

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 550. NEWBORN SCREENING PROGRAM**

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Subchapter 1. General Provisions

310:550-1-1. Purpose [AMENDED]

310:550-1-2. Definitions [AMENDED]

Subchapter 3. Testing of Newborns

310:550-3-1. Testing of newborns [AMENDED]

Subchapter 5. Blood Specimen Collection

310:550-5-1. ~~Specimen~~ Blood specimen collection [AMENDED]

310:550-5-2. ~~Technique~~ Guidelines for filter paper sample newborn screening blood specimen collection and pulse oximetry screening [AMENDED]

Subchapter 7. Hospital ~~Recording~~ Records

310:550-7-1. Hospital ~~recording~~ records [AMENDED]

Subchapter 11. Advisory Committee

310:550-11-1. Advisory committee [AMENDED]

Subchapter 13. Parent and Health Care Provider Education

310:550-13-1. Parent/Guardian and ~~Health~~ health Care care Provider provider education [AMENDED]

Subchapter 17. Follow-up for Physicians

310:550-17-1. Follow-up for physicians [AMENDED]

Subchapter 19. Reporting

310:550-19-1. Physician ~~Reporting~~ reporting and ~~Medical~~ medical Records records [AMENDED]

Subchapter 21. Information

310:550-21-1. Information [AMENDED]

Subchapter 23. Standards, Procedures, and Follow-Up for Certified Laboratories

310:550-23-1. Procedures [AMENDED]

SUMMARY:

310:550-1-1. The current rule sets forth the purpose of the rule chapter. The proposal simplifies language in an effort to align with the Governor's Executive Order. The proposal also removes one instance of the word "shall" that was non-substantive and does not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-1-2. The current Rule uses the term "mental and physical retardation" and "mental retardation". This terminology is outdated and may be considered disrespectful. This proposal replaces the aforementioned term with "Developmental Disabilities". Pursuant to 25 O.S. § 40 statutes and administrative rules should avoid language that equates persons with their condition and should replace nonrespectful language by referring to persons with disabilities as persons first. In order to promote consistency, it is necessary to amend all chapters that contain this terminology, even if those chapters do not equate persons with their condition. Further, national organizations such as the Americans with Disabilities Act National Network, American Association on Intellectual and Developmental Disabilities and Centers for Medicare and Medicaid encourage use of more respectful language that has gained wide acceptance in recent disability laws.

The proposal also simplifies and clarifies language, corrects minor grammatical errors, in an effort to align with the Governor's Executive Order 2020-03. The proposal also removes one instance of the word "shall" that was non-substantive and does not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-3-1. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. The proposal also removes two instances of the word "shall" that were non-substantive and do not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-5-1. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. In one instance the proposal changes the term "should" with "shall" to require that the birthing facility follow specimen collection guidelines for premature/sick newborns. The proposal also removes one instance of the word "shall" that was non-substantive and does not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-5-2. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. The proposal also removes two instances of the word "shall" that were non-substantive and do not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-7-1. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. The proposal also removes five instances of the word "shall" that were non-substantive and do not alter the intent or diminish responsibility or adherence to the full intent of the section. Language was also added to clarify that hospitals must keep a copy of each newborn screen kit collected on the infant in the infant's medical record, not just a copy of the initial screen.

310:550-11-1. In an effort to align with the Governor's Executive Order the proposal removes one instance of the word "shall" that was non-substantive and does not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-13-1. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. The proposal removes three instances of the word "shall" that were non-substantive and do not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-17-1. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. In one instance the proposal changes the term "should" with "shall" to require follow up physicians submit a newborn screen if one has not been previously submitted or results are unavailable. The proposal removes one instance of the word "shall" that was non-substantive and does not alter the intent or diminish responsibility or adherence to the full intent of the section.

310:550-19-1. In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document. The proposal removes three instances of the word "shall" that were non-substantive and do not alter the intent or diminish responsibility or adherence to the full intent of the section. Part (c) of this section was removed due to duplicity. Removing this portion does not alter or change the responsibilities or adherence to the full intent of the section.

310:550-21-1. The proposal ensures terms are used consistently, program contact information is corrected, adds the URL for the public health lab website, and updates the URL for the newborn screening website.

310:550-23-1 - In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language, corrects minor grammatical errors, as well as ensures terms are used consistently throughout the document.

This rule proposal was created in response to the Governor's executive order and reduces seven instances of the word "shall", simplifies and clarifies language, as well as fixes minor grammatical errors.

AUTHORITY:

Commissioner of Health, Title 63 O.S. § 1-104; Titles 25 O.S. § 40 and 63 O.S. Section 1-533(A).

COMMENT PERIOD:

November 16, 2020, through December 16, 2020, interested persons may informally discuss the proposed rules with the contact person identified below; or may, through December 16, 2020, 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 December 16, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. The alternate date and time in the event of extreme inclement weather is December 18, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, 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 December 16, 2020 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, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 550. NEWBORN SCREENING PROGRAM

1. **DESCRIPTION:**

The proposed rule changes:

- Thirty (30) instances of removing the term "shall" and utilizing other terms when needed. Terms utilized include "must", "will", "responsible", "responsibility", and "may". The reduction of the use of "shall" is in an effort to align with the Governor's Executive Order. Replacing or removing "shall" in these instances does not alter the intent or diminish responsibility or adherence to the full intent of the rules.
- Two instances of replacing the term "should" with "shall" in an effort to clarify responsibility and ensure adherence to the rules, where not adhering to the rules could have a negative outcome.
- Replacing the terms "Mental Retardation" and "Mental and Physical Retardation" with "Developmental Disabilities" as it is outdated and may be considered insensitive and disrespectful. Pursuant to 25 O.S. § 40, statutes and administrative rules should avoid language that equates persons with their condition and should replace non-respectful language by referring to persons with disabilities as persons first. In order to promote consistency, it is necessary to amend all chapters that contain this terminology, even if those chapters do not equate persons with their condition. Further, national organizations such as the Americans with Disabilities Act National Network, American Association on Intellectual and Developmental Disabilities and Centers for Medicare and Medicaid encourage use of more respectful language that has gained wide acceptance in recent disability laws.
- Multiple instances of simplifying and clarifying language, correcting minor grammatical errors, and ensuring terms are used consistently throughout the document. This was done in an effort to align with the Governor's Executive order.
- Duplicative language was removed in multiple instances. This was done in an effort to align with the Governor's Executive order.
- Language regarding sections of the Newborn Screening Refusal Form and Pulse Oximetry Screening Result Form was simplified by removing the names of individual fields that need to be completed to state "must be completed in its entirety". This was done in an effort to align with the Governor's Executive order.

