IDAPA 16 – IDAHO DEPARTMENT OF HEALTH AND WELFARE

Division of Public Health

16.02.12 – Newborn Screening

Who does this rule apply to?
Hospitals, midwives, medical professionals and providers involved with childbirth, laboratories, parents, and caregivers.

What is the purpose of this rule?
These rules specify the tests and procedures that must be performed on newborn infants for early detection of metabolic disorders, endocrine disorders, hemoglobin disorders, cystic fibrosis, critical congenital heart disease, and prevention of infant blindness.

What is the legal authority for the agency to promulgate this rule?
This rule implements the following statutes passed by the Idaho Legislature:

Health and Safety -
Prevention of Blindness and Other Preventable Diseases in Infants:
- Section 39-906, Idaho Code – Duties of Director
- Section 39-909, Idaho Code – Tests for Phenylketonuria & Preventable Diseases in Newborn Infants
- Section 39-910, Idaho Code – Duties of Director in Enforcing Act

Where can I find information on Administrative Appeals?
Administrative appeals and contested cases are governed by the provisions of IDAPA 16.05.03, "Contested Case Proceedings and Declaratory Rulings."

How do I request public records?
Unless exempted, all public records are subject to disclosure by the Department that will comply with Title 74, Chapter 1, Idaho Code, upon requests. Confidential information may be restricted by state or federal law, federal regulation, and IDAPA 16.05.01, "Use and Disclosure of Department Records."

Who do I contact for more information on this rule?

Idaho Department of Health and Welfare
Maternal & Child Health Program
450 West State Street
Boise, ID 83702

P.O. Box 83720
Boise, ID 83720-0036
Phone: (208) 334-5962
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Webpage: https://nbs.dhw.idaho.gov

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000. LEGAL AUTHORITY.
The Idaho Legislature has given the Board of Health and Welfare and the Director of the Department authority to promulgate rules governing the testing of newborn infants for phenylketonuria and other preventable diseases and governing the instillation of an ophthalmic preparation in the eyes of the newborn to prevent Ophthalmia Neonatorum, under Sections 39-906, 39-909, and 39-910, Idaho Code. (3-17-22)

001. TITLE AND SCOPE.

01. Title. These rules are titled IDAPA 16.02.12, "Newborn Screening." (3-17-22)

02. Scope. These rules specify the tests and procedures that must be performed on newborn infants for early detection of metabolic disorders, endocrine disorders, hemoglobin disorders, cystic fibrosis, critical congenital heart disease, and prevention of infant blindness. (3-17-22)

002. INCORPORATION BY REFERENCE.
The Department has incorporated by reference the following documents: (3-17-22)

01. Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard, Fifth Edition. The Department has adopted "Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard," Fifth Edition, Clinical and Laboratory Standards Institute. 2007 (ISBN 1-56238-644-1), and hereby incorporates this standard by reference. A copy is available for review at the Department, or through the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, telephone 1-610-688-0100. (3-17-22)

02. Critical Congenital Heart Defects (CHDs). The Department has adopted the Critical CHD Screening Methods as recommended by the American Academy of Pediatrics, from "Strategies of Implementing Screening for Critical Congenital Heart Diseases," Kemper, et al., 2011, and hereby incorporates this material by reference. Copies may be obtained from the Department, see online at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html. (3-17-22)

003. -- 009. (RESERVED)

010. DEFINITIONS.
The following definitions will apply in the interpretation and enforcement of this chapter: (3-17-22)

01. Critical Congenital Heart Disease (CCHD). CCHD, also known as critical congenital heart defects, is a term that refers to a group of serious heart defects, as defined by the Centers for Disease Control and Prevention (CDC), that are present from birth. (3-17-22)

02. Department. The Idaho Department of Health and Welfare. (3-17-22)

03. Dried Blood Specimen. A blood specimen obtained from an infant by means of skin puncture, not by means of venipuncture or any other method, that is placed on special filter paper and allowed to dry. (3-17-22)

04. Hyperalimentation. The administration of an amount of nutrients beyond minimum normal requirements of the appetite, in an attempt to replace nutritional deficiencies. (3-17-22)

05. Laboratory. A medical or diagnostic laboratory certified according to the provisions of the Clinical Laboratory Improvement Amendments of 1988 by the United States Department of Health and Human Services. (3-17-22)

06. Newborn Screening. Newborn screening means a laboratory procedure performed on dried blood specimens from newborns to detect those at risk for the diseases specified in Subsection 100.01 of these rules. (3-17-22)

07. Person Responsible for Registering Birth of Child. The person responsible for preparing and filing the certificate of birth is defined in Section 39-255, Idaho Code. (3-17-22)

08. Pulse Oximetry. A non-invasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen using equipment approved by the U.S. Food and Drug Administration for use with newborn infants. (3-17-22)

09. Test Kit. The materials provided by the laboratory for the purposes of dried blood specimen collection and submission of specimens for newborn screening laboratory procedures. (3-17-22)

011. -- 049. (RESERVED)

