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

1. **Date the Notice of Intended Rulemaking was published in the Oklahoma Register:**
   October 1, 2013, Vol. 31, No. 2 Ok Reg 9, Docket No. 13-1191

2. **Name and address of the Agency:**
   Oklahoma State Department of Health
   1000 N.E. Tenth Street
   Oklahoma City, Oklahoma 73117-1299

3. **Title and Number of the Rule:**
   Title 310. Oklahoma State Department of Health
   Chapter 550. Newborn Screening Program

4. **Citation to the Statutory Authority for the Rule:**
   Title 63 O.S. Section 1-104; and Title 59 O.S. Sections 1-534, 1-550.5, and 1-705

5. **Brief Summary of the Content of the Adopted Rule:**
   The proposed rule changes add amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010) - and after consultation with the Newborn Screening Subcommittee of the Oklahoma Genetics Advisory Committee. This proposal also adds pulse oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) to existing newborn screening rules as legislated by House Bill 1347 (2013) [63 O.S. Section 1-550.5].

6. **Statement explaining the Need for the Adopted Rule:**
   To comply with House Bill 1347 (2013) and to add a new screening test allowing early medical intervention in Severe Combined Immunodeficiency Syndrome.

7. **Date and Location of the Meeting at which such Rules Were Adopted:**
   Adopted January 14, 2014, in the offices of the Oklahoma State Department of Health.

8. **Summary of the Comments and Explanation of Changes or Lack of any Change Made in the Adopted Rules as a Result of Testimony Received at Public Hearings:**
   Both written and oral comments were received encouraging the addition of Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening rules and the Hospital Standard rules (Chapter 667) as lifesaving and beneficial to the citizens of the State. These comments are covered in detail in the Rule Comment Summary, hereto annexed as Exhibit A.

9. **List of Persons or Organizations Who Appeared or Registered For or Against the Adopted Rule at Any Public Hearing Held by the Agency or Those Who Have Commented in Writing Before or After the Hearing:**
   As addressed in detail in the Rule Comment Summary, the following either provided written or oral comments in the public hearing in favor of adding Severe Combined Immune Deficiency and Pulse Oximetry Screening to the Newborn Screening panel. The public hearing was held November 1, 2013.

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

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

No comments were received opposing the proposed rules.

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

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

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

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

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

RULE COMMENT SUMMARY AND RESPONSE

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

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

Rule Subchapter and Section: 310:550-1-1
Rule Subchapter and Section: 310:550-1-2
Rule Subchapter and Section: 310:550-3-1
Rule Subchapter and Section: 310:550-5-1
Rule Subchapter and Section: 310:550-5-2
Rule Subchapter and Section: 310:550-7-1
Rule Subchapter and Section: 310:550-13-1
Rule Subchapter and Section: 310:550-17-1
Rule Subchapter and Section: 310:550-19-1
Rule Subchapter and Section: 310:550-21-1

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comment: Received written comment "As a practicing immunologist in the state of Oklahoma for the past 17 years, I can speak to the necessity of newborn screening for immune deficiency. As you are

aware, data has shown that early bone marrow transplantation can prevent death and severe illness in this vulnerable group of children. And it has been shown to be cost-efficient in other states that have implemented the process. Without newborn screening, by the time these children present with overwhelming illness, it is often too late for them. Please consider adding this important test to our current panel of newborn screens."

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

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

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

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

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

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

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

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

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

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

List of person who attended on behalf of Chapter 550

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

Agency Rule Contact:

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

RULE IMPACT STATEMENT

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

1. **DESCRIPTION:** The proposed rule changes add amendatory language to the existing rule to include Severe Combined Immunodeficiency Syndrome (SCID) as a new test in the core panel of 29 genetic disorders for newborn screening (NBS) in Oklahoma, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children – Recommended Uniform Screening Panel (January 21, 2010) - and after consultation with the Newborn Screening Subcommittee of the Oklahoma Genetics Advisory Committee. This proposal also adds pulse oximetry screening for the detection of Critical Congenital Heart Disease (CCHD) to existing newborn screening rules as legislated by House Bill 1347 (2013) [63 O.S. Section 1-550.5].

   In addition, in Appendix A the newborn screening report form submitted by the infant's specialist or primary care provider is updated to include additional information based on new clinical practice; as is the requisition/collection form (Appendix B) and refusal form (Appendix C) in order to bring the rules up to date with practice. A new Appendix D and E are provided to include a recommended pulse oximetry screening protocol and a pulse oximetry screening result form.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**
   - All newborns are screened for silent disorders that can be treated if identified before symptoms occur. Adding new screening disorders to the testing panel has immediate positive health benefits for affected infants and families and long-term financial benefits for the Oklahoman health care system.
   - Several states (Wisconsin, Texas, Massachusetts, California, Louisiana, and New York) currently doing pilot studies for SCID testing have found that the incidence of the disease is as high as 1/40,000. This is much higher than our previously stated incidence (1/100,000) for this disease.
   - The classes of persons affected are newborn babies and their parents who have babies in a birthing facility in Oklahoma.
   - Additionally those affected are "birthing facilities" in Oklahoma as defined in House Bill 1347 (2013).
   - There were over 52,000 births recorded by the Division of Vital Records for the Oklahoma State Department of Health in 2012.

3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**
   - Estimate that 1-2 infants with SCID will be identified annually, based on the Oklahoma birth rate of approximately 55,000 – 60,000/annum and incidence of disease (~1/40,000).
   - Early identification improves health outcomes. Generally, this disease results in life-threatening infections within the first few months of life. Early detection provides a positive contribution to Child Health and improves rates of infant survival, which will reduce Oklahoma's rates of infant mortality and morbidity.

- The Oklahoma State Department of Health will evaluate overall benefits of SCID testing through follow-up of positively-screened infants.
- Cost of treatment (bone marrow transplant) for infants identified at birth is approximately $250,000 to $300,000 (for the procedure).
- Cost of treatment of a child not identified at birth is estimated at $2 million.
- In Oklahoma as many as 105 babies are born annually with a Critical Congenital Heart Defect. This is a rate of approximately 20 babies/10,000.
- All infants born in a birthing facility in Oklahoma will benefit from early detection and treatment for a Critical Congenital Heart Defect.

