

ADMINISTRATIVE AGENCY RULE REPORT
75 O.S. Supp. 2000, § 303.1
SUBMITTED TO THE GOVERNOR AND TO THE LEGISLATURE

1. Date the Notice of Intended Rulemaking was published in the Oklahoma Register:

October 1, 2013, Vol. 31, No. 2 Ok Reg 11, Docket No. 13-1193

2. Name and address of the Agency:

Oklahoma State Department of Health
1000 N.E. Tenth Street
Oklahoma City, Oklahoma 73117-1299

3. Title and Number of the Rule:

Title 310. Oklahoma State Department of Health
Chapter 667. Hospital Standards

4. Citation to the Statutory Authority for the Rule:

Title 63 O.S. Section 1-104; and Title 59 O.S. Sections 1-534, 1-550.5, and 1-705

5. Brief Summary of the Content of the Adopted Rule:

The Section proposed for amendment is 310:677-19-2 which describes, for Hospitals, reporting requirements for certain events. The proposed rule changes update the list of diseases and conditions previously updated in the Newborn Screening Program rules, Chapter 550, of Title 310, relating to Newborn Screening Program. The updated list includes 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. In addition this proposal adds amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010) - and after consultation with the Newborn Screening Subcommittee of the Oklahoma Genetics Advisory Committee. The updated list of conditions and diseases to this proposal include, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), This proposal also adds Pulse Oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) to existing newborn screening rules as legislated by HB House Bill 1347 (2013) [63 O.S. Section 1-550.5].

6. Statement explaining the Need for the Adopted Rule:

To comply with House Bill 1347 (2013) and to add a new screening test allowing early medical intervention in Severe Combined Immunodeficiency Syndrome and Critical Congenital Heart Disease resulting in significant cost savings to parents, insurers, hospitals and the State of Oklahoma.

7. Date and Location of the Meeting at which such Rules Were Adopted:

Adopted January 14, 2014, in the offices of the Oklahoma State Department of Health.

8. Summary of the Comments and Explanation of Changes or Lack of any Change Made in the Adopted Rules as a Result of Testimony Received at Public Hearings:

Both written and oral comments were received encouraging the addition of Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening rules and the Hospital Standard rules (Chapter 667) as lifesaving and beneficial to the citizens of the State. These comments are covered in detail in the Rule Comment Summary, hereto annexed as Exhibit A.

9. List of Persons or Organizations Who Appeared or Registered For or Against the Adopted Rule at Any Public Hearing Held by the Agency or Those Who Have Commented in Writing Before or After the Hearing:

As addressed in detail in the Rule Comment Summary, the following either provided written or oral comments in the public hearing in favor of adding Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening panel. The public hearing was held November 1, 2013.

- Joni Bruce, parent of an infant who died from a genetic disease and Executive Director of the Oklahoma Family Network.
- Gina Antipov, mother of Sam age 12, who was diagnosed with SCID at six months of age and as a public citizen.
- Vlad Antipov, father of Sam age 12, who was diagnosed with SCID at six months of age and a public citizen Dr. Tim Trojan, M.D., Oklahoma Institute of Allergy and Asthma.
- Naomi Amaha, Oklahoma Government Relations Director, American Heart Association.
- Erin Taylor, mother of Henry who was born with a congenital heart defect.
- James Love, MD., Allergy Clinic of Tulsa.
- Mary Ann Bauman, MD, Medical Director, Women's Health and Community Relations INTEGRIS Health, Volunteer, American Heart Association.
- Pat Penn, Grandmother of Samantha Penn, died at age 18 months from SCID
- Marcia Boyle, President and Founder, Immune Deficiency Foundation.

The following attended the public hearing and indicated they were in support of the proposed rule. Joni Bruce, Parent and Executive Director of the Oklahoma Family Network; Lauren Labeth, Oklahoma Family Network; Gina Antipov, Parent; Vlad Antipov, Parent; Tim Trojan, Physician, Oklahoma Institute of Allergies and Asthma; Naomi Amaha, Government Relations, American Heart Association; Erin Taylor, Parent, Malley and Henry Fund; Shannon Miller, Parent, Pulse Ox Oklahoma; Melissa Moore, Parent, Grayson's Advocates.

No comments were received opposing the proposed rules.