050. USE AND STORAGE OF DRIED BLOOD SPECIMENS.

01. Use of Dried Blood Specimens. Dried blood specimens will be used for the purpose of testing the infant from whom the specimen was taken, for congenital birth defects. Limited use of specimens for routine calibration of newborn screening laboratory equipment and quality assurance is permissible. (3-17-22)

02. Prohibited Use of Dried Blood Specimens. Dried blood specimens may not be used for any purpose other than those described in Subsection 050.01 of this rule without the express written consent of the parent(s) or guardian(s) of the infant from whom the specimen was collected. (3-17-22)

03. Storage of Dried Blood Specimens. Dried blood specimens may be stored at the testing facility for a period not to exceed eighteen (18) months. Acceptable use of stored specimens will be for re-testing the specimen in the event of a symptomatic diagnosis or death of the infant during the storage period. (3-17-22)

051. -- 099. (RESERVED)

100. DUTIES OF THE ADMINISTRATOR OF THE RESPONSIBLE INSTITUTION AND THE PERSON REQUIRED TO REGISTER THE BIRTH OF A CHILD.

01. Conditions for Which Infants Will Be Tested. All infants born in Idaho must be tested for at least the following conditions: (3-17-22)

a. Biotinidase deficiency; (3-17-22)

b. Congenital hypothyroidism; (3-17-22)

c. Galactosemia; (3-17-22)

d. Maple syrup urine disease; (3-17-22)

e. Phenylketonuria; and (3-17-22)

f. Critical congenital heart disease. (3-17-22)

02. Blood Specimen Collection. (3-17-22)

a. The dried blood specimen collection procedures must follow the document listed in Subsection 004.01 of these rules. (3-17-22)

b. For infants admitted to the neonatal intensive care unit (NICU), the initial dried blood specimen for newborn screening must be obtained upon admission to the NICU. (3-17-22)

c. For non-premature infants, in-hospital, the initial dried blood specimen for newborn screening must be obtained between twenty-four (24) and forty-eight (48) hours of age. (3-17-22)

d. For newborns transferred from one hospital to another, the originating hospital must assure that the dried blood specimen is drawn. If the newborn is too premature or too sick to have a dried blood specimen drawn for screening prior to transfer and a dried blood specimen is not obtained, the originating hospital must document this, and notify the hospital to which the newborn is being transferred that a dried blood specimen for newborn screening has not been obtained. (3-17-22)

e. Prior to the discharge of an infant from the institution where initial newborn care or specialized medical care was rendered, the Administrator of the institution must assure that an adequate dried blood specimen has been collected regardless of the time the infant is discharged from the institution. (3-17-22)

f. For births occurring outside of a hospital, the birth attendant is responsible for assuring that an acceptable dried blood specimen is properly collected for newborn screening as stipulated in Section 100 of this rule. (3-17-22)

g. Newborns who require a blood transfusion, hyperalimentation, or dialysis must have a dried blood specimen collected for screening prior to these procedures. (3-17-22)

h. If a dried blood specimen cannot be obtained for newborn screening before transfusion, hyperalimentation, or dialysis, the hospital must ensure that a repeat dried blood specimen is obtained at the appropriate time when the specimen will reflect the infant's own metabolic processes and phenotype. (3-17-22)

i. All infants must be retested. A test kit must be given to the parents or responsible party at the time of discharge from the institution where initial newborn care was rendered, with instructions to have a second dried blood specimen collected. The preferred time for sample collection is between ten (10) and fifteen (15) days of age. (3-17-22)

03. Specimen Data Card. The person obtaining the newborn screening specimen must complete the demographic information card attached to the sample kit. The First Specimen Card must include the infant's mother's date of birth, address, and phone number. Both the First and Second Specimen's Card must include the items listed in 100.03.a. through 100.03.k. of this rule, optional fields may be completed as needed. (3-17-22)

a. Name of the infant; (3-17-22)

b. Whether the birth was a single or multiple-infant birth; (3-17-22)

c. Name of the infant's mother; (3-17-22)

d, Gender of the infant; (3-17-22)

e. Method of feeding the infant; (3-17-22)

f. Name of the birthing facility; (3-17-22)

g. Date and time of the birth; (3-17-22)

h. Date and time the specimen was obtained; (3-17-22)

i. Name of the attending physician or other attendant; (3-17-22)

j. Date specimen was collected; and (3-17-22)

k. Name of person collecting the specimen. (3-17-22)

04. Specimen Mailing. Within twenty-four (24) hours after collection, the dried blood specimen must be mailed to the laboratory by first class mail or its equivalent, except when mailing service is not available. When mailing service is not available on weekends and holidays, dried blood specimens must be mailed to the laboratory on the first available mail pick-up day. The preferred method of mailing, following a weekend or holiday, is by expedited mail service. (3-17-22)

05. Record Keeping. Maintain a record of all dried blood specimens collected for newborn screening. This record must indicate: (3-17-22)

a. Name of the infant; (3-17-22)

b. Name of the attending physician or other attendant; (3-17-22)

c. Date specimen was collected; and (3-17-22)

d. Name of person collecting specimen. (3-17-22)