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

- Cost for treatment, a bone marrow transplant, of infants identified at birth with SCID is approximately $250,000 to $300,000 for the procedure.
- Cost for treatment of a child not identified at birth = $2 million
- Initial cost to NBS for Short Term Follow-up =- $149,220
    - Cost of public education materials, one time publication of revised rules and regulations, travel and training for in house staff and for hospital staff, MD/PhD consultant and 0.5 FTE for a registered nurse to do Short Term Follow up.
- Annual cost to NBS for Short Term Follow-up - $141,220
    - Ongoing annual hospital training, in–house staff and MD/PhD consultant.
- Initial cost to the Public Health Laboratory (PHL) NBS program = $370,914
    - Capital outlay in purchase of new laboratory instrumentation (real-time PCR thermocyclers, centrifuges, paper punching system, plate shakers, freezer, refrigerator, pipettors), warranties, laboratory furniture, computer, personnel, personnel training, consumables and reagents for test development and validation prior to offering test as part of NBS panel
- Annual cost to PHL NBS = $159,235
    - FY2014 = $71,846 (estimating 6 months of testing)
    - FY2015 = $159,235 (includes additional maintenance contract costs that are not incurred in 2013 budget since new instrumentation is under warranty)
- Laboratory, Short Term Follow-up and administrative costs associated with the current NBS panel is $152.62 per infant. Once SCID testing is developed and added to the NBS panel, it is estimated that the total laboratory/administrative costs of the new NBS panel would be $158.62 per infant.

Part of the expenses incurred for initial establishment of a laboratory test and follow-up infrastructure for SCID and continued testing by the PHL will be defrayed by a $576,534 2-year grant awarded to the PHL by the CDC. The current fee for the newborn screening panel is $152.62 and will increase to $158.62 upon full SCID testing implementation pursuant to the Public Health Laboratory Service fee schedule at OAC 310:546-1-2. This fee assures sustained funding for newborn screening.

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

Cost of implementation SCID:

Total Cost of Rule Development and Dissemination -	$3,104
Cost of implementation for NBS Short Term Follow-up -	$149,220
Cost of implementation for PHL	$370,914
Total Cost	$523,238

Cost of implementation CCHD rules

Total cost of CCHD implementation (Includes 1.5 FTE, education and travel)	$124,492

Avoidable Medical Costs

Approximate treatment costs avoided per discovered cases: Lifetime cost of treatment for a child not identified at birth is $2 million less the $300,000 cost of a bone marrow transplant for an infant identified at birth with SCID	$ 1,700,000
Number of new cases detected per year	1
Avoided Medical Expenses from twenty years of testing = Not adjusted for inflation	$ 34,000,000

6. **IMPACT ON POLITICAL SUBDIVISIONS:** There will be no impact on political subdivisions.

7. **ADVERSE EFFECT ON SMALL BUSINESS:** There will be an impact on those birthing facilities that meet the definition of a small business. The impact will be to perform the newborn screening test that is currently being performed with the addition of the pulse oximetry screen and to recoup that cost from insurance or the consumer.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**
Proposed SCID testing to be performed in-house in the Public Health Laboratory (PHL) (versus send-out) using a CDC-developed protocol that obviates the need for extensive test development and validation. Training for SCID testing has been provided free by the CDC. This protocol does not require nucleic acid isolation, whereas alternate protocols have the added cost of this step. The PHL has chosen a qPCR system that is at the lower price end of available commercial systems.

The proposed CCHD screening rules implement statutory requirements for screening. The methodology devised is of the lowest cost identified to date.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
- Changes to the Newborn Screening rule will improve the core public health services of Children's Health in Oklahoma. Early identification of at-risk infants can lead to reduction in infant mortality and morbidity.

- **http://statepublichealth.org/Internal.aspx?id=4822** - ASTHO Applauds HHS Adoption of New National Standard for Newborn Screening

- http://www.astho.org/Internal.aspx?id=3634&terms=newborn+screening ***Newborn Screening*** Is a Core Public Health Service and Should Be Mandatory and Consistent, Says Association of State and Territorial Health Officials.

The CDC reports that pulse oximetry screenings can identify infants with Critical Congenital Heart Defects (CCHD). Infants with CCHDs are at significant risk for morbidity or mortality. The CDC reports that pulse oximetry screenings can detect seven to twelve different CCHDs that represent 17-31% of all congenital heart disease in newborns. The detection of the CCHD will allow the newborn to receive a surgical procedure, shortly after birth to correct the CCHD and reduce the morbidity and mortality rate.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION: Oklahoma currently ranks 44th in the country for infant mortality. Cases of SCID are undiagnosed because infants die due to overwhelming infections in the first few months of life. Addition of this screening test to the Newborn Screening Panel will ensure that Oklahoma is following the national Recommended Uniform Screening Panel as recommended by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and is aligned with newborn screening algorithms in bordering states.

Undetected CCHDs will lead to a higher morbidity and mortality rate among newborns. The newborns will be discharged from the birthing facility without any evidence of a problem.

11. This rule impact statement was prepared on August 5, 2013, revised September 24, 2013, and January 23, 2014.

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), ~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health. This chapter establishes the following rules and regulations concerning screening all infants born at a birthing facility in Oklahoma for critical congenital heart disease (CCDH) via pulse oximetry screening 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 disability, mental retardation 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 their 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 are 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 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" will refer to 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 a male's, 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.

"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 membranes causes dehydration of secretions. The result is a production of a thick, viscous mucus that clogs the lungs. This leads to chronic lung infections, fatal lung disease, and also interferes 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 mental retardation 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 or death.

"Form Kit" or **"Newborn Screening Form Kit"** is a FDA approved (or licensed) filter paper kit bearing a stamped lot number that has been approved by the Commissioner of Health. For an example of a FDA approved kit, see Appendix A, Oklahoma Health Department (OHD) Form Kit #450.

"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 mental retardation or death.

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

"Hemoglobinopathy" means an inherited hemoglobin disorder.

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

"Infant's Physician" means the licensed medical or osteopathic physician responsible for the care of the newborn.

"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, including parent education, networking, referral, and case coordination.

"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.

"Newborn" means an infant 30 days of age and under.

"Newborn Screening" or "newborn screening tests" means screening infants for the disorders of phenylketonuria, congenital hypothyroidism, galactosemia, sickle cell diseases, cystic fibrosis, congenital adrenal hyperplasia, medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD), ~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health and critical congenital heart

disease (CCHD) via pulse oximetry screening conducted by birthing facilities on all newborns born in the state of Oklahoma.