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

- Stakeholders that are responsible for adhering to the rules need clear guidance in order to understand and follow the rules.
- Hospitals and physicians refer to the rules for guidance regarding newborn screening. It is important that the rules use respectful language when referring to individuals with these conditions. Adopting such language has the potential to affect numerous other individuals by encouraging its use by caregivers and the general public.
- There is no cost impact in regards to the proposed rule changes.

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

- The proposed changes will benefit the citizens of Oklahoma by increasing clarity and understanding of the rules, reducing regulatory burden where possible through decreasing duplicative language and reduction of the use of "shall".
- Persons benefiting from having removal of non-respectful language from the rules will benefit the children of Oklahoma who have these and other disabling conditions, their families, caregivers, and the public in general.

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

- There are no economic impacts or costs associated with the proposed changes.

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

- There are no costs associated with implementation.

6. **IMPACT ON POLITICAL SUBDIVISIONS:**

- There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

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

- There is no 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 are no less costly means currently identified.

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

- Public health and safety will not be impacted if the proposed policy change is not adopted.

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

- Public health and safety will not be impacted if the proposed policy change is not adopted.

11. **PREPARATION AND MODIFICATION DATES:**

- This rule impact statement was prepared on September 30, 2020.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 550. NEWBORN SCREENING PROGRAM**

SUBCHAPTER 1. GENERAL PROVISIONS

310:550-1-1. Purpose

Under 63 O.S., Sections 1-533 and 1-534 the following rules and regulations are established concerning the screening of all infants born in Oklahoma for the disorders of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), ~~infants shall be screened for~~ 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, and establishment of short-term follow-up services, and approval by the Commissioner of Health. This chapter also establishes ~~the following~~ rules and regulations concerning pulse oximetry screening of all infants born at a birthing ~~facility~~ facilities in Oklahoma for critical congenital heart disease (CCDH) ~~via pulse oximetry screening to be performed by the birthing facility pursuant to 63 O.S. Section 1-550.5.~~

310:550-1-2. Definitions

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

"Amino Acid Disorders" refers to a group of inherited metabolic conditions in which the body is unable to metabolize or process amino acids properly due to a defective enzyme function. This causes an amino acid or protein build up in the body. If not treated early in life, these defects can cause developmental disability or death. Each amino acid disorder is associated with a specific enzyme deficiency. Treatment depends on the specific amino acid disorder.

"Biotinidase Deficiency" means an inherited disease caused by the lack of an enzyme that recycles the B vitamin biotin, which if not treated, may cause serious complications, including coma and death.

"Birth Defects Registry" means a registry established by the Commissioner of Health to monitor and track birth defects for all infants born in Oklahoma.

"Birthing Facility" means a facility that provides care during labor and delivery, and to the newborn ~~infants~~. This includes a unit of a hospital that is licensed and accredited to provide birthing services, or a freestanding birthing center.

"Certified Laboratory" refers to the Oklahoma State Public Health Laboratory and/or a laboratory approved by the Oklahoma State Department of Health to conduct newborn screening.

"CCHD Screening" means the screening test for the detection of critical congenital heart disease that is recommended by the United States Department of Health and Human Services.

"CLIA '88" means the Clinical Laboratory Improvement Amendments of 1988, public law 100-578. This amendment applies to the Federal Law that governs laboratories ~~who~~ that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings.

"Confirmatory Testing" means definitive laboratory testing needed to confirm a diagnosis.

"Congenital Adrenal Hyperplasia" or "CAH" means the most common form of CAH, 21-hydroxylase deficiency. This genetic disorder is caused by the lack of an enzyme that the adrenal gland uses to process hormones. Serious loss of body salt and water can result in death. In girls the genitalia may appear as those of a male's male, and can result in incorrect sex assignment. Hormone treatment is required for life.

"Congenital Hypothyroidism" means a disease caused by a deficiency of thyroid hormone

(thyroxine) production, which if not treated, leads to ~~mental and physical retardation~~ developmental disabilities.

"Critical Congenital Heart Disease" means a congenital heart defect that places an infant at significant risk for disability or death if not diagnosed soon after birth.

"Cystic Fibrosis" means a multisystem genetic disorder in which defective chloride transport across mucous membranes causes dehydration of secretions. The result is a production of a thick, viscous ~~mucus~~ mucous that ~~elogs the lungs~~ disrupts the normal function of the lungs, gut, and pancreas. This leads to chronic lung infections, fatal lung disease, and ~~also interferes problems~~ with digestion. Early detection and treatment can prevent malnutrition, and enhance surveillance and treatment of lung infections.

"Days of Age" means the age of a newborn in 24-hour periods so that a newborn is one day of age 24 hours following the hour of birth for both blood spot screening and pulse oximetry screening.

"Department" refers to the Oklahoma State Department of Health.

"Discharge" means release of the newborn from care and custody of a perinatal licensed health facility to the parents or into the community.

"Disorder" means any condition detectable by newborn screening that allows opportunities, not available without screening, for early treatment and management to prevent developmental disability and/or reduce infant morbidity and mortality.

"Echocardiogram" means a test that uses ultrasound to provide an image of the heart.

