



Certification Page
Regular and Emergency Rules
 Revised September 2016

Emergency Rules (After completing all of Sections 1 through 3, proceed to Section 5 below)

Regular Rules

1. General Information

a. Agency/Board Name Wyoming Department of Health		
b. Agency/Board Address 6101 Yellowstone Rd., Ste. 420	c. City Cheyenne	d. Zip Code 82002
e. Name of Agency Liaison Danielle Marks	f. Agency Liaison Telephone Number 307-777-7944	
g. Agency Liaison Email Address danielle.marks@wyo.gov	h. Adoption Date August 4, 2017	
i. Program Mandatory Screening of Newborn Infants		

2. Legislative Enactment For purposes of this Section 2, "new" only applies to regular rules promulgated in response to a Wyoming legislative enactment not previously addressed in whole or in part by prior rulemaking and does not include rules adopted in response to a federal mandate.

a. Are these rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

No. Yes. Please provide the Enrolled Act Numbers and Years Enacted:

3. Rule Type and Information

a. Provide the Chapter Number, Title, and Proposed Action for Each Chapter.
 (Please use the Additional Rule Information form for more than 10 chapters and attach it to this certification)

Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input checked="" type="checkbox"/> Amended	<input type="checkbox"/> Repealed
1	Mandatory Screening of Newborns for Metabolic and Genetic Conditions	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2	Mandatory Screening of Newborn Infants for Inborn Errors of Hearing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. State Government Notice of Intended Rulemaking

a. Date on which the Proposed Rule Packet (consisting of the Notice of Intent as per W.S. 16-3-103(a), Statement of Principal Reasons, strike and underscore format and a clean copy of each chapter of rules were: **June 21, 2017**

- approved as to form by the **Registrar of Rules**; and
- provided to the **Legislative Service Office** and **Attorney General**:

4. Public Notice of Intended Rulemaking

a. Notice was mailed 45 days in advance to all persons who made a timely request for advance notice. No. Yes. N/A

b. A public hearing was held on the proposed rules. No. Yes. Please complete the boxes below.

Date:	Time:	City:	Location:

c. If applicable, describe the **emergency** which requires promulgation of these rules without providing notice or an opportunity for a public hearing:

5. Final Filing of Rules

a. Date on which the Certification Page with original signatures and final rules were sent to the **Attorney General's Office for the Governor's signature**: **August 4, 2017**

b. Date on which final rules were approved as to form by the **Secretary of State** and sent to the **Legislative Service Office**: **August 4, 2017**

c. The Statement of Reasons is attached to this certification.

6. Agency/Board Certification

The undersigned certifies that the foregoing information is correct.

Signature of Authorized Individual



Printed Name of Signatory

Thomas O. Forslund

Signatory Title

Director

Date of Signature

August 4, 2017

7. Governor's Certification

I have reviewed these rules and determined that they:

1. Are within the scope of the statutory authority delegated to the adopting agency;
2. Appear to be within the scope of the legislative purpose of the statutory authority; and, if emergency rules,
3. Are necessary and that I concur in the finding that they are an emergency.

Therefore, I approve the same.

Governor's Signature

Date of Signature

CHAPTER 1
Mandatory Screening of Newborns for Inborn Errors of Metabolism
[to be re-titled Mandatory Screening of Newborns for Metabolic and Genetic Conditions]

Statement of Reasons

The Wyoming Department of Health proposes to amend *Rules, Wyoming Department of Health, Mandatory Screening of Newborn Infants*, Chapter 1 (2008) pursuant to the provisions of Wyo. Stat. Ann. §§ 35-4-801 through -802. The Department proposes the following changes to Chapter 1:

The Chapter is revised to clarify that the screening covers both metabolic and genetic conditions. This change is reflected throughout the Rule.

Throughout the Rule, the term “child” replaces “infant” and “newborn” to reduce confusion and inconsistency.

Section 3, Definitions, is revised to include the definition of qualified healthcare professional. This revision clarifies the type of provider authorized by this Rule to perform newborn screening.