"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" refers to the Public Health Laboratory and ~~Family Health~~ Prevention and Preparedness Services Short-term Follow-up Program at the Oklahoma State Department of Health.

"Newborn Screening Program Coordinator" refers to the coordinator of the ~~Family Health~~ Prevention and Preparedness Services Short-term Follow-up Program at the Oklahoma State Department of Health.

"Organic Acid Disorders" refers to a group of inherited metabolic conditions in which the body is unable to metabolize or process organic acids properly. Each organic acid disorder is associated with a specific enzyme deficiency 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 mental retardation and death.

"Pediatric Sub-Specialist" means a physician licensed in Oklahoma, board certified in pediatrics and board certified in a pediatric sub-specialty 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 mental retardation.

"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.

"Premature Infant" means an infant 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 specimen collected using a single form kit which is suitable in both blood quantity and

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), ~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health. All requested demographic information on the form kit must be completed. Federal CLIA '88 regulations require that the form kit's laboratory requisition contain sufficient patient data that must include 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 apparently well persons who probably have a disease or defect from those who probably do 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 when the laboratory reports an abnormal or unsatisfactory screen result and ends with a diagnosis of normal, lost (repeat testing not achieved), or affected with appropriate treatment and referral has been initiated.

"Sick Infant" means an infant 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) which if not treated early in life may result in severe illness, mental retardation or death (one variation is commonly referred to as sickle cell anemia).

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

"Submitter" means a hospital, other facility, or physician submitting a Newborn Screening specimen.

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

"Unsatisfactory Specimen" means a specimen which is not collected on a form kit and/or is not suitable in blood quantity

and 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), ~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health and/or Federal CLIA '88 regulations are not followed and the form kit's laboratory requisition does not include patient's name, date of birth, sex, date of collection, test(s) to be performed, and complete name and address of person requesting test.

SUBCHAPTER 3. TESTING OF NEWBORNS

310:550-3-1. Testing of newborns

(a) 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)~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services, infants shall be screened for~~, biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health; a parent or guardian may refuse screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices.

(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 refuses the newborn screening blood test or pulse oximetry screening of their newborn on the grounds that such examination conflicts with their religious tenets and practices shall also indicate in writing this refusal utilizing the Newborn Screening Program Parent Refusal Form as illustrated in Appendix C of this Chapter. This signed refusal form shall be placed in the newborn's medical record with a copy sent to the

Newborn Screening Program Coordinator.

SUBCHAPTER 5. SPECIMEN COLLECTION

310:550-5-1. Specimen collection

(a) **Specimen collection for hospital births.** For all live hospital births, the physician, licensed or certified birth attendant shall order the collection of a newborn screening specimen on all newborns 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 identify infants at risk for the disorders quickly, the specimen should 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. The hospital is responsible for collecting specimens on all infants.

(1) If the initial specimen for any infant is collected prior to 24 hours of age, the hospital and the physician are responsible for notifying the infant's parents 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. The infant's physician is responsible for insuring 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/guardian's name, address, phone or contact phone number and the planned health care provider who will be providing well care for the infant after discharge or if the infant is to be hospitalized for an extended period of time the name of the infant's physician.

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

(4) Infants 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 physician and the receiving hospital to ensure the specimen is collected.

(5) It is the responsibility of the hospital and physician to ensure that all infants are screened prior to discharge. If an infant is discharged prior to specimen collection, the Newborn Screening Program Coordinator shall be notified. The physician is responsible for ensuring the specimen is collected as required.

(b) **Screening for premature/sick infants.** For all premature/sick infants, the physician shall order the collection of a newborn screening specimen prior to red blood cell transfusion, at three

to seven days of age or immediately prior to discharge, whichever comes first. Due to the need to identify infants at risk for the disorders quickly, the specimen should be collected as early as possible after 24 hours of age. It is recommended that a repeat newborn screening specimen be collected at 14 days of age. Specimens shall be collected on the Newborn Screening Form Kit using capillary or venous blood. The hospital and the physician are responsible for ensuring that specimens are collected on all premature/sick infants.

(1) Premature/sick infants screened prior to 24 hours of age must be re-screened between 7-14 days of age.

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

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

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

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

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

(a) **Filter paper sample collection.**

(1) Specimens obtained with a Newborn Screening Form Kit should be collected in accordance with Appendix A of this Chapter. Failure to follow these methods of blood collection may cause inaccurate results and require repeat specimens.

~~(b)~~ (2) Submitters are responsible for submitting a Satisfactory Newborn Screening Specimen.

(b) **Pulse oximetry screening.**

(1) **Pulse oximetry screening.** Pulse oximetry screening will be performed utilizing hospital protocol. See Appendix E for recommended protocol.

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

(3) **Newborn Infants Receiving Routine Care.**

(A) The birthing facility or nurse shall:

(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 the infant to be screened at the facility between twenty-four (24) hours and forty-eight (48) hours of life; or

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

(B) If the newborn infant is discharged from a facility after 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 is discharged before 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 in Special Care or Intensive Care.** Birthing facilities shall perform pulse oximetry screening on infants prior to discharge utilizing protocol recommended in appendix E, unless the infant has an identified congenital heart defect or has an echocardiogram done. Continuous pulse oximetry monitoring may not be substituted for CCHD screening.

(5) **Circumstances Where Pulse Oximetry Screening is not Indicated.** There may be instances where screening for CCHD is not indicated, including but not limited to instances where:

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

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

(C) Indicate on NBS filter paper the pulse oximetry screening was not performed.

SUBCHAPTER 7. HOSPITAL RECORDING

310:550-7-1. Hospital recording

(a) **Newborn Screening Results.**

(1) The hospital shall implement a procedure to ensure that a newborn screening specimen has been collected on every newborn and transported to the Newborn Screening Laboratory within ~~24 – 48~~ twenty-four (24) to forty-eight (48) hours of collection.

~~(b)~~ (2) The hospital shall immediately notify the infant's

physician, parents or guardians, and Newborn Screening Program Coordinator if an infant is discharged without a sample having been collected. This notification shall be documented in the infant's hospital record.

~~(c)~~ (3) If no test results are received within fifteen (15) days after the date of collection, the hospital shall contact the Newborn Screening Laboratory to verify that a specimen had been received. If no specimen has been received, the hospital shall notify the physician.