"Fatty Acid Oxidation Disorders" refers to a group of inherited metabolic conditions in which the body is unable to oxidize (breakdown) fatty acids for energy due to a defective enzyme function. If not treated early in life, this defect may cause ~~mental retardation~~ developmental disability or death.

"Galactosemia" means an inherited disease caused by the body's failure to break down galactose due to a defective enzyme function, which if not treated early in life, may cause developmental disability or death.

"Hemoglobin" means a protein in the red blood cell that carries oxygen.

"Hemoglobinopathy" means an inherited ~~hemoglobin~~ disorder associated with structural abnormality of hemoglobin, anemia, and variable impaired ability of the red blood cells to carry oxygen.

"Infant" means a child 6 months of age and ~~under~~ younger.

"Infant's Physician" means the licensed medical or osteopathic physician listed by the submitter or the individual responsible for the medical care of the ~~newborn infant~~ after discharge from the birthing facility.

"Initial Specimen" means the first blood specimen collected subsequent to birth, pursuant to these procedures.

"Long-term Follow-up" means follow-up services that begin with diagnosis and treatment and continues throughout the lifespan. This includes parent education, networking, referral, and ~~ease~~ care coordination.

"Medical Home" means a Planned Health Care Provider.

"Medium-chain acyl coenzyme A dehydrogenase deficiency" or **"MCAD"** means a genetic disorder of fatty acid metabolism. This disorder can cause metabolic crisis when an infant/child fasts. This crisis can lead to seizures, failure to breathe, cardiac arrest, and death. Treatment is effective by preventing fasting.

"Mucopolysaccharidosis Type I" or **"MPS I"** means a condition in which individuals are missing an enzyme to break down large sugar molecules. This disorder can impact many different organs and tissue leading to developmental delays if not identified and treated early.

"Newborn" means an infant thirty (30) days of age and ~~under~~ younger.

"Newborn Screening" or **"newborn screening tests"** means the use of various laboratory and clinical tests to screening screen infants for the certain inherited disorders where a potential net benefit and availability of effective treatments have been demonstrated. ~~of phenylketonuria, congenital hypothyroidism, galactosemia, 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. Also includes critical congenital heart disease (CCHD) via pulse oximetry screening conducted by birthing facilities on all newborns born in the state of Oklahoma.

"Newborn Screening Form Kit" or "Form Kit" means ~~an a~~ filter paper approved by the Department for collection of the newborn screening specimen and associated demographic data.

"Newborn Screening Laboratory" means a laboratory operated by the Department or a laboratory certified by the Department to conduct the tests and carry out the follow-up required by these procedures.

"Newborn Screening Program" or "The Program" refers to the Public Health Laboratory and Short-term Follow-up Program at the Department.

"Newborn Screening Program Coordinator" refers to the coordinator of the Short-term Follow-up Program at the Department.

"Organic Acid Disorders" refers to a group of inherited metabolic conditions in which the body is unable to metabolize or process organic acids properly due to. ~~Each organic acid disorder is associated with a specific enzyme deficiency, which if not treated early in life, that causes the accumulation of organic acids in blood and urine. The accumulated compounds or their metabolites are toxic, resulting in the clinical features of these disorders including may cause developmental disability and death.~~

"Pediatric Sub-Specialist Subspecialist" means a physician licensed in Oklahoma, board certified in pediatrics and ~~board certified in a pediatric sub-specialty subspecialty~~ of pediatric endocrinology, pediatric pulmonology, or pediatric hematology; or a physician licensed in Oklahoma, board certified in pediatrics whose primary area of practice is pediatric endocrinology, pediatric hematology, pediatric pulmonology, or metabolic specialist.

"Phenylketonuria" or "PKU" means an inherited disease caused by the body's failure to convert the amino acid phenylalanine to tyrosine due to defective enzyme function, which if not treated early in life, causes developmental disability.

"Planned Health Care Provider" or "Medical Home" means the health care provider who will be providing health care for the infant after discharge from the hospital.

"Pompe" or "Pompe Disease" means a condition in which individuals are missing an enzyme to break down complex sugar molecules. This disorder can lead to muscle weakness, poor muscle tone and heart defects if not identified and treated early.

"Premature Infant Newborn" means ~~an a~~ an infant newborn weighing less than 2500 grams or any live birth before the thirty-seventh week of gestation.

"Pulse Oximetry Screening" means a test using a device placed on an extremity to measure the percentage of oxygen in the blood.

"Repeat Specimen" means an additional newborn screening specimen to be collected after the initial specimen.

"Satisfactory Specimen" means a blood specimen collected using a single ~~form-Form kit-Kit~~ Kit which that is suitable in both blood quantity and quality to perform newborn screening for phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell disease, 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 the disorders approved by the Commissioner of Health and listed in 310:550-1-1. All requested demographic information on the form kit must be completed. Federal CLIA '88 regulations require that the ~~form-Form kit-Kit~~ Kit ~~must include~~ includes the patient's name, date of birth, sex, date of collection, test(s) to be performed, and complete name and address of person requesting the test.

"Screened" means a specimen that has been collected and tested on an infant less than 6 months of age.

"Screening" means a test to sort out well persons who may have a disease or defect from those who may not. A screening test is not intended to be diagnostic.

"Severe Combined Immunodeficiency" means a group of potentially fatal inherited disorders related to the immune system, which if not treated, can lead to potentially deadly infections.

"Short-term Follow-up" includes services provided by the Department and the health care provider that ~~begins~~ begin when the laboratory reports an abnormal ~~or~~ unsatisfactory screen result, or a result is not reported due to specific collection criteria, and ends with a diagnosis of ~~normal~~ "normal", the infant is lost to follow-up (repeat testing not achieved), the parent(s) or guardian(s) refuse follow-up, or the affected infant receives with appropriate treatment and referral has been initiated to a pediatric subspecialist.