An entire section, Section 4, Wyoming Newborn Screening Panel, is added to summarize the metabolic and genetic conditions included on the Wyoming Newborn Screening Panel determined by the committee designated by Wyo. Stat. Ann. §§ 35-4-801(b). The list includes general categories of conditions instead of specific conditions. The list is separated by the type of screening method: (i) bloodspot collection and (ii) pulse oximetry screening. The list adds critical congenital heart disease (CCHD). On May 6, 2016, the designated committee voted to add CCHD, a group of heart defects, or structural or functional heart abnormalities present at birth that cause serious often life-threatening symptoms to the Wyoming Newborn Screening Panel.

Section 5, Bloodspot Specimen Collection replaces the previous Section 6, Blood Collection. Section 5 covers the process of collecting bloodspot specimens including collection timelines, collection procedures, delivery, and documentation. Edits to this section include:

- Section 5(c)(i)(A)
The recommended timeline for specimen collection is updated to align with best medical practice.
- Section 5(c)(i)(C)
The bloodspot specimen collection process for newborns requiring exchange transfusions is revised to add clarification and documentation instructions when a bloodspot specimen is not collected prior to transfusion.
- Section 5(c)(i)(D)

The program now requires transferring hospitals to notify the Wyoming Department of Health Newborn Screening Program when an infant is transferred before collection of the bloodspot specimen. This change will aid program tracking of bloodspot specimen collection when completed at a different hospital than the delivery hospital.

- Section 5(c)(ii)
This section describes the process of collecting the bloodspot specimen, including proper technique. This addition will require that providers performing the newborn screen do so in a high quality and timely manner.
- Former Section 6(f) is deleted due to the ability of the program data system to collect this information. The deletion of this provision will reduce hospital's reporting burden.
- Section 5(c)(iii)
Instructions for completing the specimen collection form are clarified in order to improve completeness and quality of data entered onto the card.
- Section 5(c)(iv)
This section describes the process and recommended timing for transporting bloodspot specimens to the contracted laboratory in Denver, Colorado. The Wyoming Department of Health ensures access to contracted courier services, and providers performing the newborn screen must be aware of this service and use it in a timely manner. The transportation of specimens greatly impacts timeliness so therefore additional clarification in this section is warranted. If the contracted courier service is not available to a qualified healthcare professional, the Department recommends use of overnight express services to transport specimens.
- Section 5(d)
This section is revised to clarify the types and manner in which educational materials and forms are provided to hospitals by the Wyoming Department of Health.
- Section 5(e)
This section is revised to clarify the Department's responsibility to ensure access to contracted laboratory services for analysis of bloodspot specimens.

An entire section, Section 6, is added to summarize new requirements for pulse oximetry screening for CCHD. On May 6, 2016, the Wyoming Newborn Screening Panel Advisory Committee, a committee designated by Wyo. Stat. Ann. §§ 35-4-801(b), voted to add CCHD to the Wyoming Newborn Screening Panel. Hospitals are required to perform pulse oximetry screening for CCHD and collect data on CCHD screening using a method prescribed by the Wyoming Department of Health.

Section 7(a) adds the requirement of the qualified healthcare professional performing the newborn screen to provide parents or guardians education on the importance of a second bloodspot specimen collection between ten (10) days and two (2) weeks of age. This content was removed from the former Section 7, Second Test.

Section 7(b)(iii) adds a requirement that written waiver forms shall be sent to the Wyoming Department of Health Newborn Screening Program within ten (10) days of birth. This requirement will help the program collect and monitor data on the reasons for missed screens.

Section 8 increases the fee assessed for each initial newborn metabolic and genetic screen. On May 6, 2016, the Wyoming Newborn Screening Panel Advisory Committee, a committee designated by Wyo. Stat. Ann. §§ 35-4-801(b), voted to increase the newborn screening fee billed to hospitals and providers who perform the first (initial) newborn screen to \$84.00. This change will allow the self-funded program to cover increasing costs associated with laboratory, courier, and specialty follow-up services.

CHAPTER 2

Mandatory Screening of Newborn Infants for Inborn Errors of Hearing

Statement of Reasons

The Wyoming Department of Health proposes to amend *Rules Wyoming Department of Health, Mandatory Screening of Newborn Infants*, Chapter 2 (2008) pursuant to the provisions of Wyo. Stat. Ann. §§ 35-4-801, -802.