~~(d)~~ (4) Any hospital or any other laboratory which collects, handles or forwards newborn screening samples shall keep a log containing name and date of birth of the infant, name of the attending physician, name of the planned health care 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 specimen was drawn, date the specimen was forwarded, date the test results were received and the test results.

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

(b) **Pulse Oximetry Screening Results.**

(1) **Recordation of Results.**

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

(B) All pulse oximetry screening results shall be recorded on the Newborn Screening Collection Kit (ODH #450), found in Appendix A, 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.

(C) If the infant is not screened for CCHD prior to the Newborn Screening Collection Kit being forwarded to the Public Health Laboratory for testing, fax documentation of CCHD screen results to the Oklahoma State Department of Health (OSDH) Newborn Screening (NBS) Program utilizing Appendix E. Include information listed above along with screen results.

(2) **Abnormal Pulse Oximetry Screen Results.**

(A) Abnormal pulse oximetry screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or attending clinician immediately.

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

(C) A 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 parent or guardian.

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

(E) The birthing facility shall provide notification 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 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 to screen the infant at their facility between twenty-four (24) and forty-eight (48) hours of life; or

(ii) Follow-up with the family to refer 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 form in Appendix E and indicating the reason for not screening which shall be "early discharge".

(B) If the newborn infant is not screened for CCHD secondary to screening not being indicated, the birthing facility shall report results to the Department utilizing the form in Appendix E 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 secondary to parent or guardian refusal, the birthing facility shall fax a refusal form to the Department utilizing the form in Appendix C and indicate the reason for not screening, which shall be "parent refusal".

SUBCHAPTER 13. PARENT AND HEALTH CARE PROVIDER EDUCATION

310:550-13-1. Parent and Health Care Provider education

(a) The infant's physician or designee shall have the responsibility to ensure that at least one of each newborn's parent or legal guardian is notified about newborn screening and is provided information about the disorders and instructed 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 that at least one of each of the newborn's parent or legal guardian is notified about the pulse oximetry screening and is provided information about the pulse oximetry screening and instructed to obtain screen results from the birthing facility or the planned health care provider.

(c) The hospital will be responsible or designate a responsible party to distribute the Newborn Screening Program's written educational materials on newborn screening and pulse oximetry screening provided by the Department to at least one of each newborn's parent or legal guardian.

~~(c)~~ (d) Hospitals 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 Specimen~~ satisfactory newborn screening specimen and proper pulse oximetry screening method.

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

SUBCHAPTER 17. FOLLOW-UP FOR PHYSICIANS

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

(a) If a physician examines a child in the first three months of life, the physician will verify that the child has been screened, and document results in the infant's medical record. If the child has not been screened or if results of screening are not available, the physician should submit a Satisfactory Newborn Screening 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 and less than 24 hours of age at time of

collection; the infant's physician or designee will obtain required repeat screening, confirmatory testing, or diagnostic studies, in the timeframe specified so that therapy, when indicated, can be initiated expediently.
(c) The infant's physician may selectively rescreen infants as clinically indicated.
(d) Because patients may relocate without a forwarding address or contact information, where these rules place responsibility upon physicians and hospitals to follow-up or notify parents, then that shall be deemed to require only that a reasonable search be made and that if the parents are not contacted that the Newborn Screening Program Coordinator be notified of the non-follow-up or non-notification after efforts to contact the parents 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), ~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders,~~ and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health, should have a referral to a pediatric sub-specialist, and the parent 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 and Medical Records

(a) If confirmatory or follow-up testing is not performed by the Newborn Screening Laboratory or through a contract laboratory designated by the Newborn Screening Program, the infant's physician must report to the Newborn Screening Program Coordinator the results within 7 days after the completion of the medical evaluation, using the Department's Newborn Screening Report Form as illustrated in Appendix B of this Chapter. A copy of the confirmatory test results must accompany the report form.
(b) 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), ~~and after October 1, 2007, upon completion of validation studies and establishment of short-term follow-up services,~~ biotinidase deficiency, amino acid disorders, fatty acid oxidation disorders, ~~and~~ organic acid disorders, and upon completion of laboratory validation studies and establishment of short-term follow-up services, Severe Combined Immunodeficiency (SCID) detectable via the Department's laboratory technology utilized in newborn screening and approved by the Commissioner of Health, 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 as illustrated in Appendix B of this Chapter.

(c) These reports shall be 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 OSDH NBS 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 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 kits, contact 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.

(b) For general information or information regarding follow-up for newborn screening or pulse oximetry screening, contact Newborn Screening Short-term Follow-up Program, ~~Family Health~~ Prevention and Preparedness Services, Oklahoma State Department of Health, 1000 NE Tenth Street, Oklahoma City, Oklahoma 73117-1299, (405) 271-6617, FAX (405) 271-4892, 1-800-766-2223, ext. 6617. General information about the Newborn Screening Program is available on the OSDH Web site at www.health.ok.gov.

APPENDIX A. INSTRUCTIONS FOR FILTER PAPER SAMPLE COLLECTION [REVOKED]

APPENDIX A. INSTRUCTIONS FOR FILTER PAPER SAMPLE COLLECTION [NEW]

Adapted from CLSI *Blood Collection on Filter Paper for Newborn Screening Programs;* Approved Standard-Fifth Edition, LA4-A5, Vol.27 No.20, 2007.

Preliminary Steps

Ensure that the expiration date of the filter paper form kit has not passed. Complete the required information on the filter paper form kit. A ballpoint pen should be used; soft-tip pins will not copy through to the other sheets of paper. Address imprint devices (or adhesive labels) should never be used unless the handling process ensures that the patient information is not obscured and the blood collection area is not compromised. Do not use typewriters or printers that might compress the paper. Avoid touching the area within the circles on the filter paper section before, during and after collection (blood spots) of the specimen. Do not allow water, feeding formulas, antiseptic solutions, glove powder, hand lotion, or other materials to come into contact with the specimen card before or after use.

Precautions

Confirm the identity of the infant and ensure accuracy of the demographic data on the card. Wash hands vigorously before proceeding. All appropriate precautions, including wearing powder-free gloves (changing gloves between infants), should be taken for handling blood and disposing of used lancets in a biohazard container for sharp objects.

Site Preparation

Warm the newborn's heel, since warming the skin-puncture site can help increase blood flow. A warm, moist towel or diaper at a temperature no higher than 42° C may be used to cover the site for 3 minutes. This technique increases the blood flow sufficiently and will not burn the skin. In addition, positioning the infant's leg lower than the heart will increase venous pressure.