"Sick Infant-Newborn" means ~~an a~~ an infant newborn with any condition or episode marked by pronounced deviation from the normal healthy state; illness.

"Sickle Cell Disease" means an inherited disease caused by abnormal hemoglobin(s) (hemoglobinopathy), which may cause anemia and variable impaired ability of the red blood cells to carry oxygen, and if not treated early in life, may result in severe illness, developmental disability or death (one variation is commonly referred to as sickle cell anemia).

"Specimen" means blood collected on the ~~filter paper~~ Newborn Screening Form Kit.

"Spinal Muscular Atrophy" or "SMA" means conditions in which the loss of specialized nerves cells, ~~which control muscle movement~~ leads to progressive weakness and atrophy of muscles used for crawling, walking, sitting up and controlling head movement, and developmental disability. In severe cases, the muscles used for breathing and swallowing may be affected.

"Submitter" means a hospital, other facility, or physician submitting a blood specimen on a Newborn Screening specimen Form Kit.

"The Program" means the Newborn Screening Program in the Department.

"Transfer" means release of the newborn or infant from care and custody from one licensed health facility to another.

"Unsatisfactory Specimen" means a blood specimen which submitted on a Form Kit that is not collected on a form kit and/or is not suitable in blood quantity and/or quality to perform screening for phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell disease, 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 the disorders approved by the Commissioner of Health and listed in 310:550-1-1 and/or Federal CLIA '88 regulations are not followed and the form Form kit's Kit laboratory requisition does not include the required patient's name, date of birth, sex, date of collection, test(s) to be performed, and complete name and address of person requesting test the provider ordering the newborn screen.

"X-Linked Adrenoleukodystrophy" or "X-ALD" means a condition in which affecting the nervous system and adrenal glands are affected. Impact to the nervous system reduces in which the ability of the nerves to relay information to the brain and the adrenal glands to make certain hormones (adrenocortical insufficiency) are impacted. Impact to the adrenal glands may cause Affected individuals may experience learning and developmental disability, difficulty swallowing, muscle weakness, weight loss, skin changes, vomiting, and coma.

SUBCHAPTER 3. TESTING OF NEWBORNS

310:550-3-1. Testing of newborns

(a) A blood sample from All newborns in Oklahoma shall be tested by a Certified Newborn Screening Laboratory for ~~phenylketonuria, congenital hypothyroidism, galactosemia, 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; a parent or guardian may refuse screening of their newborn on the grounds that such examination conflicts with their religious tenets and/or practices the disorders approved by the Commissioner of Health and listed in 310:550-1-1.

(b) All newborns in Oklahoma shall be tested for CCHD by a pulse oximetry screening after twenty-four (24) hours of age or prior to discharge from the birthing facility.

(c) A parent or guardian ~~who may refuses~~ refuse the newborn screening blood test blood test screening, hearing screening, and/or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and/or practices; refusal of screening shall also be indicate indicated in writing this refusal utilizing the Newborn Screening Program Parent Refusal Form provided by the program Program.

(d) ~~The refusal form Newborn Screening Program Refusal Form shall include~~ must be completed in its entirety. the infant's name, date of birth, gender, demographic information, location of birth, name of the attending physician or provider, medical record number, indication of which screen is being refused (newborn blood test, newborn hearing screening, pulse oximetry screening), parent/guardian's printed name and signature as well as a witness' printed name, signature, and date. This signed refusal form shall will be placed in the newborn's medical record with a copy sent to the Newborn Screening Program Coordinator.

SUBCHAPTER 5. BLOOD SPECIMEN COLLECTION

310:550-5-1. Specimen Blood specimen collection

(a) ~~Specimen Blood specimen collection for hospital births.~~ For all live hospital births, the physician, or licensed or certified birth attendant shall order the collection of a newborn screening blood specimen prior to transfusion, as early as possible after 24 hours of age or immediately prior to discharge, whichever comes first. Due to the need to Since prompt identify identification of infants newborns at risk for the screened disorders quickly is extremely important, the specimen shall be collected as early as possible after 24 hours of age. Specimens shall be collected on a single Newborn Screening Form Kit using capillary or venous blood. ~~Cord blood is unacceptable~~ Umbilical cord blood is not recommended for use. The hospital is responsible for collecting specimens on all ~~infants newborns~~.

(1) If the initial specimen for any ~~infant newborn~~ is collected at or prior to 24 hours of age, the hospital and the physician are responsible for notifying the ~~infant's newborn's parents parent(s) or guardian(s)~~ verbally and in writing, utilizing the parent educational form on the Newborn Screening Form Kit, that a repeat specimen ~~is necessary at three to five days of age~~ must be submitted as soon as possible after 24 hours of age. The infant's physician is responsible for ensuring that the repeat specimen is collected.

(2) The hospital is responsible for submitting a ~~Satisfactory satisfactory Specimen specimen~~ and for documenting all requested information on the ~~form Form kit Kit~~ including the ~~parent parent's/guardian's name, address, and phone or contact alternate phone number, the provider ordering the newborn screen, 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.~~

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

(4) ~~Infants Newborns~~ who are 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 ~~infant's~~ physician and the receiving hospital to ensure the specimen is collected and submitted to the Program.

(5) It is the responsibility of the hospital and physician to ensure that all ~~infants newborns~~ are

screened prior to discharge. If ~~an~~ an infant-newborn is discharged prior to specimen collection, it is the responsibility of the hospital to notify the Newborn Screening Program Coordinator ~~shall be notified as soon as possible~~. The infant's physician is responsible for ensuring the specimen is collected as required.

(b) **Screening for premature/sick infants-newborns.** For all premature/sick ~~infants-newborns~~, the physician shall order the collection of a newborn screening blood specimen prior to ~~red blood cell~~ transfusion, as early as possible after twenty-four (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~~ Since prompt identification of infants-newborns at risk for the screened disorders quickly is extremely important, the specimen ~~should~~ shall 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. Umbilical cord blood is not recommended for use. The hospital and the physician are responsible for ensuring that specimens are collected on all premature/sick ~~infants-newborns~~.

