CHAPTER 550. NEWBORN SCREENING AND RESOURCES FOR TRISOMY 13, 18, AND 21

[**Authority:**63 O.S., §§ 1-103a, 1-104, and 1-533 et seq.]
[**Source:**Codified 12-31-91]

SUBCHAPTER 1. NEWBORN SCREENING 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), 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), mucopolysaccharidoisis 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 rules and regulations concerning pulse oximetry screening of all infants born at birthing facilities in Oklahoma for critical congenital heart disease (CCDH) to be performed by the birthing facility pursuant to 63 O.S. Section 1-550.5.

[**Source:** Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 25 Ok Reg 1151, eff 5-25-08; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21]

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. 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 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, 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 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 mucous that disrupts the normal function of the lungs, gut, and pancreas. This leads to chronic lung infections, fatal lung disease, and 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 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 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 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 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 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 younger.

"Newborn Screening" means the use of various laboratory and clinical tests to screen infants for certain inherited disorders where a potential net benefit and availability of effective treatments have been demonstrated.

"Newborn Screening Form Kit" or **"Form Kit"** means 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 a specific enzyme deficiency, which if not treated early in life, may cause developmental disability and death.

"Pediatric Subspecialist" means a physician licensed in Oklahoma, board certified in pediatrics and a pediatric subspecialty.

"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 Newborn" means a 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 Kit that is suitable in both quantity and quality to perform newborn screening for the disorders approved by the Commissioner of Health and listed in 310:550-1-1. Federal CLIA '88 regulations require that the Form Kit 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 begin when the laboratory reports an abnormal , unsatisfactory screen result, or a result is not reported due to specific collection criteria, and ends with a diagnosis of "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 appropriate treatment and referral to a pediatric subspecialist.

"Sick Newborn" means a 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.

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

"Spinal Muscular Atrophy" or **"SMA"** means conditions in which the loss of specialized nerves cells leads to progressive weakness and atrophy of muscles, 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 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 submitted on a Form Kit that is not suitable in quantity or quality to perform screening for 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 Kit does not

include the required patient's name, date of birth, sex, date of collection, test(s) to be performed, and the provider ordering the newborn screen.

"X-Linked Adrenoleukodystrophy" or **"X-ALD"** means a condition affecting the nervous system and adrenal glands 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. Affected individuals may experience learning and developmental disability, difficulty swallowing, muscle weakness, weight loss, skin changes, vomiting, and coma.

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21; Amended at 40 Ok Reg 1570, eff 9-11-23]

SUBCHAPTER 3. TESTING OF NEWBORNS

310:550-3-1. Testing of newborns

(a) A blood sample fromall newborns in Oklahoma shall be tested by a Certified Newborn Screening Laboratory for 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 may refuse the 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 beindicated in writing utilizing the Newborn Screening Program Refusal Form provided by the Program.
(d) The Newborn Screening Program Refusal Formmust be completed in its entirety. This signed refusal form will be placed in the newborn's medical record with a copy sent to the Newborn Screening Program Coordinator.

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21]

SUBCHAPTER 5. NEWBORN SCREENING BLOOD SPECIMEN COLLECTION

310:550-5-1. Blood specimen collection

(a) **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. Since prompt identification of newborns at risk for screened disorders 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. Umbilical cord blood is not recommended for use. The hospital is responsible for collecting specimens on all newborns.

(1) If the initial specimen for any newborn is collected at or prior to 24 hours of age, the hospital and the physician are responsible for notifying the newborn's parent(s) or guardian(s) verbally and in writing, utilizing the parent educational form on the Newborn Screening Form Kit, that a repeat specimen 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 specimen and for documenting all requested information on the Form Kit including the parent's/guardian's name, address, and phone or alternate phone number, the provider ordering the newborn screen, and the infant's physician.
(3) The hospital is responsible for documenting specimen collection and results in the infant's hospital record.

(4) Newborns who are transferred from one hospital to another 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 newborns are screened prior to discharge. If anewborn is discharged prior to specimen collection, it is the responsibility of the hospital to notify the Newborn Screening Program Coordinator as soon as possible. The infant's physician is responsible for ensuring the specimen is collected as required.