Cleaning the Site

The skin should be wiped with alcohol (isopropanol/water: 70/30 by volume, "70%"). Allow the skin to air dry.

Puncture

To obtain sufficient blood flow, puncture the infant's heel on the plantar surface of the heel with a sterile lancet or with a heel incision device. The incision device provides excellent blood flow by making a standardized incision 1.0 mm deep by 2.5 mm long. Any puncture device used should be selected so that the puncture does not exceed 2.0 mm in depth. For infant safety, scalpel blades or needles must not be used to puncture the skin for blood collection. Disposable skin puncture lancets of different designs are commercially available for performing the heel stick on infants. For worker safety, disposable skin puncture

devices that protect the user from unintentional self-inflicted skin punctures should be used.

In small, premature infants, the heel bone (calcaneus) might be no more than 2.0 mm beneath the plantar heel skin surface and half this depth at the posterior curvature of the heel. Studies indicate that for some infants (including full-term infants) a puncturing depth of 2.0 mm might be excessive and might cause bone damage. In this situation other collection methods should be considered.

Direct Application

After the heel has been punctured, wipe away the first drop of blood with a sterile gauze pad or cotton ball and allow a larger drop of blood to form. (Intermittently apply gentle pressure to the heel with the thumb, and ease this pressure as drops of blood form). Touch the filter paper gently against the large blood drop and, in one step, allow a sufficient quantity of blood to soak through and completely fill a preprinted circle on the filter paper. Do not press the filter paper against the puncture site on the heel. Blood should be applied only to one side of the filter paper. Both sides of the filter paper should be examined to assure that the blood uniformly penetrated and saturated the paper. During collection avoid milking or layering:

Milking: Excessive milking or squeezing the puncture might cause hemolysis of the specimen or result in an admixture of tissue fluids with the specimen and might adversely affect the test result.

Layering: Do not apply layers of successive blood drops to the same printed circle. Applying successive drops of blood to already partially dried spots causes nonuniform analyte concentrations and invalidates the specimens.

After blood has been collected from the heel of the newborn, the foot should be elevated above the body, and a sterile gauze pad or cotton swab pressed against the puncture site until the bleeding stops. It is not advisable to apply adhesive bandages over skin puncture site on newborns.

Collection

The required blood spots should be collected so that there is one in each pre-printed circle of the filter paper. Failure to collect and fill each pre-printed circle might result in the specimen being rejected (unsatisfactory) for testing. If blood flow diminishes so that a circle is not completely filled, repeat the sampling technique using a new circle or, if necessary, a new blood collection card.

For alternative methods to specimen collection (e.g., capillary tube, dorsal hand vein, umbilical venous catheter or umbilical arterial catheter) refer to the CLSI *Blood Collection on Filter Paper for Newborn Screening Programs;* Approved Standard-Fifth Edition (LA4-A5, Vol. 27 No. 20) or contact the Newborn Screening Program Coordinator.

Drying
Avoid touching or smearing the blood spots. Allow the blood specimen to air dry on a horizontally level, nonabsorbent, open surface for at least 3 hours at an ambient temperature of 15° C to 22° C. Keep the specimen away from direct sunlight (indirect room light is not usually detrimental unless accompanied by heat). Blood spots on the filter paper should not be heated, stacked, or allowed to touch other surfaces during the drying process.

The Filter Paper has a new fold-over protective cover. This protective cover is used to protect the blood spots from contamination and can be used in the drying process. To use the protective cover in the drying process simply elevate the blood spots to gently rest on the edge of the protective cover. After drying, the protective cover should be placed over the spots to prevent contamination.

Stacking
Since leaching (cross-contamination) between specimens might occur, specimen-to-specimen contact is not appropriate. Before placing the specimens in a paper envelope for mailing, use the fold-over protective cover to cover each individual blood spot. When stacking of exposed blood spots cannot be avoided, the following procedure should be done:

Before placing the specimens in a paper envelope for mailing, the dried blood spots on the collection card should be rotated 180° from the blood spots on the cards in the stack immediately above and below.

If the physical barrier is used (fold-over protective cover), specimen rotation is not necessary.

Mailing
Specimens should be transported in the manner designated by the Department. The collection card should be transported or mailed to the Newborn Screening Program laboratory within twenty-four (24) hours after collection. Mailing delays at collection sites should be avoided, and the postal or transport environment relative to possible delays should be considered. Never place the filter paper specimen in plastic bags. Use the form kit's protective overlay to cover the filter paper spots when mailing or transporting. If mailing the specimens use a U.S. Postal Service approved envelope.

Information
For information regarding specimen collection, Postal regulations, envelope and form kit purchasing, please contact the Newborn Screening Program Laboratory at (405) 271-5070.

Newborn Screening Form
Oklahoma State Department of Health-P.O. Box 24106,
Oklahoma City, OK 73124-0106 (405) 271-5070
ODH #450 REV02-2007

DO NOT WRITE IN THIS BOX

SN 1391373

INFANT'S INFORMATION
1. Infant's Last Name / Infant's First Name
2. Sex: M F
3. Date of Birth: MM DD YY
4. Birth Time: : 24 Hour Clock
5. Birthweight in Grams
6. If Multiple Birth Indicate Birth Order: A-H
7. Infant's Medical Record or I.D.
8. Provider ID
9. Infant's Provider or Physician's Name
10. Mom's Medicaid Number
11. ( ) - Provider's Phone Number

MOM'S INFORMATION
1. Mom's Last Name, First Name
2. Mom's Age
3. Mom's Address
4. Apt. #
5. Mom's City
6. State
7. Zip
8. ( ) - Mom's Telephone or Contact
9. - Mom's Social Security #
10. Mom's Race/Ethnic: 1. White 2. Black 3. Hispanic 4. Asian 5. Indian American 6. Other

Pulse Oximetry (CCHD) Screen
☐ Not Performed ☐ Pass ☐ Fail

SUBMITTING HEALTH PROVIDER ID #
Return to Submitter at this address:

Hearing Screening Results:

Right Ear	Left Ear
☐ Pass	☐ Pass
☐ Refer	☐ Refer

If not screened, reason:
☐ Technical problem
☐ Caregiver refused
☐ No equipment
☐ Baby discharged
☐ Delayed
☐ Other _____

Screen Method
☐ ABR ☐ Other (Specify)_____
☐ OAE

Hearing risk status–Check all that apply:
☐ Blood relatives of the infant have a permanent hearing loss that began at birth or in early childhood.
☐ Infant is suspected of having a congenital infection (neonatal herpes, cmv, rubella, syphilis, toxoplasmosis).
☐ Infant has craniofacial anomalies (pinna/ear canal abnormality, cleft lip/palate, hydrocephalus).
☐ Infant had exchange transfusion.
☐ Infant has serum bilirubin level ≥ 15 mg/dL.
☐ Infant was placed in a Level II or III nursery for more than 24 hours.