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

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

(3) The recommended follow-up study for an abnormal thyroid screen in a premature ~~infant-newborn~~ is a serum free T4 (measured by direct dialysis or an equivalent method) and TSH-thyroid stimulating hormone (TSH) level at seven to fourteen (7-14) days of age.

(c) **Specimen collection for out-of-hospital births.**

(1) ~~All~~ For all infants-newborns who are not born in a hospital shall be tested as early as possible after twenty-four (24) hours of age. ~~The~~ the infant's physician, or licensed or certified birth attendant is responsible for submitting collection and submission of a Satisfactory satisfactory Newborn newborn Screening screening Specimen blood specimen as early as possible after twenty-four (24) hours of age. If there is not a physician, or licensed or certified birth attendant involved in a non-hospital birth, the person attending the birth and the parents of the ~~infant-newborn~~ are responsible for submitting collection and submission of a Satisfactory satisfactory Newborn newborn Screening screening Specimen specimen.

(2) If a physician examines a child in the first three months of life who was not born in a hospital, or was born out of state, the physician will verify that the child has been screened. If the child has not been screened or if results of screening are not available, the physician ~~should~~ is responsible for collecting and submit submitting a Satisfactory satisfactory Newborn newborn Screening screening Specimen blood specimen.

310:550-5-2. Technique Guidelines for filter paper sample newborn screening blood specimen collection and pulse oximetry screening

(a) **Filter paper sample Newborn screening blood specimen collection.**

(1) Specimens obtained with a Newborn Screening Form Kit should be collected in accordance with the standard for Blood Collection on Filter Paper for Newborn Screening Programs, NBS01-A6, Sixth Edition, as adopted and published by the Clinical and Laboratory Standards Institute on July 31, 2013, or most recent version. Failure to follow these methods of blood collection may cause inaccurate results, or unsatisfactory specimen results, and that require repeat ~~specimens collection~~.

(2) Submitters are responsible for submitting a Satisfactory satisfactory Newborn newborn Screening screening Specimen blood specimen.

(b) **Pulse oximetry screening.**

(1) **Pulse oximetry screening.** Pulse oximetry screening will be performed utilizing the hospital

protocol. A recommended protocol is provided by the ~~program~~ Program.

(2) **Authorized provider.** An authorized health care provider shall perform the pulse oximetry screening.

(3) **~~Newborn~~ Newborns Infants Receiving-receiving Routine routine Care-care.**

(A) The duties of the birthing facility or nurse shall include the following:

(i) Perform pulse oximetry screening on the newborn ~~Infant~~ between twenty-four (24) hours and forty-eight(48) hours of life; or

(ii) ~~If unable to perform the pulse oximetry screening, schedule~~ Schedule the infant newborn to be screened at the facility between twenty-four (24) hours and forty- eight (48) hours of life, if unable to perform the pulse oximetry screening; or

(iii) Notify the infant's physician if screening was not performed.

(B) If the newborn ~~infant~~ is scheduled for discharged discharge from a birthing facility after twelve (12) hours of life but before twenty-four (24) hours of life, the birthing facility shall perform pulse oximetry screening as late as is practical before the newborn ~~infant~~ is discharged ~~from the birthing facility~~ and shall notify the infant's physician of the early screening.

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

(4) **~~Newborn infants~~ Newborns in Special special Care-care or Intensive-intensive Care-care settings.**

~~Birthing~~ For newborns who have been in special care or intensive care units, birthing facilities shall perform pulse oximetry screening on infants prior to discharge utilizing the hospital protocol recommended by the program, unless the infant newborn has an identified congenital heart defect or has had an echocardiogram done performed. A recommended protocol is provided by the Program. Continuous pulse oximetry monitoring may not be substituted for CCHD screening.

(5) **Circumstances Where-in which Pulse-pulse Oximetry-oximetry Screening-screening is not Indicated-indicated.** ~~Document on NBS filter paper the pulse oximetry screening was not performed. If pulse oximetry screening is not performed, the reason shall be documented on the Newborn Screening Form Kit. There may be instances~~ Instances where pulse oximetry screening for CCHD is not indicated, including include but are not limited to instances where:

(A) ~~The~~ Clinical evaluation of the newborn infant's newborn clinical evaluation to date has included an echocardiogram which ruled-out ruled-out CCHD; or

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

SUBCHAPTER 7. HOSPITAL RECORDINGRECORDS

310:550-7-1. Hospital recording-records

(a) **Newborn Screening-screening blood test Results-results.**

(1) The hospital ~~shall implement~~ is responsible for implementing a procedure to ensure that a newborn screening blood specimen has been collected on every newborn and transported to the Newborn Screening Laboratory within twenty-four (24) to forty-eight (48) hours of collection. If more than one newborn screen is collected on an infant, each copy of the newborn screen kit should be placed in the infant's medical record. Specimens should be transported in the manner designated by the Department and/or receiving laboratory.

(2) The hospital shall immediately notify the infant's physician, ~~parents~~ parent(s) or guardians guardian(s), and Newborn Screening Program Coordinator if an infant is discharged without a sample having been collected. ~~This-These notification-notifications~~ shall be documented in the infant's hospital record.

(3) ~~If no~~ test results are not received by the hospital within fifteen (15) days after the date of collection, the hospital shall contact the Newborn Screening Laboratory to verify that a specimen ~~had been~~ was received. ~~If no-a specimen has been~~ was not received, the hospital shall notify the physician.

(4) Any hospital or any other laboratory ~~which that~~ collects, handles or forwards newborn screening

~~samples blood specimens~~ shall keep a log containing the name and date of birth of the infant, name of the attending ordering physician, name of the planned health care infant's provider who will be providing well care for the infant after discharge, medical record number, serial number of the Newborn Screening Form Kit used, date the of specimen was drawn collection, date the specimen was forwarded sent to the certified laboratory, date the that test results were transmitted or received and the test results.