Section 9, Consent for Newborn Hearing Screening, includes an updated reference to revised Chapter 1, Mandatory Screening of Newborns for Metabolic and Genetic Conditions.

No additional changes are made to Chapter 2. After Chapter 1 is promulgated, the Department intends to revise Chapter 2 in the same form as Chapter 1.

Newborn Screening Rule Change- Public Comments

Date	5/11/17
Name	Stephanie Pitt, steffipitt2@gmail.com
Address	125 Virginian Ln Jackson, WY 83001
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p>
Date	5/11/17
Name	DeSharia Uribe, desharia.uribe@hotmail.com
Address	1208 W Hill Rd Laramie, WY 82072
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p>
Date	5/11/17
Name	Joanna Behrens, jbehrens32@gmail.com
Address	178 Piute Dr Star Valley Ranch, WY 83127
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p>
Date	5/15/17

Name	Cameon Berkovitz, camberkovitz@gmail.com
Address	112 W Kendrick St Rawlins, WY 82301
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>My son was born with CHD and I was a miracle that he lived long enough to be dignosed. This simple test would have caught it sooner.</p> <p>I know I don't need to tell you how prevalent this condition is so please help us</p> <p>Thank you for your time and consideration.</p>
Date	5/11/17
Name	Jenny Karns, jennykarnski@gmail.com >
Address	3145 Mallard Rd Jackson, WY 83001
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p>
Date	5/12/17
Name	Jamey Miles, ladymiles13@hotmail.com
Address	PO Box 3356 Jackson, WY 83001
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p>
Date	5/12/17
Name	Mary Sternitzke, mesrox@gmail.com

Address	821 W Pershing Blvd Cheyenne, WY 82001
Content	<p>To Whom It May Concern,</p> <p>As a child psychologist working with young children, I constantly see the need for health screening and identification of problems at the earliest ages possible. The sooner we know a child needs intervention and it is implemented, the greater productivity and contribution each and every child is able to make to our economy and communities.</p> <p>Thank you to the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration</p>
Date	6/15/17
Name	Kristen Waters, kristen.waters@heart.org
Address	315 Blair Dr Jackson, WY 83001
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p> <p>Regards, Kristen Waters</p>
Date	6/15/17
Name	Victoria Mann-Olson, vmolson@gmail.com
Address	910 Ln 10 Powell, WY 82435
Content	<p>To Whom It May Concern,</p> <p>I applaud the Wyoming Department of Health for recognizing the need to screen Wyoming newborns for critical congenital heart defects using pulse oximetry testing.</p> <p>Please move this life-saving policy forward with urgency so that Wyoming newborns will receive a required screening. Early detection is key and through pulse oximetry screening, we can catch life threatening heart conditions in newborns before they go home from the hospital.</p> <p>Thank you for your time and consideration.</p> <p>Regards,</p>

	Victoria Mann-Olson
Date	6/19/17
Name	Kristen Waters, Kristen.Waters@heart.org
Address	Teton Village, WY 83025
Content	<p>Dear Ms. Marks,</p> <p>The American Heart Association (AHA) would like to applaud the efforts of the Department of Health, Newborn Screening Committee, the Attorney General's office and Governor Matt Mead for moving forward to amend the newborn screening tests required by the state to include critical congenital heart defect (CCHD) screening in all newborns. There is no doubt that this resolution will save the lives and lifestyles of Wyoming's smallest and most vulnerable residents.</p> <p>In 2011 U.S. Secretary of Health and Human Services Kathleen Sebelius suggested that CCHD screening be added to the recommended uniform screening panel for all newborns before they are released from a hospital or birthing facility. Since then, 45 states and the District of Columbia, now screen for critical congenital heart defects using a small, non-invasive device, called Pulse Oximetry. Pulse Oximetry is the most accurate method to screen for CCHD according to research by The American Heart Association and the American Academy of Pediatrics. On behalf of the AHA, I am pleased that Wyoming will soon be joining that list.</p> <p>But, there is still a sense of urgency that Wyoming move quickly to implement this life-saving tool in all 21 birthing facilities located across the state. As of now, there are still many hospitals that are not using this simple test to screen for CCHDs, and there is not a centralized process to ensure if all newborns are screened.</p> <p>With each day that passes without this requirement, there is a risk of parents bringing home a newborn from the hospital with an undetected life-threatening illness. In fact, the risk is high because CCHD is the most common form of birth defects, affecting 1 in 100 babies, making it the No. 1 killer of infants. As an example of how each day matters, just hours after a law requiring pulse oximetry testing on all newborns went into effect in New Jersey, a baby's life was saved. This story is not uncommon upon passage of pulse oximetry requirements.</p> <p>Again, on behalf of the AHA, would like to extend my gratitude and appreciation for the work that the state of Wyoming and Newborn Screening Committee have done thus far in preparing to amend the newborn screening rules to include CCHD screening by use of pulse oximetry. I hope that the state will continue to move swiftly to implement these rules, so that no baby goes home undetected and that each new parent can go home and rest easy, knowing that the newest addition to their family has been screened. Thank you for considering my comments.</p> <p>Kristen Waters Wyoming Government Relations and Community Integration Director American Heart Association – American Stroke Association</p>
Date	6/20/17
Name	James A Boxall, Jboxall@acc.org
Address	American College of Cardiology 2400 N Street, NW Washington, DC 2003
Content	<p>Dear Ms. Marks:</p> <p>The American College of Cardiology (ACC) welcomes the opportunity to comment on the Wyoming Health Department's amended rules for Chapter 1 Mandatory Screening of Newborns for Metabolic and Genetic Conditions.</p>