(b) **Screening for premature/sick newborns.** For all premature/sick newborns, the physician shall order the collection of a newborn screening blood specimen prior to 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. Since prompt identification ofnewborns at risk for screened disorders is extremely important, the specimen 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 newborns.

(1) Premature/sick 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 newborns who could not be screened prior to a transfusion should be screened by the seventh (7th) day of life, with a repeat specimen collected whena blood specimen will again reflect the 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 newborn is a serum free T4 (measured by direct dialysis or an equivalent method) and thyroid stimulating hormone (TSH) level at seven to fourteen (7-14) days of age.

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

(1) For all newborns who are not born in a hospital, the infant's physician, or licensed or certified birth attendant is responsible for collection and submission of a satisfactory newborn screening 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 newborn are responsible for collection and submission of a satisfactory newborn screening 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 is responsible for collecting and submitting a satisfactory newborn screening blood specimen.

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 22 Ok Reg 392, eff 12-21-04 (emergency); Amended at 22 Ok Reg 794, eff 5-12-05; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21]

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

(a) **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 ,that require repeat collection.

(2) Submitters are responsible for submitting a satisfactory newborn screening 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.

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

(3) **Newborns receiving routine care.**

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

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

(ii) Schedule the 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 is scheduled for 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 is discharged and notify the infant's physician of the early screening.

(C) If the 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) **Newborns in special care or intensive care settings.** For newborns who have been in special care or intensive care units, birthing facilities shall perform pulse oximetry screening prior to discharge utilizing the hospital protocol, unless the newborn has an identified congenital heart defect or has had an echocardiogram performed. A recommended protocol is provided by the Program. Continuous pulse oximetry monitoring may not be substituted for CCHD screening.

(5) **Circumstances in which pulse oximetry screening is not indicated.** If pulse oximetry screening is not performed, the reason shall be documented on the Newborn Screening Form Kit. Instances where pulse oximetry screening is not indicated include but are not limited to:

(A) Clinical evaluation of the newborn has included an echocardiogram which ruled-out CCHD; or

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

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 12 Ok Reg 41, eff 10-5-94; Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21; Amended at 40 Ok Reg 1570, eff 9-11-23]

SUBCHAPTER 7. NEWBORN SCREENING HOSPITAL RECORDS

310:550-7-1. Hospital records

(a) **Newborn screening blood test results.**

(1) The hospital 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, parent(s) or guardian(s), and Newborn Screening Program Coordinator if an infant is discharged without a sample having been collected. These notifications shall be documented in the infant's hospital record.

(3) If 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 was received. If a specimen was not received, the hospital shall notify the physician.

(4) Any hospital or any other laboratory that collects, handles or forwards newborn screening blood specimens shall keep a log containing the name and date of birth of the infant, name of the ordering physician, name of infant's provider, medical record number, serial number of the Newborn Screening Form Kit, date of specimen collection, date specimen was sent to the certified laboratory, date that test results were transmitted or received and the test results.

(b) **Pulse oximetry screening results.**

(1) **Record of results.**

(A) All pulse oximetry screening results shall be recorded in the infant's medical record and the results reported to a parent(s) or 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 infant's name, date of birth, submitting facility, mother's name, and the infant's physician.

(C) If the newborn is not screened for CCHD prior to the Newborn Screening Form Kit being forwarded to the Newborn Screening Laboratory for testing, CCHD screen results shall be communicated to the Newborn Screening Program Coordinator utilizing the Pulse Oximetry Screening Result Form provided by the Program.

(D) The Pulse Oximetry Screening Result Form must be completed in its entirety.

(2) **Abnormal pulse oximetry screen results.**

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

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

(C) The newborn 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 newborn's parent(s) or guardian(s).

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

(E) It is the responsibility of the birthing facility to 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.

(3) **Newborns not screened for CCHD.**

(A) If a newborn is not screened for CCHD secondary to discharge before 12 hours of life, the birthing facility shall:

(i) Follow-up with the parent(s) or guardian(s) to schedule screening of the newborn at the birthing facility between twenty-four (24) and forty-eight (48) hours of life; or

(ii) Follow-up with the parent(s) or guardian(s) to schedule referral of the newborn to an authorized facility for screening between twenty-four (24) and forty-eight (48) hours of life; and

(iii) Report screening results to the Department utilizing the Pulse Oximetry Screening Result Form provided by the Program, and indicating the reason for not screening which may be "early discharge".