~~(5) Specimens should be transported in the manner designated by the Department.~~

(b) ~~Pulse Oximetry oximetry Screening screening Results results.~~

(1) ~~Recordation Record of Results results.~~

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

(B) All pulse oximetry screening results shall be recorded on the Newborn Screening Form Kit, along with the following information:

~~(i) Newborn infant's:~~

~~(I) Name;~~

~~(II) Date of birth;~~

~~(III) Place of birth; and~~

~~(IV) Primary care physician after discharge; and~~

~~(ii) Mother's Name the infant's name, date of birth, submitting facility, mother's name, and the infant's physician.~~

(C) If the ~~infant newborn~~ is not screened for CCHD prior to the Newborn Screening Form Kit being forwarded to the ~~Public Health Newborn Screening Laboratory~~ for testing, ~~fax documentation of CCHD screen results shall be communicated to the Oklahoma State Department of Health (OSDH) Newborn Screening (NBS) Program Coordinator~~ utilizing the Pulse Oximetry Screening Result Form provided by the ~~program Program~~.

(D) The ~~pulse Pulse oximetry Oximetry Screening result Result form Form~~ shall include must be completed in its entirety, the infant's name, date of birth, mother's name, primary physician, birth hospital, medical record number, date of pulse oximetry screening, age at time of screening, pulse oximetry screening result, reason pulse oximetry screening was not performed (if applicable), printed screener's name and signature, and date the form was signed.

(2) ~~Abnormal Pulse pulse Oximetry oximetry Screen screen Results results.~~

(A) ~~Abnormal~~ It is the responsibility of the authorized health care provider who conducted the pulse oximetry screening to communicate abnormal results shall be reported by the authorized health care provider who conducted the screening to the attending physician or attending clinician immediately.

(B) ~~A~~ The newborn ~~infant~~ shall be evaluated immediately by an attending physician in order to complete the recommended protocol.

(C) ~~A~~ The newborn ~~infant~~ may not be discharged from care until:

~~(i) A cause for the abnormal pulse oximetry screen has been determined;~~

~~(ii) An echocardiogram has been performed, read, and determined not to indicate CCHD; and/or~~

~~(iii) A plan of care and follow-up has been established with the infant's newborn's parent parent(s) or guardian guardian(s).~~

(D) The birthing facility shall report pulse oximetry screening results to the Department as specified in this ~~regulation Chapter~~.

(E) ~~The~~ It is the responsibility of the birthing facility ~~shall to provide notification~~ notify the newborn's parent(s) or guardian(s), the physician or clinician following the newborn in the hospital, and the infant's physician of abnormal pulse oximetry results to the newborn infant's:

~~(i) Parent or guardian;~~

~~(ii) Physician or clinician following the inpatient infant; and~~

- (iii) ~~Primary care provider.~~
- (3) ~~Newborn Infants~~ **Newborns Not Screened for CCHD.**
- (A) If a newborn ~~infant~~ is not screened for CCHD secondary to discharge before 12 hours of life, the birthing facility shall:
- (i) Follow-up with the ~~family parent(s) or guardian(s)~~ to ~~schedule screen~~ schedule screening of the infant newborn at their the birthing facility between twenty-four (24) and forty-eight (48) hours of life; or
 - (ii) Follow-up with the ~~family parent(s) or guardian(s)~~ to ~~schedule refer~~ schedule referral of the newborn to an authorized facility for screening between twenty-four (24) and forty-eight (48) hours of life ~~after discharge from the facility~~; and
 - (iii) Report screening results to the Department utilizing the Pulse Oximetry Screening Result form ~~Form~~ provided by the ~~program~~ Program, and indicating the reason for not screening which ~~shall~~ may be "early discharge".
- (B) If the newborn ~~infant~~ pulse oximetry screening is not ~~screened for CCHD secondary to screening not being indicated for the newborn~~, the birthing facility shall report ~~results~~ the reason for not screening, which may be "screening not indicated due to," and provide other CCHD findings for the newborn to the Department utilizing the ~~form~~ Pulse Oximetry Screening Result Form provided by the ~~program~~ Program and ~~indicate the reason for not screening, which shall be "screening not indicated," with a notation for the reason pulse oximetry screening was not performed~~
- (C) If the newborn ~~infant~~ is not screened for CCHD ~~secondary to because of parent or guardian refusal~~, the birthing facility shall ~~fax send a refusal form~~ the Newborn Screening Program Refusal Form to the Department utilizing the form provided by the ~~program~~ Program and indicate the reason for not screening, which ~~shall~~ may be "parent refusal".

SUBCHAPTER 11. ADVISORY COMMITTEE

310:550-11-1. Advisory committee

The Infant and Children's Health Advisory Council ~~shall advise~~ advises the Department on newborn screening issues.

SUBCHAPTER 13. PARENT AND HEALTH CARE PROVIDER EDUCATION

310:550-13-1. Parent/Guardian and ~~Health~~ health Care ~~care~~ Provider provider education

- (a) The infant's physician or designee ~~shall have the is responsibility~~ responsible to for ensure ~~ensuring~~ that at least one ~~of each newborn's~~ parent or legal guardian of each newborn is notified about newborn screening and is provided information about the disorders and instructed how to obtain screen results from the planned health care provider or Newborn Screening Program.
- (b) The infant's physician or designee ~~shall have the responsibility to ensure~~ is responsible for ensuring that at least one ~~of each of the newborn's~~ parent or legal guardian of each newborn is notified and provided information about the pulse oximetry screening and is provided information about the pulse oximetry screening and instructed how to obtain screen results from the birthing facility or the planned health care provider.
- (c) The ~~hospital birthing facility~~ will be responsible or designate ~~designated~~ a responsible party is responsible to for distribute ~~distributing~~ 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 of each newborn.
- (d) ~~Hospitals~~ Birthing facilities shall provide ongoing training programs for their employees involved with newborn screening and pulse oximetry screening procedures. These training programs ~~shall include~~ methods of collecting a satisfactory newborn screening blood specimen and proper pulse oximetry screening method.