10. Rule Impact Statement: Hereto annexed as Exhibit B.

11. Incorporation by Reference Statement: "n/a"

12. Members of the Governing Board of the Agency Adopting the Rules and the Recorded Vote of Each Member:

Murali Krishna, President, M.D. – aye
Ronald Woodson, Vice-President, M.D. – aye
Martha Burger, M.B.A, Secretary-Treasurer – absent
Jenny Alexopoulos, D.O. – aye
Charles W. Grim, D.D.S., M.H.S.A. – aye
Terry Gerard, D.O. – aye
Robert S. Stewart, M.D. – aye
Tim Starkey, M.B.A. – aye
Cris Hart-Wolfe – aye

13. Additional information: Information regarding this rule may be obtained by contacting Sharon Vaz, Director, Screening and Special Services, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-6617, e-mail sharonav@health.ok.gov.

RULE COMMENT SUMMARY AND RESPONSE

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

The rule report submitted to the Governor, the Speaker of the House of Representatives and the President Pro Tempore of the Senate, pursuant 75:303.1(A) of the Administrative Procedures Act, shall include: (9) *A summary of the comments and explanation of changes or lack of any change made in the adopted rules as a result of testimony received at all hearings or meetings held or sponsored by an agency for the purpose of providing the public an opportunity to comment on the rules or of any written comments received prior to the adoption of the rule. The summary shall include all comments received about the cost impact of the proposed rules;* (10) *A list of persons or organizations who appeared or registered for or against the adopted rule at any public hearing held by the agency or those who have commented in writing before or after the hearing.*[75:303.1(E)(9)&(10)]

Rule Subchapter and Section: 310:667-19-2

Name & Organization: Joni Bruce, parent of an infant who died from a genetic disease and Executive Director of the Oklahoma Family Network.

Comment: Ms. Bruce encouraged the addition of Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening rules and the Hospital Standard rules as lifesaving and beneficial to the citizens of the State.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Gina Antipov, mother of Sam age 12, who was diagnosed with SCID at six months of age and as a public citizen.

Comment: Ms. Antipov presented oral comments on behalf of Jeremy and Sara Penn whose daughter Samantha died at 20 months from SCID. They documented Samantha's illness and diagnostic odyssey, with the ultimate diagnosis of SCID. They strongly advocate for the addition of SCID to the Newborn Screening panel because they feel that if there had been early identification through newborn screening that their daughter would have survived. They stated that medical care for Samantha cost over \$1.1 million and if her disease had been identified earlier the cost of a bone marrow transplant would have been \$350,000 saving \$750,000 (which could be used to cover the cost of SCID screening for over 150,000 births).

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Vlad Antipov, father of Sam age 12, who was diagnosed with SCID at six months of age and a public citizen.

Comment: Mr. Antipov presented oral comments in favor of adding SCID to the Newborn Screening panel. He outlined the diagnostic odyssey that he and his wife underwent when his son got sick and was diagnosed at 6 months of age. He reiterated the financial burden placed on his family when they hit their \$1 million dollar insurance cap and had to change to the state's high risk pool. In addition, he stated that he had to leave a job that he liked to take another one for the health insurance.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Dr. Tim Trojan, M.D., Oklahoma Institute of Allergy and Asthma.

Comment: Dr. Trojan, M.D. is Board Certified in Immunology. He presented oral comments in favor of adding SCID to the Newborn Screening panel. He provided information regarding sensitivity and specificity of testing; stating that sensitivity was demonstrated to be 100% for detecting SCID patients and the specificity is at 99.98%. He reviewed the Infant Mortality statistics for Oklahoma and offered that SCID screening would be financially cost effective at \$5.44/ child. In addition, he stated that “given the 9% Native American population in Oklahoma and SCID incidence up to 4 times higher in Native American populations” he believes that the SCID incidence in Oklahoma will be much higher than the anticipated 1-2 infants per year.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Naomi Amaha, Oklahoma Government Relations Director, American Heart Association.

Comment: Ms. Amaha provided oral and written testimony urging the Board of Health to approve proposed rules regarding the Newborn Screening Program, as legislated by HB 1347.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Erin Taylor, mother of Henry who was born with a congenital heart defect.

