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16.02.12 - RULES GOVERNING PROCEDURES AND TESTING TO BE PERFORMED ON NEWBORN INFANTS

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16.02.12 - RULES GOVERNING PROCEDURES AND TESTING TO BE PERFORMED ON NEWBORN INFANTS

000. LEGAL AUTHORITY.

The Idaho Legislature has given the Board of Health and Welfare legislative power 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, pursuant to Sections 39-906, 39-909, 39-910 and 39-911, Idaho Code. (12-31-91)

001. TITLE AND SCOPE.

01. Title. These rules are to be cited in full as Idaho Department of Health and Welfare Rules, IDAPA 16.02.12, "Rules Governing Procedures and Testing To Be Performed on Newborn Infants". (11-1-80)

02. Scope. These rules specify the tests and/or procedures that must be performed on newborn infants for early detection of mental retardation, developmental disabilities, blood amino acid levels, and prevention of infant blindness. (11-1-80)

002. DEFINITIONS.

The following definitions will apply in the interpretation and enforcement of this chapter: (12-31-91)

01. Bacterial Inhibition Assay. A biological laboratory test procedure using particular strains of bacteria and specific chemical inhibitors of bacterial growth used to assay quantitatively specific amino acids or other chemicals of intermediary metabolism in blood, urine, or other biological specimens. It is commonly described in the scientific literature as a "Guthrie Test". (5-20-87)

02. Board. Idaho State Board of Health and Welfare. (12-31-91)

03. Department. Idaho Department of Health and Welfare. (12-31-91)

04. Director. Director of the Idaho Department of Health and Welfare or his designee. (12-31-91)

05. Germicide. A substance which kills germs. (11-1-80)

06. Bureau Of Laboratories. The Central Laboratory in Boise, operated by the Bureau of Laboratories of the Idaho Department of Health and Welfare. (12-31-91)

07. Newborn Metabolic Screening Test Kit. Any or all parts of the combined materials, laboratory slips, tubes, mailing containers, or other components provided by the Idaho Department of Health and Welfare Bureau of Laboratories for the purposes of collection or submission of specimens for laboratory tests. (5-20-87)

08. Ophthalmia Neonatorum. A bacterially-caused inflammatory condition of the eyes occurring within the first three (3) weeks of life which is a major cause of blindness, if untreated. (11-1-80)

09. Ophthalmic Preparation. A substance for use in the eye. (11-1-80)

10. Other Detectable Conditions As Prescribed By The State Board Of Health And Welfare. Genetic and infectious diseases affecting the newborn population which may cause developmental disabilities of various types are amendable to early detection by available testing procedures. (5-20-87)

11. 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. (5-20-87)

12. Phenylketonuria. Any disease, usually due to a single enyzme deficiency of genetic origin, in

which the individual is completely or partially incapable of normal metabolism of phenylalanine, which results in an abnormal increase in the concentration of phenylalanine in the blood. (5-20-87)

003. -- 099. (RESERVED).

100. TESTING FOR PHENYLKETONURIA AND OTHER DETECTABLE CONDITIONS AS PRESCRIBED BY THE BOARD.
The rules contained in Sections 100 through 499 pertain to the requirements concerning testing newborns for phenylketonuria and other preventable diseases. (12-31-91)

01. Prescribed Test Procedure. The bacterial inhibition assay procedure and other procedures approved by the Director, performed by Laboratories or other regional laboratories officially approved for this purpose, are specified as the only tests for phenylketonuria and other preventable diseases fulfilling the requirements for testing, as prescribed in Section 39-910, Idaho Code. (12-31-91)