(B) If pulse oximetry screening is not indicated for the newborn, the birthing facility shall report 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 Pulse Oximetry Screening Result Form provided by the Program.

(C) If the newborn is not screened for CCHD because of parent or guardian refusal, the birthing facility shall send the Newborn Screening Program Refusal Form to the Department utilizing the form provided by the Program and indicate the reason for not screening, which may be "parent refusal".

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 22 Ok Reg 392, eff 12-21-04 (emergency); Amended at 22 Ok Reg 794, eff 5-12-05; Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21; Amended at 40 Ok Reg 1570, eff 9-11-23]

SUBCHAPTER 9. STANDARD FOR CERTIFIED LABORATORIES [REVOKED]

310:550-9-1. Standard for certified laboratories [REVOKED]

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Revoked at 21 Ok Reg 1286, eff 5-27-04]

SUBCHAPTER 11. ADVISORY COMMITTEE FOR NEWBORN SCREENING

310:550-11-1. Advisory committee

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

[**Source:** Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21]

SUBCHAPTER 13. NEWBORN SCREENING PARENT AND HEALTH CARE PROVIDER EDUCATION

310:550-13-1. Parent/Guardian and health care provider education

(a) The infant's physician or designee is responsible for ensuring that at least one 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 is responsible for ensuring that at least one parent or legal guardian of each newborn is notified and provided information about pulse oximetry screening and instructed how to obtain screen results from the birthing facility or the planned health care provider.
(c) The birthing facility or designated party is responsible for distributing the Newborn Screening Program's written educational materials on newborn screening and pulse oximetry screening provided by the Department to at least one parent or legal guardian of each newborn.
(d) Birthing facilities shall provide ongoing training programs for their employees involved with newborn screening and pulse oximetry screening procedures. These training programs include methods of collecting a satisfactory newborn screening blood specimen and proper pulse oximetry screening method.
(e) Birthing facilities are responsible for ensuring that employees who collect, and/or handle newborn screening blood specimens or perform pulse oximetry screening are informed of their responsibilities with respect to screening procedures.

[**Source:** Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 38 Ok Reg 2040, eff 9-11-21]

SUBCHAPTER 15. FOLLOW-UP FOR CERTIFIED LABORATORIES [REVOKED]

310:550-15-1. Follow-up for certified laboratories [REVOKED]

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 9 Ok Reg 3121, eff 7-1-92 (emergency); Amended at 10 Ok Reg 1637, eff 6-1-93; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95 (emergency); Revoked at 21 Ok Reg 1286, eff 5-27-04]

SUBCHAPTER 17. NEWBORN SCREENING FOLLOW-UP FOR PHYSICIANS

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

(a) If a physician examines an infant in its first three months of life, the physician will verify that the infant has been screened, and document results in the infant's medical record. If the infant has not been screened

or if results of screening are not available, the physician shall submit a satisfactory newborn screening blood specimen 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; the infant's physician or designee will 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 infant as clinically indicated.
(d) Because patients may relocate without a forwarding address or contact information, physicians and birthing facilities have the burden to make a reasonable search and effort to locate and notify the parent(s) or guardian(s). If the parent(s) or guardian(s) are not contacted, then the Newborn Screening Program Coordinator will be notified of the inability to notify after efforts to contact the parent(s) or guardian(s) have been exhausted.
(e) For appropriate comprehensive medical care, all confirmed cases of a disorder on the newborn screening blood testing panel, should have a referral to a pediatric subspecialist, and the 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, contact the Newborn Screening Short-term Follow-up Program at (405) 426-8310 or 1-800-766-2223.