Comment: Ms. Taylor provided testimony stating that “Congenital Heart Defects are the most common birth defects in the State of Oklahoma and that there is a large financial impact to the state. Henry has had dozens of heart surgeries and over 35 heart catheterizations and a heart transplant. His medical care is over \$2 million and she has had to get health care for her child in four different states. The tests will track how common these complex congenital heart defects are so that maybe we can increase our capacity and infrastructure in the State of Oklahoma. For the past several years most of the children with complex congenital heart conditions have had to obtain their care out of state. Since 2002, 1200 children in the state have been born with the same condition as Henry costing the state millions of dollars”.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: James Love, MD., Allergy Clinic of Tulsa.

Comment: Received written comment “As a practicing immunologist in the state of Oklahoma for the past 17 years, I can speak to the necessity of newborn screening for immune deficiency. As you are aware, data has shown that early bone marrow transplantation can prevent death and severe illness in this vulnerable group of children. And it has been shown to be cost-efficient in other states that have implemented the process. Without newborn screening, by the time these children present with overwhelming illness, it is often too late for them. Please consider adding this important test to our current panel of newborn screens.”

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Mary Ann Bauman, MD, Medical Director, Women's Health and Community Relations INTEGRIS Health, Volunteer, American Heart Association.

Comment: Received written comment "During the 2013 legislative session, the Oklahoma Legislature and Governor Fallin approved House Bill 1347, a bill that ensured all newborns are screened for a critical congenital heart defect (CCHD) using a simple and non-invasive "pulse-ox" test. A pulse-ox test is a highly effective method to catch a congenital heart defect before a baby is sent home. Every minute is critical when the heart is not functioning properly, and early detection of a heart defect will allow for immediate treatment. I urge the Board of Health to approve the proposed rule 63 O.S. § 1-550.5 and support this solution to ensure detection of critical congenital heart defects in newborns. Thank you for your consideration".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Pat Penn, Grandmother of Samantha Penn, died at age 18 months from SCID.

Comment: Received written comment "My grand-daughter, who was born in Stillwater, died from this disease because no-one gave her the simple blood test. After she died, her doctor in Stillwater identified another child with this disease, but, was able to send her to Cincinnati for treatment. How many other babies are there in Oklahoma who have SCID? Please, our family would like to help save other babies, perhaps even someone you know and love. Thanks for listening, Grandma Penn, 1220 S. Holly Dr., Sioux Falls SD 57105".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Marcia Boyle, President and Founder, Immune Deficiency Foundation.

Comment: Received written comment stating that the "IDF supports the amendment to Title 310. Oklahoma State Department of Health Chapter 550. Newborn Screening Program to add SCID to the Newborn Screening panel in Oklahoma. Statement reiterates that infants affected by SCID lack T lymphocytes, the white blood cells that help resist infections due to a wide array of viruses, bacteria and fungi. The diagnosis of SCID very early in life is a true pediatric emergency, and the decision to screen for SCID will literally save the lives of infants in Oklahoma".

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

List of person who attended on behalf of Chapter 667

Name	Representing
Joni Bruce	Parent and Executive Director of the Oklahoma Family Network
Lauren Labeth	Oklahoma Family Network
Gina Antipov	Parent
Vlad Antipov	Parent
Tim Trojan	Physician, Oklahoma Institute of Allergies and Asthma
Naomi Amaha	Government Relations, American Heart Association
Erin Taylor	Parent, Malley and Henry Fund
Shannon Miller	Parent, Pulse Ox Oklahoma
Melissa Moore	Parent, Grayson's Advocates

Agency Rule Contact:

Sharon Vaz, Director, Screening and Special Services, phone (405) 271-6617, e-mail Sharonav@health.ok.gov.

RULE IMPACT STATEMENT

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

1. **DESCRIPTION:**

The Section proposed for amendment is 310:677-19-2 which describes, for Hospitals, reporting requirements for certain events. The proposed rule changes update the list of diseases and conditions previously updated in the Newborn Screening Program rules, Chapter 550, of Title 310, relating to Newborn Screening Program. The updated list includes 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. In addition this proposal adds amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010) - and after consultation with the Newborn Screening Subcommittee of the Oklahoma Genetics Advisory Committee. The updated list of conditions and diseases to this proposal include, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), This proposal also adds Pulse Oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) to existing newborn screening rules as legislated by HB House Bill 1347 (2013) [63 O.S. Section 1-550.5].

