

Wyoming Administrative Rules

Health, Department of

Mandatory Screening of Newborn Infants

Chapter 1: Mandatory Screening of Newborns for Metabolic and Genetic Conditions

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CHAPTER 1

MANDATORY SCREENING OF NEWBORNS FOR METABOLIC AND GENETIC CONDITIONS

Section 1. Authority. The Wyoming Department of Health (“Department”) promulgates these Rules under Wyoming Statutes 35-4-801, -802.

Section 2. Purpose and Applicability.

(a) The purpose of these Rules is to implement the mandatory screening of newborns program, as provided under W.S. 35-4-801, -802.

(b) The purpose of this Chapter is to establish the requirements and procedures for the mandatory screening of newborns for metabolic and genetic conditions.

Section 3. Definitions.

(a) Except as otherwise specified, the terminology used in these rules is the standard terminology and has the standard meaning used in healthcare, including newborn screening.

(b) The following definitions shall apply in the interpretation and enforcement of these Rules.

(i) “Qualified healthcare professional” means a person licensed to provide healthcare in the state of Wyoming and operating within a scope of practice that includes collecting bloodspot specimens and performing pulse oximetry, as appropriate.

(ii) “Wyoming Newborn Screening Panel” means the mandatory screening for metabolic and genetic conditions to be administered to each child born in Wyoming as contemplated under W.S. 35-4-801(a), which is made publicly available at <https://health.wyo.gov/publichealth/mch/newbornscreening/>.

Section 4. Wyoming Newborn Screening Panel.

(a) As determined by the committee established under W.S. 35-4-801(b), the Wyoming Newborn Screening Panel must include the following tests for metabolic and genetic conditions:

(i) Initial bloodspot specimen collection performed according to section 5 of this Chapter, which screens for amino acid disorders, endocrine disorders, fatty acid oxidation disorders, hemoglobin disorders, organic acid disorders, and other metabolic and genetic disorders.

(ii) Second bloodspot specimen collection performed according to section 6 of this Chapter, which screens for an abbreviated panel; and

(iii) Pulse oximetry screening performed according to section 7 of this Chapter,

which screens for critical congenital heart disease (CCHD).

Section 5. Initial Bloodspot Specimen Collection.

(a) If a child is born in a Wyoming hospital, the hospital shall collect and deliver the child's initial bloodspot specimen for the Wyoming Newborn Screening Panel according to subsection (c) of this section.

(b) If a child is not born in a Wyoming hospital, the person attending the delivery shall arrange to have the child's initial bloodspot specimen collected and delivered according to subsection (c) of this section.

(c) A qualified healthcare professional shall collect a child's initial bloodspot specimen for the Wyoming Newborn Screening Panel according to the following requirements and procedures.

(i) The initial bloodspot specimen must be collected according to the following timelines.

(A) If the child is full-term and healthy, the qualified healthcare professional shall collect the initial bloodspot specimen between twenty-four (24) and forty-eight (48) hours after birth.

(B) If the child is to be discharged before twenty-four (24) hours after birth, the qualified healthcare professional shall collect the initial bloodspot specimen before discharge according to best medical practices.

(C) If the child is not full-term or healthy, the qualified healthcare professional shall collect the initial bloodspot specimen according to best medical practices.

(D) If the child requires an exchange transfusion, the qualified healthcare professional shall collect the initial bloodspot specimen prior to the exchange transfusion and according to best medical practices. If the qualified healthcare professional fails to collect the initial bloodspot specimen prior to the exchange transfusion, the qualified healthcare professional shall indicate that the child was transfused in the appropriate section of the bloodspot specimen collection card.

(E) If the child needs to be transferred to another hospital, the transferring hospital shall ensure that a qualified healthcare professional collect the initial bloodspot specimen prior to transfer or make arrangements with the receiving hospital to collect the initial bloodspot specimen. The transferring hospital shall notify the Wyoming Department of Health Newborn Screening Program if a child is transferred prior to initial bloodspot specimen collection.

(ii) The initial bloodspot specimen must be collected according to the following procedure.

(A) The qualified healthcare professional shall collect the initial bloodspot specimen from capillary blood drawn by heel prick or an alternative method authorized by the Department.

(B) The qualified healthcare professional shall transfer the collected bloodspot specimen directly onto the bloodspot section of the bloodspot specimen collection form provided by the Department. All circles on the form must be saturated with blood from one side only. After saturation, the form must air-dry horizontally on a dry, clean, and non-absorbent surface for three (3) to four (4) hours.

(iii) The initial bloodspot specimen collection form provided by the Department must be completed according to the following procedure.

(A) The qualified healthcare professional shall complete the bloodspot specimen collection form accurately and legibly.

(B) A complete bloodspot specimen collection form must provide all required information including maternal and infant demographics, infant birth weight, time of birth, specimen collection time, physician information, and submitter information.

(iv) The initial bloodspot specimen must be delivered according to the following procedures.