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 9 Ok Reg 3121, eff 7-1-92 (emergency); Amended at 10 Ok Reg 1637, eff 6-1-93; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21; Amended at 40 Ok Reg 1570, eff 9-11-23]

SUBCHAPTER 19. NEWBORN SCREENING REPORTING

310:550-19-1. Physician reporting and medicalrecords

(a) If confirmatory or follow-up testing is not performed by the Newborn Screening Laboratory or by a contract laboratory designated by the Newborn Screening Program, the infant's physician is responsible for reporting the results of confirmatory follow-up testing to the Newborn Screening Program Coordinator within seven (7) days after the completion of the medical evaluationof the infant.
(b) Final diagnosis will be conveyed using the Department's Newborn Screening Report Form, provided by the Program,whichincludes 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 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) These newborn screening reports are confidential and may be utilized only for the purpose of ensuring service delivery, Program administration, data analysis, and evaluation.
(d) On request, a birthing facility or health care provider shall make available to the 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.

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

(1) To provide services to the 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.

[**Source:** Amended at 8 Ok Reg 3115, eff 7-12-91 (emergency); Amended at 9 Ok Reg 1475, eff 5-1-92; Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21]

SUBCHAPTER 21. NEWBORN SCREENING INFORMATION

310:550-21-1. Information

(a) For information regarding laboratory procedures, results of laboratory tests, or to order Form Kits, contact the Public Health Laboratory Service, Oklahoma State Department of Health, 4615 W Lakeview Dr, Stillwater, OK 74075, (405) 564-7750, FAX (405) 900-7611 or visit the website at https://oklahoma.gov/health/locations/public-health-laboratory.html.
(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, 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma 73102, (405)-426-8310, or 1-800-766-2223, option 2, FAX (405) 900-7556. General information about the Newborn Screening Program is available on the OSDH Newborn Screening website at https://Oklahoma.gov/health/newbornscreening.

[**Source:** Amended at 12 Ok Reg 41, eff 10-5-94 (emergency); Amended at 12 Ok Reg 1685, eff 6-12-95; Amended at 15 Ok Reg 121, eff 10-15-97 (emergency); Amended at 15 Ok Reg 1979, eff 5-26-98; Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 22 Ok Reg 794, eff 5-12-05; Amended at 25 Ok Reg 105, eff 10-2-07 (emergency); Amended at 25 Ok Reg 1153, eff 5-25-08; Amended at 31 Ok Reg 1596, eff 9-12-14; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21; Amended at 40 Ok Reg 1570, eff 9-11-23]

SUBCHAPTER 23. NEWBORN SCREENING 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 that 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 that include quality assurance, notification of providers and parent(s) or guardian(s), follow-up guidelines, and parent or guardian and provider education.
(c) 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 laboratory desiring certification as a Newborn Screening Laboratory shall make written application to the Public Health Laboratory 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 laboratory must have the capacity to provide testing for the mandated newborn screening panel on a single satisfactory Newborn Screening Form Kit submitted by the birthing facility or provider.
(2) **Minimum tests.** A laboratory shall test, a minimum of 300 blood specimens from different Oklahoma infants 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 each specimen received using at least two unique identifiers. All patient information and test results 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,proficiency test records, and 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 Newborn Screening Form Kit.

(B) The Certified Laboratory will reject any unsatisfactory 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 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 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 and State Laws, and regulations. The compliance with the requirements 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 is contingent upon the following:

(i) A laboratory cannot apply for reinstatement until a minimum of three months has elapsed from date of revocation; and

(ii) All factors that lead to revocation of certification 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 the Department may be appealed pursuant to Article II of the Oklahoma APA.

[**Source:** Amended at 21 Ok Reg 1286, eff 5-27-04; Amended at 22 Ok Reg 794, eff 5-12-05; Amended at 36 Ok Reg 1688, eff 9-13-19; Amended at 38 Ok Reg 2040, eff 9-11-21]

SUBCHAPTER 24. RESOURCES FOR TRISOMY 13, 18, AND 21

310:550-24-1. Resources for Trisomy 13, 18, and 21 Purpose

The rules in this Subchapter implement Courtney's Law, as codified in 63 O.S. § 1-575.

[**Source:** Added at 40 Ok Reg 1570, eff 9-11-23]

310:550-24-2. Resources for Trisomy 13, 18, and 21 Definitions

The following words or terms, used in this Chapter, shall have the following meaning unless the context of the sentence requires another meaning:

"Chromosomal disorder" means:

(A) Trisomy 13, otherwise known as Patau syndrome;

(B) Trisomy 18, otherwise known as Edwards syndrome; or

(C) Trisomy 21, otherwise known as Down syndrome.