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

- Updated list of disease and conditions is to maintain consistency between Chapter 550 and Chapter 667.
- There is no additional cost to Hospitals and birthing facilities for these named tests. The updated list are already required to conduct newborn screening as listed in Chapter 550.
- Severe Combined Immunodeficiency Syndrome (SCID) is proposed as a new test to the newborn screening panel.
- All newborns are screened for silent disorders that can be treated if identified before symptoms occur. Adding new screening disorders to the testing panel has immediate positive health benefits for affected infants and families and long-term financial benefits for the Oklahoman health care system.
- Several states (Wisconsin, Texas, Massachusetts, California, Louisiana, and New York) currently doing pilot studies for SCID testing have found that the incidence of the disease is as high as 1/40,000. This is much higher than our previously stated incidence (1/100,000) for this disease.
- The second proposed addition to Chapter 667 is Pulse Oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) as legislated by HB 1347 (2013).
- The classes of persons affected are newborn babies and their parents who have babies in a birthing facility in Oklahoma.

- Additionally those affected are “birthing facilities” in Oklahoma as defined in House Bill 1347 (2013).
- There were over 52,000 births recorded by the Division of Vital Records for the Oklahoma State Department of Health in 2012.

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

- Estimate that 1-2 infants with SCID will be identified annually, based on the Oklahoma birth rate of approximately 55,000 – 60,000/annum and incidence of disease (~1/40,000).
- Early identification improves health outcomes. Generally, this disease results in life-threatening infections within the first few months of life. Early detection provides a positive contribution to Child Health and improves rates of infant survival, which will reduce Oklahoma’s rates of infant mortality and morbidity.
- The Oklahoma State Department of Health will evaluate overall benefits of SCID testing through follow-up of positively-screened infants.
- Cost of treatment (bone marrow transplant) for infants identified at birth is approximately \$250,000 to \$300,000 (for the procedure).
- Cost of treatment of a child not identified at birth is estimated at \$2 million.
- In Oklahoma as many as 105 babies are born annually with a Critical Congenital Heart Defect. This is a rate of approximately 20 babies/10,000.
- All infants born in a birthing facility in Oklahoma will benefit from early detection and treatment for a Critical Congenital Heart Defect.

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

There will be no cost to the department for compliance requirements. Compliance monitoring will be absorbed into the current inspection process. There should be no cost of compliance to the “birthing facilities” as a birthing facility was already required by federal requirement to have obtained the equipment necessary to perform a “pulse oximetry screening.” The CDC reports the cost of the screening itself ranges between \$5.00-\$10.00 per newborn and takes between 1-5 minutes per each screening conducted. This cost will be added to the bundle of costs for newborn screenings and paid by insurance or the consumer. There is a proposed request pursuant to the Public Health Laboratory Service fee schedule at OAC 310:546-1-2, to increase the newborn screening fee by \$6.00 from \$152.62 to \$158.62 to cover the cost of the Public Health Laboratory and the Newborn Screening follow-up department for implementation of SCID testing and monitoring.

For implementation of CCHD screening there will be no cost to the birthing facilities.

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

Additional staff time will be required to inspect for compliance of the birthing facilities for the new screening requirement and there will be a cost to the agency to track compliance and to undertake enforcement if compliance is not met. Compliance tracking will be done in collaboration with Prevention and Preparedness Division – Screening and Special Services.

6. **IMPACT ON POLITICAL SUBDIVISIONS:** There will be no impact on political subdivisions
7. **ADVERSE EFFECT ON SMALL BUSINESS:** There will be an impact on those birthing facilities that meet the definition of a small business. The impact will be to perform the newborn screening test that is currently being performed with the addition of the pulse oximetry screen and to recoup that cost from insurance or the consumer.
8. **EFFORTS TO MINIMIZE COSTS OF RULE:**
Proposed SCID testing to be performed in-house in the Public Health Laboratory (PHL) (versus send-out) using a CDC-developed protocol that obviates the need for extensive test development and validation. Training for SCID testing has been provided free by the CDC. This protocol does not require nucleic acid isolation, whereas alternate protocols have the added cost of this step. The PHL has chosen a qPCR system that is at the lower price end of available commercial systems.