06. Collection Protocol. Ensure that a protocol for collection and submission for newborn screening of adequate dried blood specimens has been developed, documented, and implemented. Individual responsibilities must be clearly defined and documented. The attending physician must request that the test be done. The hospital may make an appropriate charge for this service. (3-17-22)

07. Responsibility for Recording Specimen Collection. (3-17-22)

a. The administrator of the responsible institution, or their designee, must record on the birth certificate whether the dried blood specimen for newborn screening has been collected. (3-17-22)

b. When a birth occurs outside a hospital, the person responsible for registering the birth of the child must record on the birth certificate whether the dried blood specimen for newborn screening has been collected and submitted within twenty-four (24) hours following collection. (3-17-22)

08. Fees. The Department will provide access to newborn screening laboratory services. If the administration of the responsible institution or the person required to register the birth of a child chooses to utilize this service, the Department will collect a fee equal to the cost of the test kit, analytical, and diagnostic services provided by the laboratory. The fees must be remitted to the Department before the laboratory provides the test kit to those responsible for ensuring the infant is tested according to these rules. (3-17-22)

101. -- 199. (RESERVED)

200. LABORATORY DUTIES.

01. Participation in Centers for Disease Control and Prevention (CDC) Newborn Screening Quality Assurance Program. All laboratories receiving dried blood specimens for newborn screening on infants born in Idaho must participate in the Newborn Screening Quality Assurance Program operated by the CDC. (3-17-22)

02. Specimen Processing. Dried blood specimens for newborn screening must be processed within twenty-four (24) hours of receipt by the laboratory or before the close of the next business day. (3-17-22)

03. Result Notification. Normal test results may be reported by mail to the submitter. Other results must be reported in accordance with Section 300 of these rules. (3-17-22)

201. -- 299. (RESERVED)

300. FOLLOW-UP FOR UNSATISFACTORY SPECIMENS, PRESUMPTIVE POSITIVE RESULTS AND POSITIVE CASES.

01. Follow-Up for Unsatisfactory Specimens. (3-17-22)

a. The laboratory will immediately report any unsatisfactory dried blood specimens to the submitting institution that originated the dried blood specimen or to the healthcare provider responsible for the newborn's care, with an explanation of the results. The laboratory will request a repeat dried blood specimen for newborn screening from the institution or individual submitting the original sample, or from the responsible provider. (3-17-22)

b. Upon notification from the laboratory, the health care provider responsible for the newborn's care at the time of the report will cause another dried blood specimen to be appropriately forwarded to the laboratory for screening. (3-17-22)

02. Follow-Up of Presumptive Positive Results. The laboratory will report positive or suspicious results on an infant's dried blood specimen to the attending physician or midwife, or, if there is none or the physician or midwife is unknown, to the person who registered the infant's birth, and make recommendations on the necessity of follow-up testing. (3-17-22)

03. Positive Case Notification. Confirmed positive cases of biotinidase deficiency, congenital hypothyroidism, galactosemia, maple syrup urine disease, and phenylketonuria must be reported as described in IDAPA 16.02.10, "Idaho Reportable Diseases." (3-17-22)

301. NEWBORN CRITICAL CONGENITAL HEART DISEASE (CCHD) SCREENING.

01. Pulse Oximetry for the Screening of CCHD. (3-17-22)

a. For births occurring in a hospital, the administrator of the institution or their designee must assure that all infants who meet the CDC criteria for CCHD screening are screened following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html. (3-17-22)

b. For births occurring outside of a hospital, the birth attendant must assure that screening for congenital heart disease is conducted through the use of pulse oximetry no sooner than twenty-four (24) hours after birth and no later than forty-eight (48) hours after birth following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html. (3-17-22)

02. Responsibility of Recording CCHD Screening Results. (3-17-22)

a. For births occurring in a hospital, the administrator of the responsible institution or their designee must record the pulse oximetry results on the birth certificate and whether the CCHD screening was determined as "passed" or "failed" following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html, or "not screened." (3-17-22)

b. For births occurring outside of a hospital, the birth attendant or their designee must record the pulse oximetry results on the birth certificate and whether the CCHD screening was determined as "passed" or "failed" following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html, or "not screened." (3-17-22)

03. Follow Up for Abnormal CCHD Screening Results. (3-17-22)

a. For births occurring in a hospital, the administrator of the responsible institution or their designee must make a referral for further evaluation of the newborn whose CCHD results are abnormal and inform the parent or legal guardian of the need for appropriate intervention. (3-17-22)

b. For births occurring outside of a hospital, the person performing the screening is responsible for making an immediate referral for further evaluation of the newborn whose CCHD results are abnormal and informing the parent or legal guardian of the need for appropriate intervention. (3-17-22)

302. -- 399. (RESERVED)

400. SUBSTANCES THAT FULFILL REQUIREMENTS FOR OPHTHALMIC PREPARATION.

Only those germicides proven to be effective in preventing ophthalmia neonatorum and recommended for use in its prevention by the U.S. Department of Health and Human Services (including the U.S. Public Health Service, the Center for Disease Control and Prevention, and the U.S. Food and Drug Administration) will satisfy the requirements established herein, under Section 39-903, Idaho Code. (3-17-22)

401. -- 999. (RESERVED)