"Department" means the Oklahoma State Department of Health.

"Genetic counselor" means any person who is licensed pursuant to the provisions of the Genetic Counseling Licensure Act or offers to or engages in genetic counseling. The term does not include those professions exempted by Section 1-566 of the Act.

"Health care facility" means a facility licensed or certified by the State Department of Health, but shall not include a nursing care facility, assisted living facility or home care agency.

"Health care provider" means a person who is licensed, certified or registered by this state to provide health care services or a medical group, independent practice association or professional corporation providing health care services.

[**Source:** Added at 40 Ok Reg 1570, eff 9-11-23]

310:550-24-3. Resources for Trisomy 13, 18, and 21 Duty to provide information

Any health care facility, health care provider, or genetic counselor, upon receipt of a positive test result from a test for a chromosomal disorder, shall provide the expectant or new parent with information provided by the Department if such information is made available by the Department for the specific disorder.

[**Source:** Added at 40 Ok Reg 1570, eff 9-11-23]

310:550-24-4. Resources for Trisomy 13, 18, and 21 Availability of information from the Department

To the extent the information is available, the Department shall maintain on its website:

(1) Up-to-date, evidence-based written information about chromosomal disorders that has been reviewed by medical experts and national advocacy organizations for people with intellectual and other developmental disorders. The written information will be compiled from credible sources and will include physical, developmental, educational and psychosocial outcomes, life expectancy, clinical course, and intellectual and functional development and treatment options; and

(2) Contact information for programs and support services including one or more hotlines specific to a chromosomal disorder, resource centers or clearinghouses, national and local organizations, and other education and support programs.

[**Source:** Added at 40 Ok Reg 1570, eff 9-11-23]

APPENDIX A. Instructions for Filter Paper Sample Collection [REVOKED]

[**Source:** Revoked and reenacted at 13 Ok Reg 345, eff 12-11-95; Revoked and reenacted at 15 Ok Reg 121, eff 10-15-97 (emergency); Revoked and reenacted at 15 Ok Reg 1979, eff 5-26-98; Revoked and reenacted at 21 Ok Reg 1286, eff 5-27-04; Revoked and reenacted at 22 Ok Reg 392, eff 12-21-04 (emergency); Revoked and reenacted at 22 Ok Reg 749, eff 5-12-05; Revoked and reenacted at 31 Ok Reg 1596, eff 9-12-14; Revoked at 36 Ok Reg 1688, eff 9-13-19]

APPENDIX B. Report Form [REVOKED]

[**Source:** Revoked and reenacted at 12 Ok Reg 345, eff 12-11-95; Revoked and reenacted at 15 Ok Reg 121, eff 10-15-97 (emergency); Revoked and reenacted at 15 Ok Reg 1979, eff 5-26-98; Revoked and reenacted at 21 Ok Reg 1286, eff 5-27-04; Revoked and reenacted at 25 Ok Reg 105, eff 10-2-07 (emergency); Revoked and reenacted at 25 Ok Reg 1153, eff 5-25-08; Revoked and reenacted at 31 Ok Reg 1596, eff 9-12-14; Revoked at 36 Ok Reg 1688, eff 9-13-19]

APPENDIX C. Refusal Form [REVOKED]

[**Source:** Added at 21 Ok Reg 1286, eff 5-27-04; Revoked and reenacted at 25 Ok Reg 105, eff 10-2-07 (emergency); Revoked and reenacted at 25 Ok Reg 1153, eff 5-25-08; Revoked and reenacted at 31 Ok Reg 1596, eff 9-12-14; Revoked at 36 Ok Reg 1688, eff 9-13-19]

APPENDIX D. Recommended Pulse Oximetry Screening Protocol [REVOKED]

[**Source:** Added at 31 Ok Reg 1596, eff 9-12-14; Revoked at 36 Ok Reg 1688, eff 9-13-19]

APPENDIX E. Pulse Oximetry Screening Result Form [REVOKED]

[**Source:** Added at 31 Ok Reg 1596, eff 9-12-14; Revoked at 36 Ok Reg 1688, eff 9-13-19]