02. Time And Place Of Collecting Specimens For Testing. The policy of the Department is that the optimum time to obtain the blood specimen is when the infant is between forty-eight (48) hours and five (5) days of age. In small premature infants this time may be extended to forty-eight (48) hours and ten (10) days of age. Specific specimen collection procedures are as follows: (12-31-91)

a. A blood specimen shall be collected from each newborn infant on the day of discharge from the institution where initial newborn care was rendered. (9-1-65)

b. In the event of transfer of a newborn infant to another institution for specialized medical care the blood samples shall be collected as follows: (5-20-87)

i. In the event that an infant is transferred from the initial care unit a blood specimen shall be taken before transfer. (5-20-87)

ii. An infant transferred to a second unit shall have an additional blood specimen taken at the receiving institution before ten (10) days of age. (5-20-87)

iii. A newborn screening test kit for sample collection and submission shall accompany the infant to the receiving institution. (5-20-87)

c. Infants receiving domiciliary care in the institution where initial newborn care was rendered shall have a blood specimen collected after forty-eight (48) hours but before five (5) days after birth. (5-20-87)

d. Infants born outside of an institution and not subsequently admitted to an institution for initial newborn care shall have a blood specimen collected no later than ten (10) days of age. It shall be the duty of the person responsible for registering the birth of the child to cause the sample to be collected and submitted as prescribed. (5-20-87)

e. Infants from whom the blood sample has been collected less than forty-eight (48) hours after birth shall be retested. A test kit shall 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 blood specimen collected. In such cases the preferred time for sample collection is after five (5) but before fifteen (15) days of age. (5-20-87)

f. In the event that there is a question in the record whether or not an infant has been tested or a specimen appropriately collected it shall be the responsibility of the attending practitioner or health professional to have a specimen collected regardless of the age of the infant. (5-20-87)

101. -- 104. (RESERVED).

105. DUTIES OF RESPONSIBLE PERSONS AND LABORATORIES.

01. Duties Of The Administrator Of The Responsible Institution And/Or The Person Required

To Register The Birth Of A Child. (5-20-87)

a. Provide that prior to the discharge of an infant from the institution where initial newborn care or specialized medical care was rendered, that an adequate blood specimen for testing has been collected. (5-20-87)

b. Within twenty-four (24) hours after collection of the specimen, cause such specimen to be forwarded to the laboratory designated by the Laboratories by first-class mail or its equivalent. All information requested shall accompany the specimen including the name of the infant, the name of hospital, attending physician, birth date and time, specimen date, birth weight, sex, feeding status, and indication of prematurity if applicable. (12-31-91)

c. Maintain a record of all specimens collected. This record shall indicate the name of the infant, name of the attending physician or other attendant, date specimen was collected, and name of person collecting specimen. (5-20-87)

d. Ensure that a protocol for collection and submission of adequate blood specimens has been developed, documented and implemented. Individual responsibilities shall be clearly defined and documented. The attending physician shall automatically request that the test be done. The hospital may make an appropriate charge for this service. (5-20-87)

e. The party responsible for submitting specimens for testing may be charged a fee by the Department for each specimen tested in accordance with the Laboratories fee schedule which has been duly promulgated. (12-31-91)

f. The administrator of the responsible institution or his designee shall be responsible for recording on the birth certificate whether the newborn metabolic screening blood specimen has been collected. (5-20-87)

g. When a birth occurs outside a hospital, the person responsible for registering the birth of the child shall also be responsible for recording on the birth certificate whether the newborn metabolic screening blood specimen has been collected and submitted within twenty-four (24) hours following collection. (5-20-87)

02. Duties Of The Laboratories. (5-20-87)

a. Provide to all Idaho hospitals, physicians and other birth attendants the newborn metabolic screening test kit and preaddressed envelopes for mailing specimens. (5-20-87)

b. Provide the hospital or physician responsible for the collection of the specimen a report on each specimen tested. If no hospital or physician is identified the test results shall be sent to the legal guardian. The hospital, physician, district health department and other attending health professionals shall be notified immediately of abnormal test results and a course of follow-up testing shall be recommended. (5-20-87)

c. Assure that the physician or other attending health professionals collect appropriate follow-up specimens from all infants giving abnormal test results. (5-20-87)

d. Keep a permanent record of name of infant, hospital, attending physician, and a result of test. (9-1-65)

e. Provide follow-up testing services in connection with confirmation of presumptive positive results, and provide for the monitoring of patients on diet therapy. Follow-up testing services must also be provided if the attending physician has reason to believe that the initial sampling may not be valid. (11-1-77)