(e) ~~The hospital birthing facilities is~~ are responsible for ensuring that employees who collect, and/or handle ~~or perform~~ newborn screening tests blood specimens or perform pulse oximetry screening are informed of their responsibilities with respect to screening procedures.

SUBCHAPTER 17. FOLLOW-UP FOR PHYSICIANS

310:550-17-1. Follow-up for physicians

(a) If a physician examines a ~~child-infant~~ in the ~~it's~~ first three months of life, the physician will verify that the ~~child-infant~~ has been screened, and document results in the infant's medical record. If the ~~child-infant~~ has not been screened or if results of screening are not available, the physician ~~should~~ shall submit a ~~Satisfactory~~ satisfactory ~~Newborn-newborn~~ Screening-screening ~~Specimen~~ blood specimen ~~within 48 hours~~ or as soon as possible.

(b) On written notification by the Newborn Screening Program of follow-up requirements for a newborn screen result of abnormal, unsatisfactory, or for specimens collected from a newborn at or less than 24 hours of age ~~at time of collection~~; the infant's physician or designee will ~~obtain~~ ensure that required repeat screening, confirmatory testing, or diagnostic studies are performed; in the timeframe specified so that therapy, when indicated, can be initiated expediently.

(c) The infant's physician may selectively rescreen ~~the infants~~ infant as clinically indicated.

(d) Because patients may relocate without a forwarding address or contact information, ~~where these rules place responsibility upon~~ physicians and ~~hospitals birthing facilities to notify parents~~ the have the burden to make a reasonable search and effort to locate and notify the parent(s) or guardian(s), that shall require only a reasonable search be made. If the ~~parents~~ parent(s) or guardian(s) are not contacted, then the Newborn Screening Program Coordinator ~~shall~~ will be notified of the inability to notify after efforts to contact the ~~parents~~ the parent(s) or guardian(s) have been exhausted.

(e) For appropriate comprehensive medical care, all confirmed cases of ~~congenital hypothyroidism, galactosemia, phenylketonuria, sickle cell disease, 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 a disorder on the newborn screening blood testing panel, should have a referral to a pediatric sub-specialist subspecialist, and the parents parent(s) or guardian(s) should be referred for enrollment in newborn screening long-term follow-up services as designated by the Newborn Screening Program. For referral information, ~~please~~ contact the Newborn Screening Short-term Follow-up Program at (405) 271-6617 or 1-800-766-2223-ext. 6617.

SUBCHAPTER 19. REPORTING

310:550-19-1. Physician ~~Reporting~~ reporting and ~~Medical~~ medical ~~Records~~ records

(a) If confirmatory or follow-up testing is not performed by the Newborn Screening Laboratory or ~~through~~ by a contract laboratory designated by the Newborn Screening Program, the infant's physician ~~must~~ is responsible for ~~report~~ reporting the results of confirmatory follow-up testing to the Newborn Screening Program Coordinator ~~the results~~ within seven (7) days after the completion of the medical evaluation, using the Department's Newborn Screening Report Form provided by the program of the infant.

(b) ~~The report form~~ Final diagnosis will be conveyed using the Department's Newborn Screening Report Form, provided by the Program, and shall ~~which include~~ includes infant's name, date of birth, newborn screening laboratory number, mother's name, final diagnosis, notation of initiation of treatment and start date, notation of referral to pediatric ~~sub-specialist~~ subspecialist, notation if family was referred to other services, printed name and signature of physician determining diagnosis, telephone number and date form

is completed. A copy of the confirmatory test results must accompany the report form.

~~(c)~~ For all diagnosed cases of phenylketonuria, congenital hypothyroidism, galactosemia, 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, the infant's physician shall report treatment date if applicable, and referral information to the Newborn Screening Program Coordinator by completing the Department's Newborn Screening Report Form provided by the program.

~~(d)~~(c) These newborn screening reports shall be are confidential and may be utilized only for the purpose of ensuring service delivery, program administration, data analysis, and evaluation.

~~(e)~~(d) On request, a birthing facility or health care provider shall make available to the NBS Newborn Screening Program or Oklahoma Birth Defects Registry:

- (1) Medical records;
- (2) Records of laboratory test; and
- (3) Any other medical information considered necessary to:
 - (A) Determine final outcomes of abnormal CCHD screening results; and
 - (B) Evaluate CCHD screening activities in the State; including:
 - (i) Performance of follow-up evaluations and diagnostic tests;
 - (ii) Initiation of treatment when necessary; and
 - (iii) Surveillance of the accuracy and efficacy of the screening.

~~(f)~~(e) Information that the Department receives under this chapter is confidential and may only be used or disclosed:

- (1) To provide services to the newborn infant and the infant's family;
- (2) To study the relationships of the various factors determining the frequency and distribution of CCHD;
- (3) For State or federally mandated statistical reports; and
- (4) To ensure that the information received by the Department is accurate and reliable.

SUBCHAPTER 21. INFORMATION

310:550-21-1. Information

(a) For information regarding laboratory procedures, ~~or~~ results of laboratory tests, or to order ~~form~~ Form kit-s Kits, contact the Public Health Laboratory Service, Oklahoma State Department of Health, P.O. Box 24106, Oklahoma City, Oklahoma 73124-0106, (405) 271-5070, FAX (405) 271-4850 or visit the website at <http://phl.health.ok.gov>.

(b) For general information or information regarding follow-up for newborn screening or pulse oximetry screening, contact Newborn Screening Short-term Follow-up 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~~. General information about the Newborn Screening Program is available on the OSDH Newborn Screening Web site website at www.health.ok.gov <http://nsp.health.ok.gov>.