(A) The Department shall ensure access to contracted courier services for timely transport of initial bloodspot specimens collected by qualified healthcare professionals. Timely transport is delivery to the contracted laboratory within twenty-four (24) hours of collection, or as early as possible.

(B) The qualified healthcare professional shall arrange for timely transport of the initial bloodspot specimen via contracted courier service or overnight express services to the contracted laboratory after appropriate dry time and completion of the bloodspot specimen collection form. Timely transport means as defined in subsection (c)(iv)(A) of this section.

(C) A contracted courier service shall pick up initial bloodspot specimens from birthing hospitals and deliver bloodspot specimens to the contracted laboratory.

(d) The Department shall provide program brochures, consent and waiver forms, and specimen collection forms to hospitals, physicians, and other qualified healthcare professionals twice yearly and upon request.

(e) The Department shall ensure access to contracted laboratory services for analysis of initial bloodspot specimens.

Section 6. Second Bloodspot Specimen Collection.

(a) A qualified healthcare professional shall collect a child's second bloodspot specimen for the Wyoming Newborn Screening Panel according to the following requirements and procedures.

(i) The second bloodspot specimen must be collected by a qualified healthcare professional between seven (7) and fourteen (14) days after birth.

(ii) The second bloodspot specimen must be collected according to the following procedure.

(A) The qualified healthcare professional shall collect the second bloodspot specimen from capillary blood drawn by heel prick or an alternative method authorized by the Department.

(B) The qualified healthcare professional shall transfer the collected bloodspot specimen directly onto the bloodspot section of the bloodspot specimen collection form provided by the Department. All circles on the form must be saturated with blood from one side only. After saturation, the form must air-dry horizontally on a dry, clean, and non-absorbent surface for three (3) to four (4) hours.

(iii) The bloodspot specimen collection form provided by the Department must be completed according to the following procedure.

(A) The qualified healthcare professional shall complete the bloodspot specimen collection form accurately and legibly.

(B) A complete bloodspot specimen collection form must provide all required information including maternal and infant demographics, specimen collection time, physician information, and submitter information.

(iv) The qualified healthcare professional shall arrange for transport of the second bloodspot specimen to the contracted laboratory after appropriate dry time and completion of the bloodspot specimen collection form.

(b) The Department shall provide program brochures and specimen collection forms to hospitals, physicians, and other qualified healthcare professionals twice yearly and upon request.

(c) The Department shall ensure access to contracted laboratory services for analysis of second bloodspot specimens.

Section 7. Pulse Oximetry Screening.

(a) If a child is born in a Wyoming hospital, the hospital shall perform pulse oximetry screening for Critical Congenital Heart Disease (CCHD).

(b) If a child is not born in a Wyoming hospital, the person attending the delivery shall arrange for a qualified healthcare professional to perform pulse oximetry screening for CCHD.

(c) Pulse oximetry screening for CCHD must be performed according to best medical practices.

(d) The hospital or qualified healthcare professional shall collect CCHD screening data using a method prescribed by the Department.

(e) The Department shall offer hospitals, physicians, and other qualified healthcare professionals training and resources on national recommendations for CCHD screening.

(f) The Department shall provide brochures to hospitals, physicians, and other qualified healthcare professionals for the purpose of informing families about CCHD screening.

Section 8. Informed Consent.

(a) Before performing the initial and second bloodspot specimen collection or pulse oximetry screening, the qualified healthcare professional shall obtain the informed consent of the child's parent or guardian, according to W.S. 35-4-801(c). The qualified healthcare professional performing the initial bloodspot specimen collection shall inform the child's parent or guardian about the importance of a second bloodspot specimen collection between approximately seven (7) and fourteen (14) days of age.

(b) If a parent or guardian objects to the initial bloodspot specimen collection or pulse oximetry screening:

(i) The child is exempt from the objected screening;

(ii) The parent or guardian shall complete a written waiver form; and

(iii) The qualified healthcare professional shall assure completion of the written waiver form documenting the objection and submit the waiver form to the Department within ten (10) days of birth.

(c) If a parent or guardian objects to the second bloodspot specimen collection:

(i) The child is exempt from the objected screening; and

(ii) The parent or guardian shall complete a written waiver form.

Section 9. Fees.

(a) If a child's initial bloodspot specimen is collected by a qualified healthcare professional at a hospital, the hospital shall pay the Department a fee of \$97.32 per initial bloodspot specimen collection performed.

(b) If a child's initial bloodspot specimen is collected by a qualified healthcare professional in a non-hospital setting, the qualified healthcare professional shall pay the Department a fee of \$97.32 per initial bloodspot specimen collection performed.

(c) The fees assessed under this section cover the reasonable costs of the initial and second bloodspot specimen collection for the same child, initial confirmatory testing, courier services, laboratory services, specialty follow-up services, program education, and other services necessary to maintain functionality and sustainability of this self-funded program.

(d) The Department, in consultation with the designated committee pursuant to W.S. 35-4-801(d), may increase the fees assessed under this section, if it is determined that the cost of the program necessitates such increase, but in no instance may this fee be increased more than twenty-five percent (25%) without revising these rules.