03. Duties Of Approved Laboratories. (5-20-87)

a. Perform the bacterial inhibition assay test and such other tests as are necessary for detection of metabolic defects, as specified by the Director on all satisfactory specimens at least once each week. (12-31-91)

b. Provide a report on each specimen tested to the Laboratories for distribution to the hospital and/or

physician responsible for the collection of the specimen. Notification of abnormal test results shall be made immediately to the Department Laboratories and attending physicians and health professionals. (12-31-91)

c. Assure that the attending physician and/or other health professionals collect follow-up specimens as required from all infants giving abnormal test results. (5-20-87)

d. Report all positive findings to the Laboratory immediately. (12-31-91)

e. Provide a monthly report to the Laboratories indicating the total number of infants tested. (12-31-91)

f. Keep a permanent record of the name of the infant, hospital, attending physician, and results of all tests. (9-1-65)

106. -- 149. (RESERVED).

150. EXEMPTION.
Compulsory testing for phenylketonuria and other detectable diseases will not apply in the event a religious exemption is claimed from the requirements for prescribed newborn testing for detectable conditions and the person otherwise responsible for submitting the specimen submits a completed statement to the Laboratories signed by the infant's parent(s). (12-31-91)

151. -- 499. (RESERVED).

500. PROCEDURES FOR PREVENTING OPHTHALMIA NEONATORUM.
The rules contained in Sections 500 through 599 pertain to procedures required for the prevention of Ophthalmia Neonatorum. (12-31-91)

01. Duties And Responsibilities Of Physicians And Midwives. (11-1-80)

a. Pursuant to Section 39-903, Idaho Code, any physician or midwife attending the birth of a newborn infant must instill or have instilled in the eyes of the newborn immediately following its birth, some germicide of proven efficiency in preventing the development of ophthalmia neonatorum (see Subsection 500.02). (12-31-91)

b. Pursuant to Section 39-904, Idaho Code, every physician or midwife, in making a report of a birth, must state whether or not the required germicide was instilled in the eyes of the newborn. (11-1-80)

02. Substances Which Fulfill Requirements For Ophthalmic Preparations. 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 the Food and Drug Administration) will satisfy the requirements established herein, pursuant to Section 39-903, Idaho Code. (11-1-80)

03. Duties Of Local Health Officer. Pursuant to Section 39-905, Idaho Code, the local health officer is responsible for the investigation of all cases reported to, or known by him, of inflammation of the eyes of the newborn, and to report all such cases and the results of the investigations to the Board through the Bureau of Preventive Medicine, Department of Health and Welfare. (12-31-91)

04. Duties Of County Clerk. Pursuant to Section 39-907, Idaho Code, all reports of births which fail to show that the required substance was instilled in the eyes of the newborn must be reported by the clerk of the county court to the county prosecuting attorney. (11-1-80)

501. -- 995. (RESERVED).

996. ADMINISTRATIVE PROVISIONS.
Contested case appeals shall be governed by Idaho Department of Health and Welfare Rules, IDAPA 16.05.03, Sections 000, et seq., "Rules Governing Contested Cases and Declaratory Rulings". (12-31-91)

997. CONFIDENTIALITY OF RECORDS.
Any disclosure of information obtained by the Department is subject to the restrictions contained in Idaho Department of Health and Welfare Rules, IDAPA 16.05.01, "Rules Governing the Protection and Disclosure of Department Records". (12-31-91)

998. INCLUSIVE GENDER.
For the purposes of these rules, words used in the masculine gender include the feminine, or vice versa, where appropriate. (11-1-77)

999. SEVERABILITY.
The rules of IDAPA 16.02.12, "Rules Governing Procedures and Testing To Be Performed on Newborn Infants," are severable. If any rule or part thereof, or the application of such rule to any person or circumstance, is declared invalid, that invalidity does not affect the validity of any remaining portion of this chapter. (11-1-77)

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