The ACC is the professional home for the entire cardiovascular care team. The mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines.

Since 2011 the ACC has supported the mandatory adoption of pulse oximetry screening to detect critical congenital heart defects (CCHD) in all states and the District of Columbia. ACC commends the Wyoming Department of Health for the amended rules in Chapter 1 Mandatory Screening of Newborns for Metabolic and Genetic Conditions which will require that every child born in Wyoming be screened for CCHD. ACC strongly supports these amended rules and offers the following comments.

Section 6 Pulse Oximetry Screening

The ACC supports the comprehensiveness of this section. Section 6 (a) requires hospitals to provide pulse oximetry screening for CCHD. Section 6 (b) assures that all Wyoming children wherever they are born will be screened for CCHD. Section 6 (d) fulfills an important goal of the pediatric cardiology community by requiring the collection of data upon newborn screening for CCHD. Sections 6 (e) and 6 (f) require the Department of Health to offer training in pulse oximetry screening to healthcare professionals and educational materials that healthcare professionals can use to educate parents or guardians on the importance of pulse oximetry screening.

Section 7 Informed Consent

The ACC recommends the addition of the following sentence at the end of Section 7 (a) "The qualified healthcare professional shall also educate the parent or guardian on the importance of performing pulse oximetry screening to detect CCHD." The College supports the remainder of Section 7 as proposed.

Respectfully Submitted,

James A. Boxall, Jr.
Associate Director, State Government Affairs

Date	6/20/17
Name	Matt LaHiff, NCQA CCE, Matt.LaHiff@crmcwy.org
Address	Cheyenne Regional Medical Center
Content	https://drive.google.com/open?id=0B8W6al9MchOdTmJnbnJ1cGJHMxEzYkVHRmk3LUJURmJMTFJv

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.

CHAPTER 1

MANDATORY SCREENING OF NEWBORNS INFANTS FOR INBORN ERRORS OF METABOLISM METABOLIC AND GENETIC CONDITIONS

CHAPTER 1

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 1. Authority.

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

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 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, -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. 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~~

Effective 04/28/2008

~~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 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 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 objection shall be in written form and the child exempt from such testing.~~

Section 4. Wyoming Newborn Screening Panel.

Effective 04/28/2008

(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 6. — Blood Collection.

~~(a) The optimal timing for newborn screening in full-term healthy infants is between 48 and 72 hours of age. In early discharge, the blood should be collected as late as possible before discharge, but no later than 72 hours of age.~~

~~(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~~

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~~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 will provide information brochures and consent forms on request.~~

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.

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(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 7. — Second Test.~~

~~Effective 04/28/2008~~

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

(e) 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.

~~The Wyoming Department of Health will assess all hospitals a fee of \$70.00 for~~

~~Effective 04/28/2008~~

~~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%).~~

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.