The proposed CCHD screening rules implement statutory requirements for screening. The methodology devised is of the lowest cost identified to date.
9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
Changes to the Newborn Screening rule will improve the core public health services of Children's Health in Oklahoma. Early identification of at-risk infants can lead to reduction in infant mortality and morbidity. The CDC reports that pulse oximetry screenings can identify infants with critical congenital heart defects (CCHD). Infants with CCHDs are at significant risk for morbidity or mortality. The CDC reports that pulse oximetry screenings can detect seven to twelve different CCHDs that represent 17-31% of all congenital heart disease in newborns. The detection of the CCHD will allow the newborn to receive a surgical procedure, shortly after birth to correct the CCHD and reduce the morbidity and mortality rate.
10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:** Oklahoma currently ranks 44th in the country for infant mortality. Cases of SCID are undiagnosed because infants die due to overwhelming infections in the first few months of life. Addition of this screening test to the Newborn Screening Panel will ensure that Oklahoma is following the national Recommended Uniform Screening Panel as recommended by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and is aligned with newborn screening algorithms in bordering states. Addition of pulse oximetry screening for CCHD will allow for early intervention and treatment. Undetected CCHDs will lead to a higher morbidity and mortality rate among newborns.
11. This rule impact statement was prepared on August 5, 2013 and revised January 23, 2014.

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

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.

(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 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 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 ~~by a Certified Newborn Metabolic Disorder Screening Laboratory as defined in Chapter 550 of this Title,~~ 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, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved 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~~^a parent or guardian may refuse metabolic disorder newborn screening and/or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices. A parent or guardian who refuses metabolic disorder newborn screening or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices shall also indicate in writing this refusal in the newborn's medical record with a copy sent to the Newborn ~~Metabolic Disorder Screening Program, Maternal and Child Health Prevention and Preparedness Service~~^{Services}, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299.

(B) **Specimen collection for hospital births.** For all live hospital births, the physician or licensed independent practitioner shall order the collection of a newborn ~~metabolic disorder~~ screening specimen on all newborns prior to transfusion, ~~at three to five days of age as early as possible after 24 hours of age~~ or immediately prior to discharge, whichever comes first. Specimens shall be collected on the Newborn ~~Metabolic Disorder Screening Form Kit~~ as described in Appendix A of Chapter 550 of this Title 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 prior to 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 insuring 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 insure that all infants are screened prior to discharge. If an infant is discharged prior to specimen collection, the ~~Newborn Metabolic Disorder~~ Screening Program Coordinator shall be notified by contacting ~~Maternal and Child Health~~ Newborn Screening Program, Prevention and Preparedness Service Services, 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 insuring the specimen is collected ~~at three to five days of age~~ as early as possible after 24 hours of age.

(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 24 hours of age or prior to discharge from a facility.

(i) If unable to perform the screening after 24 hours of age or prior to discharge, schedule the infant to be screened at the hospital between 24 hours and 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 12 hours of life but before 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 12 hours of life, the birthing facility shall perform the screening between 24 hours and 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.

(D) Screening for premature/sick infants. For all premature/sick infants, the physician or licensed independent practitioner shall order the collection of a newborn ~~metabolic disorder~~ screening specimen prior to red blood cell transfusion, ~~at three to seven days of age~~ as early as possible after 24 hours of age, or immediately prior to discharge, whichever comes first. It is recommended that a repeat newborn ~~metabolic disorder~~ screening specimen be collected at 14 days of age. Specimens shall be collected on the Newborn ~~Metabolic Disorder~~ 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 24 hours of age must be re-screened between 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 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 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 7-14 days of age.

~~(D)~~ **(E) Newborn Screening 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 ~~Metabolic Disorder~~ Screening Laboratory within 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 Metabolic Disorder 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 ~~metabolic disorder~~ 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.

~~(iv) The hospital is responsible for assuring that employees who collect, handle or perform newborn metabolic screening tests are informed of their responsibilities with respect to screening procedures.~~

(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 Collection Kit (ODH #450), as described in Appendix A of Chapter 550 of this Title, or faxed to the Oklahoma State Department of Health Newborn Screening Program.

~~(E)~~ (G) **Parent and health care provider education.** The hospital will be responsible or designate a responsible party to distribute the Newborn ~~Metabolic Disorder~~ Screening Program's written educational materials on newborn ~~metabolic disorder~~ screening and pulse oximetry screening provided by the Department to at least one of each newborn's parent or legal guardian.

~~(F)~~ (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 ~~Ssatisfactory Nnewborn Metabolic Disorder Sscreening Sspecimen-~~ 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.

(6) Birth defects. Each hospital shall maintain a list of patients up to six (6) years of age who have been diagnosed with birth defects, and all women discharged with a diagnosis of stillbirth or miscarriage. 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 postpartum.
 - (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.