SPECIMEN INFORMATION
1. Collection Date: M M DD YY Collection Time: : 24 Hour Clock
2. Transfusion Date: MM DD YY Time: : 24 Hour Clock
Do not write in this box
3. Has a previous metabolic blood test been done anywhere? ☐ Yes ☐ No
Previous OSDH Lab Number
4. Check all that apply at time of screening:
___ TPN ___ Antibiotics ___ Lactose-Free Formula (Soy)
___ Meconium ileus ___ Family History of CF
5. Test Requested:
☐ All Tests ☐ HGB Only ☐ GALT ☐ CFTR ☐ Phe Monitor
☐ Adoption (check if baby is being adopted)
(See back of form for instructions)

VCS 1391373 NS LOT W112 6930612 2015-08

Baby's Last Name

Baby's First Name

Oklahoma State Department of Health

Newborn Screening Program

OKLAHOMA NEWBORN SCREENING Dried-blood Spot PROGRAM

THE NEWBORN SCREENING BLOOD TEST

A special blood test has been done to protect your baby from hidden disease. The test screens for the disorders listed on the back of this form. These disorders are harmful if treatment is not started within the first month of life (each disorder is explained on the back of this sheet).

WILL FURTHER TESTING BE REQUIRED?

If your baby is tested before 24 hours of age, the test must be repeated at 3 to 5 days of age. If the blood test is abnormal or inadequate to test, a repeat test will be needed. Please contact your baby's physician to determine if your baby needs a repeat test.

ASK YOUR BABY'S DOCTOR FOR THE TEST RESULTS

Please take this form with you to your baby's first doctor visit and ask for test results. If your baby's doctor does not have the test results and you have not been notified by mail, please call the Oklahoma State Department of Health when your baby is three weeks of age at **(405) 271-6617 or 1-800-766-2223.**

ATTENTION PROVIDER

DETACH AND GIVE TO PARENT OR GUARDIAN

NEWBORN SCREENING PROGRAM

SN 1395395

OHD #450 Form Kit (cont)

Early Detection and Treatment Provide Oklahoma Infants a Healthy Start

Congenital Hypothyroidism – Congenital hypothyroidism is usually caused by abnormal development or absence of the thyroid gland. Treatment includes daily thyroid medication to prevent mental retardation and poor growth.

Classic Galactosemia – Galactosemia occurs when the baby cannot break down a special sugar in milk called galactose. Treatment includes a galactose free diet.

Congenital Adrenal Hyperplasia 21-hydroxylase Deficiency (CAH) – CAH is caused by the lack of an enzyme that the adrenal gland uses to process hormones. In girls the genitalia may appear like that of a male, and can result in incorrect sex assignment. Treatment includes medication (hormones) to prevent serious illness and death.

Cystic Fibrosis – Cystic Fibrosis is a disorder that causes thick mucus to collect in the lungs and other body organs, which can result in breathing problems, lung infections, and poor digestion of food. Treatment includes medication and close monitoring by the Cystic Fibrosis Center.

Sickle Cell Disease & other hemoglobin disease – Sickle cell disease occurs when the hemoglobin in the red blood cells does not develop normally. Red blood cells have the important job of delivering oxygen to different parts of the body. Treatment includes medication and close monitoring by a Hematologist.

Medium-chain acyl coenzyme A dehydrogenase deficiency (MCAD) & Other Fatty Acid Oxidation Disorders – These conditions prevent the body from using certain fats for energy, particularly during periods without food (fasting). Treatment includes frequent feedings, dietary management, and medication.

Phenylketonuria (PKU) & Other Amino Acid Disorders – Amino Acid Disorders, including PKU, are caused by the body's inability to break down certain proteins in food, or by the body's inability to handle the extra nitrogen produced by the breakdown of protein. Treatment includes strict dietary management and may include medication.

Organic Acid Disorders – These conditions are caused by the body's inability to process certain proteins and/or fats properly. Treatment includes strict dietary management and may include medication.

Biotinidase Deficiency – The vitamin biotin is found in many foods, and is important for proper growth and development. Biotinidase Deficiency prevents babies from using biotin in a normal manner. Treatment includes biotin (vitamin) supplements and regular monitoring.

For all of these disorders, early treatment is needed to prevent severe illness or death.

Special Note: for sickle cell disease and cystic fibrosis screening, the blood test might find that your baby is a "carrier" of a disorder. Genetic Counseling is recommended.

Questions about the newborn screening blood test?

Call: 405-271-6617 or 800-766-2223
E-mail: newbornscreen@health.ok.gov
Web site: http://nsp.health.ok.gov

SUBMITTER RESPONSIBILITY

1. Completion of form.
2. Collection of an adequate specimen for testing.
3. Send specimens within 24 hours of collection.
4. The quality of the specimen received by the Public Health Laboratory Service.
5. Listing the planned health care provider who will be providing well care for the infant after discharge or infant's physician if the infant is to be hospitalized for extended period of time.

SCREENING REQUIREMENTS FOR ALL NEWBORNS

1. Prior to blood transfusion, as early as possible after 24 hours of age or immediately prior to discharge, whichever comes first.
2. If infant is screened at less than 24 hours of age, repeat screen at 3-5 days of age (if premature or a sick infant, repeat screen at 7-14 days of age).
3. All premature and sick infants should have a repeat screen at 14 days of age.

Instruction on Specimen Collection and Mailing (Complies with CLSI Standard LA 4 – A5)

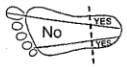
COMPLETION OF FORM

1. Legibly print and complete all information requested.
2. List submitter's return address and submitter ID number. Submitter means the facility or provider who has collected the specimen.
3. List the provider or physician who will be following the baby for well care or the attending physician if the infant is hospitalized for an extended period of time.
4. List the parent's correct address and phone number for notification of abnormal results.
5. Document results of the infant's pulse oximetry (CCHD) screen.