SUBCHAPTER 23. STANDARDS, PROCEDURES, AND FOLLOW-UP FOR CERTIFIED LABORATORIES

310:550-23-1. Procedures

(a) The Commissioner of Health shall establish procedures for newborn screening laboratories ~~which that shall~~ include laboratory methodology, proficiency testing, quality assurance, sample collection, reporting, follow-up, handling, use, retention, storage and disposition of form kits.

(b) The Commissioner of Health shall establish procedures for the Department's newborn screening

short-term follow-up program ~~which that shall~~ include quality assurance, notification of providers and ~~parents-parent(s) or guardian(s)~~, follow-up guidelines, and ~~parents-parent or guardian~~ and provider education.

(c) ~~Hospitals~~ Birthing facilities, physicians, and laboratories shall comply with procedures for the Newborn Screening Program established by the Commissioner of Health.

(d) Any laboratory performing newborn screening tests shall be certified by the Department as a Newborn Screening Laboratory. In order to be certified as a Newborn Screening Laboratory, a laboratory shall maintain technical proficiency and ensure that test reagents and equipment are properly standardized.

(e) ~~A Certified Laboratory refers to the Oklahoma State Public Health Laboratory or a laboratory approved by the Oklahoma State Department of Health to conduct newborn screening tests.~~ A laboratory desiring certification as a Newborn Screening Laboratory shall make written application to the Public Health Laboratory Service of the Department. A certified laboratory shall meet the following minimum standards:

(1) **Eligibility for approval.** A laboratory in Oklahoma that meets the requirements of Section 353 of the Public Health Service Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Public Law 100-578. The Laboratory must have a CLIA certificate for tests of High Complexity and meet the criteria for those tests as specified in CLIA '88 and amendments. The ~~lab-laboratory~~ must have the capacity to provide testing for the mandated newborn screening panel on a single satisfactory ~~filter paper specimen~~ Newborn Screening Form Kit submitted by the ~~birth~~ birthing hospital facility or provider.

(2) **Minimum tests.** A laboratory shall ~~perform a sufficient number of tests each week~~ test, a minimum of 300 blood ~~samples-specimens~~ from different Oklahoma infants ~~a week~~ for each disorder each week, to maintain technical proficiency and ensure that test reagents and equipment are properly standardized.

(3) **Record keeping.**

(A) The laboratory shall log ~~in~~ each ~~sample-specimen~~ received ~~with an~~ using at least two unique identifier-identifiers. All patient information and test results ~~shall be~~ are linked to the identifier and maintained as a permanent record for a period of at least twenty-one (21) years.

(B) The laboratory shall maintain quality control, ~~and~~ proficiency test records, ~~and shall~~ which will be available for inspection by the Department.

(C) If the laboratory should close, records must be maintained for the same time period. Records may be given to the Department for maintenance.

(4) **Standard laboratory screening assay methods.** All assay methods must be approved by the Commissioner of Health.

(5) **Follow-up for certified laboratories.**

(A) Within fifteen (15) days after specimen collection, the Certified Laboratory shall send a written report of the test results with repeat testing requirements, if indicated, to the submitter and physician listed on the ~~filter paper requisition~~ Newborn Screening Form Kit.

(B) The Certified Laboratory will reject any unsatisfactory samples-specimens for testing.

(C) The Certified Laboratory must maintain a secure database with the capacity to report abnormal test results to the Department's Newborn Screening Program Coordinator or designee.

(D) The Certified Laboratory must report abnormal test results that are possible disease conditions within eight (8) to twenty-four (24) hours to the Department's Newborn Screening Program Coordinator or designee.

(6) **Activity Reporting reports.** Certified Laboratories shall compile quarterly and annual reports of total screening tests, abnormal tests by disorder, unsatisfactory tests, and for specimens collected from newborns at or less than twenty-four (24) hours of age at time of collection test for submission to the Newborn Screening Program.

(7) **Certification of laboratories.**

(A) A Certificate of Approval will be issued upon satisfying the requirements of these standards

and demonstrating proficiency in the presence of an authorized representative from the Department. This Certificate of Approval will specify:

- (i) Name of laboratory
- (ii) Test of certification must be approved for all mandated tests.
- (iii) Date of issue and expiration: certificate issued for one (1) year and renewable annually.

(8) Revocation of certification.

(A) The laboratory shall be in compliance with all applicable Federal ~~or~~ and State Laws, ~~or~~ and regulations. The compliance with the requirements ~~thereof shall be~~ is the responsibility of the laboratory, without reliance on or direction by the Oklahoma State Department of Health.

Following notice by the Department of its intent to revoke the laboratory's certification and completion of an individual proceeding pursuant to Article II of the Oklahoma Administrative Procedures Act (APA), the certification of a laboratory may be revoked, based upon proof by a preponderance of the evidence for any of the following reasons:

- (i) Failure to meet any requirements in these regulations; or
- (ii) Failure to use a standard laboratory assay approved by the Commissioner of Health; or
- (iii) Failure to participate in a recognized proficiency program and/or maintain proficiency; or
- (iv) Failure to keep adequate records of test results and quality control; or
- (v) Failure to give prompt notice of changes in personnel performing the tests or supervising testing.

(B) Upon notice of revocation the laboratory shall cease to perform newborn screening and return their certificate of approval.

(C) Reinstatement of laboratory certification ~~shall be~~ is contingent upon the following:

- (i) A laboratory ~~shall not~~ cannot apply for reinstatement until a minimum of three months has elapsed from date of revocation; and
- (ii) All factors ~~which~~ that lead to revocation of certification can be identified ~~must be~~ are corrected; and
- (iii) A laboratory applying for reinstatement must meet the same requirements as for initial application.

(D) Revocation of certified laboratory status by ~~OSDH~~ the Department may be appealed pursuant to Article II of the Oklahoma APA.