

# **Rules and Regulations for Mandatory Screening of Newborn Infants for Inborn Errors of Metabolism**

## **CHAPTER 1**

*Emergency rules are no longer in effect 120 days after filing with the Secretary of State.*

### **GENERAL PROVISIONS**

#### **Section 1. Authority.**

The statutory authority for these regulations is contained in W.S. 35-4-801 and 35-4-802. The Statute and Regulations are administered by the Wyoming Department of Health.

#### **Section 2. Purpose and Applicability.**

(a) This Chapter defines the process for the mandatory newborn metabolic screening for infants.

(b) The Department may issue materials to providers and/or other affected parties to interpret the provisions of this Chapter. Such materials shall be consistent with and reflect the rules and regulations contained within this Chapter. The provisions contained in the materials shall be subordinate to the provisions of this Chapter.

#### **Section 3. General Provisions.**

Except as otherwise specified, the terminology used in this Chapter is the standard terminology and has the standard meaning used in accounting and healthcare, including newborn metabolic and hearing screening.

#### **Section 4. Definitions.**

The following definitions shall apply in the interpretation and enforcement of these Rules. Where the context in which words are used in these rules indicates that such is the intent, words in singular number shall include the plural and vice versa. Specific genetic and metabolic tests to be done in Wyoming as by the committee designated in W.S. 35-4-801, Section (b), are as follows:

(a) “Phenylketonuria (PKU).” Genetic metabolic disorder characterized by abnormal phenylalanine metabolism determined.

(b) “Hypothyroidism.” Metabolic disorder caused by inadequate production or secretion of thyroid hormone.

(c) “Galactosemia.” Genetic metabolic disorder characterized by abnormal galactose metabolism.

(d) “Hemoglobinopathies.” Group of genetic diseases, including sickle cell anemia, characterized by the abnormal production and function of hemoglobin.

(e) “Cystic Fibrosis.” Genetic disorder characterized by dysfunction of one or more exocrine systems.

(f) “Biotinidase Deficiency.” Genetic metabolic disorder characterized by abnormal biotinidase production.

(g) Any other genetic metabolic disease for which testing may hereinafter be required on the basis of action taken by the designated committee.

#### Section 5. Consent for Screening.

Consent for screening can be from natural parents, either custodial parent, a sole guardian, single parent having custody, prospective adoptive parents or parent of whom the child’s custody has been released. No test shall be performed until the written consent of the natural parents, the custodial parent, the guardian, or the adoptive parents is obtained. If any parent or guardian objects to the mandatory testing for a child, then the objections shall be in written form and the child exempt from such testing.

#### Section 6. Blood Collection.

(a) Best medical practice indicates that the optimal timing for newborn screening in full-term healthy infants is between twenty-four (24) and forty-eight (48) hours after birth. In early discharge, the blood should be collected as late as possible before discharge, but no later than forty-eight (48) hours after birth.

(b) Any newborn infants requiring exchange transfusions shall have the blood sample for these tests taken prior to the exchange transfusion.

(c) If the child is not born in a hospital, the attending physician, midwife, or person attending the delivery shall arrange to have the blood sample taken by a physician, hospital personnel, laboratory personnel, or local public health representative.

(d) If the child is to be transferred to another hospital, the transferring hospital shall conduct the newborn screen prior to discharge, or make arrangements with the receiving hospital to conduct the screen.

(e) Collection forms provided by the Department of Health shall be completed for each blood sample. Each sample shall be sent to the regional laboratory within 24 hours from the time the sample was collected.

(f) Hospitals will record numbers of births and numbers of infants screened. The hospital record will include the number of infants not screened and the reason why the screening was not performed. Reports will be made to the Department of Health on request, not less than once yearly.

(g) The Department of Health Newborn Metabolic Screening program will provide information brochures and consent forms on request.

Section 7. Second Test.

If the initial screen was conducted prior to 24 hours of age, a second (or follow-up) blood sample should be collected when the infant is approximately ten (10) days to two (2) weeks of age, and may be collected at a hospital laboratory, physician's office, or local public health facility.

Section 8. Fees.

The Wyoming Department of Health will assess all hospitals a fee of \$70.00 for the initial newborn metabolic screen. Said amount is assessed to cover the costs of metabolic screening, follow-up care, genetic counseling, and educational programs and functions. The fees collected also cover costs associated with handling of specimens, reimbursement of laboratory costs, and costs of providing other services necessary to maintain functionality and sustainability of this self-funded program. The Wyoming Department of Health, in consultation with the designated committee, may increase the above assessment, if it is determined that the costs of the program necessitate such increase, but in no instance may this fee be increased more than ten percent (10%).