Note: All results are sent to the submitter and the provider listed on the form.

COLLECTION OF BLOOD SPECIMEN

1. To prevent specimen contamination do not touch any of the filter paper circles before or after collection.
2. Select puncture site and cleanse with 70% isopropanol and allow heel to air dry. Usual puncture site is illustrated below.



3. Use a sterile, disposable lancet or heel incision device to perform a swift clean puncture.
4. Wipe away first drop of blood with a sterile gauze or cotton ball.
5. Gently touch the filter paper against a large drop of blood and allow a sufficient quantity of blood to soak through to completely fill the preprinted circle on the filter paper. Blood must be applied to only one side of the filter paper and circle area should be fully saturated.
6. Fill each circle with ONE large drop of blood.
7. Protect freshly collected specimens from contamination.
8. Allow blood specimen to air dry at room temperature for at least 3 hours in a horizontal position. **Do not stack wet specimens. Insufficient drying will adversely affect the test results. DO NOT PLACE FILTER PAPER SPECIMENS IN A PLASTIC BAG.**
9. Specimen may be "Unsatisfactory for Testing" for the following reasons:
   a. Circles not completely filled in or not thoroughly saturated.
   b. Uneven saturation of circles or multiple sample application.
   c. Specimen appears contaminated.
   d. Clotted or caked blood on filter paper, or damaged filter paper.
   e. Assay inhibition due to antibiotic or other substance.
   f. Incomplete elution of blood from filter paper.
   g. Laboratory requisition incomplete or improperly completed.
   h. Results inconsistent – possibly due to improper sample collection.
   i. Specimen submitted on incorrect form or expired form.
   j. No specimen received with form.
   k. Specimen placed in plastic bag while wet.
   l. Receipt of specimen was more than 14 days from date of collection.

To Order Newborn Screening Collection Kits (ODH #450): Call (405) 271-5070

Specimens should be transported in the manner designated by the OSDH Public Health Laboratory Service. Send specimens within 24 hours of collection.

Courier Service address:
NEWBORN SCREENING SECTION
Public Health Laboratory Service
1000 NE 10th Street
Oklahoma City, OK 73117-1299

Mailing address: *(using United States Postal Service)*
NEWBORN SCREENING SECTION
Public Health Laboratory Service
P.O. Box 24106
Oklahoma City, OK 73124-0106

Adoption

If infant is being adopted, check the Adoption box on the front of the form. List the agency or lawyer that is handling the adoption in the "Mom's Information" section. Please note: for proper identification, the "Infant's Information" section must be completed accurately. Questions? Please call (405) 271-6617 or (800) 766-2223.

APPENDIX B. REPORT FORM [REVOKED]
APPENDIX B. REPORT FORM [NEW]

Newborn Screening Program Report Form

Infant's Name:_____ Infant's Birth Date__ __ / __ __ / __ __

Newborn Screening Program Lab #:_____ Mother's Name:_____

[ ] Diagnosis pending, Follow-up Plan:

Final Diagnosis (please attach confirmation lab results)
[ ] Normal
[ ] Trait Condition (specify carrier status)_____
[ ] Classic Galactosemia (GG phenotype/genotype)
[ ] Duarte/Galactosemia Compound Heterozygote (DG phenotype/genotype)
[ ] Congenital Adrenal Hyperplasia due to 21-Hydroxylase Deficiency
[ ] Cystic Fibrosis
[ ] Classic Phenylketonuria (PKU)
[ ] Hyperphenylalaninemia (not clinically significant)
[ ] Hyperphenylalaninemia (clinically significant treatment required)
[ ] Congenital Hypothyroidism
[ ] Medium-chain Acyl Coenzyme A Dehydrogenase Deficiency (MCAD)
[ ] Sickle Cell Disease (specify type)_____
[ ] Hemoglobin disease (specify type)_____
[ ] Biotinidase deficiency
[ ] Fatty Acid Oxidation Disorder (specify)_____
[ ] Organic Acid Disorder (specify)_____
[ ] Amino Acid Disorder (specify)_____
[ ] Severe Combined Immunodeficiency (specify type)_____
[ ] Other(specify)_____

Treatment Indicated? [ ] yes [ ] no
Date treatment started __ __ / __ __ / __ __

Referred to pediatric sub-specialist:
[ ] Endocrinologist (specify name): _____
[ ] Hematologist (specify name): _____
[ ] Metabolic Specialist (specify name): _____
[ ] Pulmonologist (specify name): _____
[ ] Immunologist (specify name):_____

Family referred for (check all that apply):
[ ] Genetic counseling (check provider):
__ Sickle Cell Association __ Geneticist __ Other
[ ] Enrollment in Newborn Screening Long-term Follow-up Program
[ ] Early Intervention Services

Print Physician's Name _____Telephone _____

Physician Signature_____ Date __ __ / __ __ / __ __

Mail or Fax this follow-up form with complete diagnostic information and confirmation lab results to: Prevention and Preparedness Services; ATTN: Newborn Screening Program Coordinator; 1000 NE Tenth Street, Oklahoma City, OK 73117-1299; Fax: (405) 271-4892; For questions or referral information, please call the Newborn Screening Program Coordinator at (405) 271-6617 or 1-800-766-2223.

APPENDIX C. REFUSAL FORM [REVOKED]
APPENDIX C. REFUSAL FORM [NEW]

Oklahoma State Department of Health
Refusal of the Newborn Screening Blood Test
Religious Tenets and Practices Refusal

Infant's Name:_____Medical Record Number:_____

Date of Birth: __ __ / __ __ / __ __

Attending Physician or Provider, print name:_____

Place of Birth:

__ Hospital, print name_____

__ Birthing Facility, print name_____

__ Home Birth

Type of Screen Refused: ___ Newborn Blood Test ____ Pulse Oximetry Screen

I have received and read the parent educational brochure printed by the Oklahoma Department of Health on the Newborn Screening blood test and pulse oximetry screening. I understand that these disorders are easily detected by testing a small blood sample from my baby's heel or by measuring the amount of oxygen in my baby's blood.

I have been informed that all newborns are required by law (under 63 O.S. 2002, Sections 1-533 and 1-534) to have a newborn screening test collected and pulse oximetry screening performed.

