticated by an authorized physician or practitioner other than the ordering physician or practitioner when this practice is defined and approved in the medical staff bylaws. If allowed, medical staff bylaws must identify the physicians or practitioners who may authenticate another physician's or practitioner's telephone or verbal order, e.g. physician partners or attending physicians or practitioners, and define the circumstances under which this practice is allowed. The bylaws must also specify that when a covering or attending physician or practitioner authenticates the ordering physician's or practitioner's telephone or verbal order, such an authentication indicates that the covering or attending physician or practitioner assumes responsibility for his or her colleague's order and verifies the order is complete, accurate, appropriate, and final. The person taking the telephone or verbal order shall read the order back to the physician or practitioner to ensure it was correctly understood and verify on the order the fact that the order was read back. Each facility, within its own procedures and protocols, shall establish a verification process to be placed on orders to demonstrate that the order was read back to the physician.