

CHAPTER 1

MANDATORY SCREENING OF NEWBORNS FOR METABOLIC AND GENETIC CONDITIONS

Section 1. Authority.

The Wyoming Department of Health (“Department”) promulgates these Rules under Wyo. Stat. Ann. §§ 35-4-801 through -802.

Section 2. Purpose and Applicability.

(a) The purpose of these Rules is to implement the mandatory screening of newborns program, as provided under Wyo. Stat. Ann. §§ 35-4-801 through -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.

Section 4. Wyoming Newborn Screening Panel.

(a) As contemplated under Wyo. Stat. Ann. § 35-4-801(a), the Wyoming Newborn Screening Panel is the mandatory screening for metabolic and genetic conditions to be administered to each child born in Wyoming.

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

(i) Bloodspot specimen collection performed according to § 5 of this Chapter, which screens for amino acid disorders, endocrine disorders, fatty acid oxidation disorders, hemoglobin disorders, and organic acid disorders; and

(ii) Pulse oximetry screening performed according to § 6 of this Chapter, which screens for critical congenital heart disease (CCHD).

Section 5. Bloodspot Specimen Collection.

(a) If a child is born in a Wyoming hospital, the hospital shall collect and deliver the child's bloodspot specimen for the Wyoming Newborn Screening Panel according to § 5(c) of this Chapter.

(b) If a child is not born in a Wyoming hospital, the person attending the delivery shall arrange to have the child's bloodspot specimen collected and delivered according to § 5(c) of this Chapter.

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

(i) A 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 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 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 bloodspot specimen according to best medical practices.

(D) If the child requires an exchange transfusion, the qualified healthcare professional shall collect the bloodspot specimen prior to the exchange transfusion and according to best medical practices. If the qualified healthcare professional fails to collect the 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 bloodspot specimen prior to transfer or make arrangements with the receiving hospital to collect the bloodspot specimen. The transferring hospital shall notify the Wyoming Department of Health Newborn Screening Program if a child is transferred prior to bloodspot specimen collection.

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

(A) The qualified healthcare professional shall collect the 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) A 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) A bloodspot specimen must be delivered according to the following procedures.

(A) The Department shall ensure access to contracted courier services for timely transport of bloodspot specimens. 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 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 § 5(c)(iv)(A) of this Chapter.

(C) A contracted courier service shall pick up bloodspot specimens from 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 bloodspot specimens.

Section 6. 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 7. Informed Consent.

(a) Before performing a 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 Wyo. Stat. Ann. §§ 35-4-801(c). As part of the informed consent process, the qualified healthcare professional shall educate the child's parent or guardian about the importance of a second bloodspot specimen collection between approximately ten (10) days and two (2) weeks of age.

(b) If a parent or guardian objects to 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.

Section 8. 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 \$84.00 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 \$84.00 per initial bloodspot specimen collection performed.

(c) The fees assessed under §§ 8(a) and (b) of this Chapter 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.