CHAPTER 2

MANDATORY SCREENING OF NEWBORN INFANTS FOR INBORN ERRORS OF HEARING

Section 1. Authority.

The statutory authority for these regulations is contained in W.S. 35-4801 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 hearing 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. Hearing Screening.

(a) Hearing screening shall be given to every child born in the State of Wyoming.

(b) If the child is not born in a hospital, the attending physician, midwife, or person attending the delivers shall offer to arrange a hearing screening for the child at a Wyoming birthing hospital.

(c) If a newborn is transferred to another Wyoming birthing hospital, the hospital that discharges the child shall be responsible for ensuring that the hearing screening takes place. If a Wyoming resident newborn is transferred to a hospital outside of Wyoming, the discharging Wyoming hospital shall ensure that hearing screening takes place either prior to discharge or upon the infant's return to Wyoming.

(d) Newborn hearing screening and/or re-screening may be delayed due to transfers and/or medical contraindications. The hospital must document the delays, and

ensure hearing screening has taken place prior to ultimate discharge.

(e) All screening results shall be reported at least monthly to the Wyoming Department of Health and be reviewed by a State approved audiology consultant. The reported data shall include:

- (i) total number of births;
- (ii) the number of newborns initially screened before discharge;
- (iii) the number of newborns rescreened upon returning to the hospital;
- (iv) the pass-fail results of all screenings;
- (v) the number of newborns not screened due to parental/legal guardian waiver, medical contraindications, or lost to follow-up; and
- (vi) any other screening results deemed as useful by the Wyoming Department of Health.

(f) Each birthing hospital shall establish a system to facilitate the referral for diagnostic audiological assessment for neonates who fail the newborn hearing screening. This includes, but is not limited to:

(i) Written notification to the primary care physician that the child has failed the newborn hearing screening and that diagnostic audiological assessment is recommended;

and

(ii) Written notification to the parent(s)/legal guardian(s) that the child has failed the newborn hearing screening, diagnostic audiological assessment is recommended, and the primary care physician has been notified.

Section 5. Chronology of Newborn Hearing Screening.

- (a) Each newborn's hearing shall be screened before discharge from the hospital.
- (b) If a newborn fails the first screening, the screening procedure shall be immediately repeated before discharge from the hospital.

Section 6. Rescreening.

(a) Each newborn failing both initial screen(s) will be rescreened within seven (7) to ten (10) days of the initial screen(s).

Section 7. Method of Screening.

(a) Newborn screening and the documentation and dissemination of screening results shall be done by trained personnel, under the supervision of a State approved audiology consultant. Training procedure information will be audiologicaly approved and accepted.

(b) All screenings shall involve both ears.

(c) Birthing hospitals shall use one of the following screening methods:

(i) Auditory Brainstem Responses (ABR);

(ii) Automated Auditory Brainstem Responses (AABR); or

(iii) Otoacoustic Emissions (OAE), either Transient Evoked OAE (TEOAE) or Distortion Product OAE (DPOAE).

(d) Instrumentation, electrode array, and transducer arrangements shall be in accordance with recommendations/specifications from the manufacturer of the screening device.

Section 8. Criteria to Pass Hearing Screening.

(a) Normal ABR for click stimuli at 35 dBnHL (decibels of normal hearing levels) or less in each ear; or

(b) Normal TEOAE for click stimulus at 84 dB SPL (decibels of sound pressure levels) presentation level or less in each ear; or

(c) Normal DPOAE for 1500-6000 Hz (hertz) stimuli at 65-55 dB SPL or less in each ear.

Section 9. Consent for Newborn Hearing Screening.

(a) Parental/legal guardian consent for screening shall be obtained pursuant to *Rules, Wyoming Department of Health, Mandatory Screening of Newborn Infants*, Chapter 1, §7 (2017).

Section 10. Fees.

The Wyoming Department of Health will assess all hospitals a fee of \$50.00 for the initial newborn hearing screen. Said amount is assessed to cover the costs of hearing screening, follow-up care, and referrals when the initial screen detects a potential abnormality, screening equipment costs and educational programs and training. The assessed fees will only be used to provide the services necessary to maintain functionality and

sustainability of the Early Hearing Detection and Intervention Program, which is a 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%).

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OF HEARING**

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