I have been informed and I understand that this screening is done to detect these disorders because symptoms sometimes do not appear for several weeks or months, and irreversible damage can occur before symptoms become apparent to a family or a physician.

I have been informed and I understand that, if untreated, these conditions may cause permanent damage to my child, including mental retardation, growth failure, and even death. This permanent health damage can be prevented through early detection and treatment.

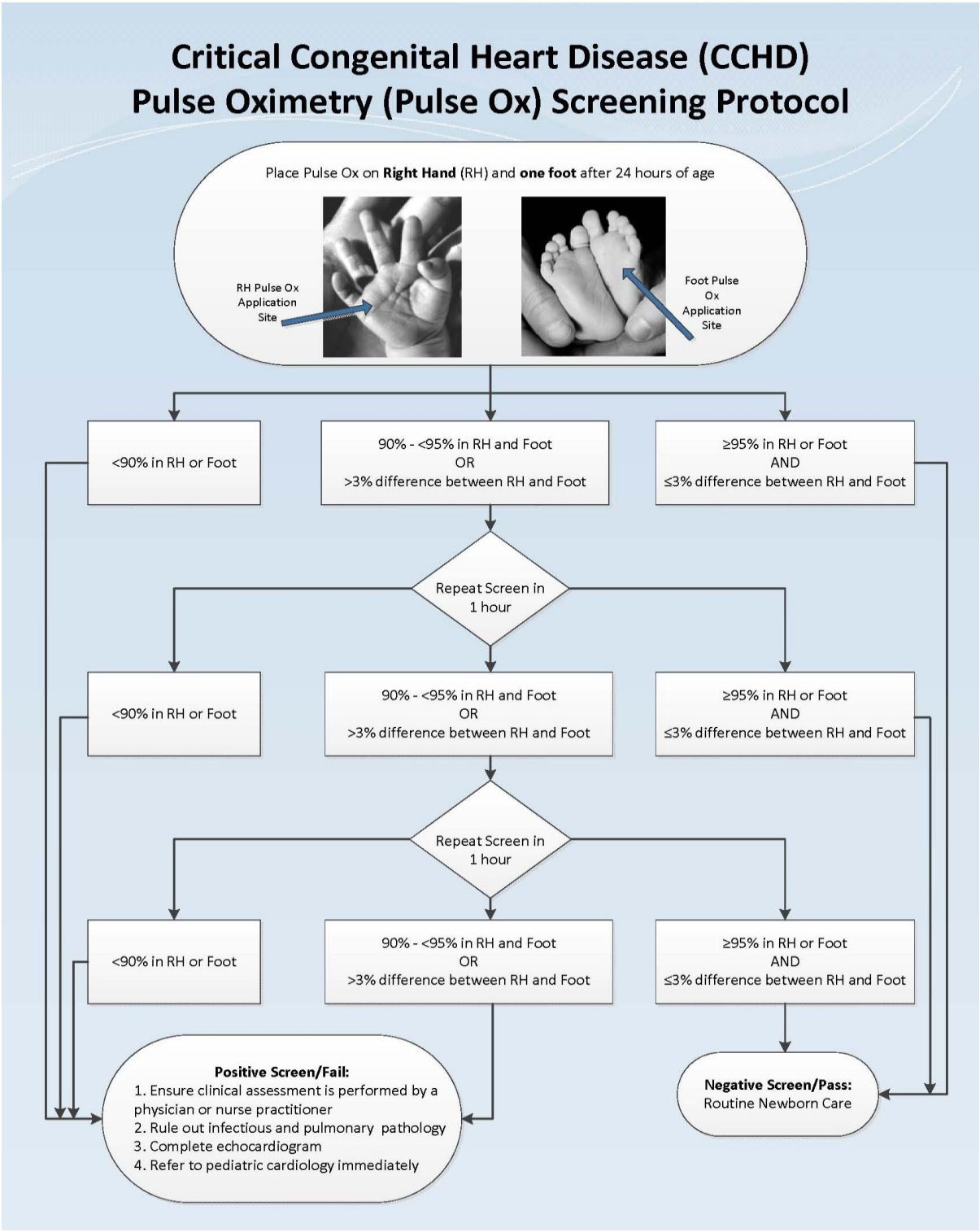
I have discussed the newborn screening test and pulse oximetry screening with my physician or health care provider and I understand the risks to my child if the screening test is not completed.

I understand that the law allows a parent or guardian to refuse newborn screening and pulse oximetry screening based on the grounds that such examination conflicts with a person's religious tenets and practices. I elect to refuse newborn screening on that such testing of my infant conflicts with my religious tenets and practices. My decision was made freely and I accept the legal responsibility for the consequences of this decision.

_____	_____	____/____/___
Printed Parent/ Guardian's Name	Parent/Guardian Signature	Date
_____	_____	____/____/___
Print Witness Name	Signature of Witness	Date

Original to infant's record, provide a copy to parent, and forward copy by fax or mail to: Oklahoma State Department of Health, Newborn Screening Program Coordinator, 1000 NE Tenth Street, Oklahoma City, OK 73117-1299, (405) 271-6617 or 1-800-766-2223; Fax (405) 271-4892.

APPENDIX D. Recommended Pulse Oximetry Screening Protocol [NEW]



APPENDIX E. Pulse Oximetry Screening Result Form [NEW]

Oklahoma State Department of Health
Pulse Oximetry Screening Result Form

Infant Information:

Infant's Last Name: _____ Infant's First Name: _____

Medical Record Number: _____ Primary Physician: _____

Date of Birth: ___/___/___ Birth Hospital: _____

Mother's Last Name: _____ Mother's First Name: _____

Pulse Oximetry Screening:

Date of Screening: ___/___/___

Age at Time of Screening: _____Days or ____Hours

Result:__Pass/Negative ____Fail/Positive ____Not Performed

Complete this section only if pulse oximetry screen was not performed:

Reason pulse oximetry screening not perform:

____Early Discharge

____Screening Not Indicated due to _____

____Parent Refusal

Screener's Name:_____

Screener's Signature:_____ Date: ___/___/___

Mail or Fax this follow-up form to: Oklahoma State Department of Health
Prevention and Preparedness Services
ATT: Newborn Screening Program Coordinator
1000 NE Tenth Street
Oklahoma City, OK 73117-1299
Fax: (405) 271-4892

For questions or referral information, please call the Newborn Screening Program Coordinator at (405) 271-6617 or 1-800-766-2223.