



# Certification Page Regular and Emergency Rules

Revised July 2019

**Emergency Rules** (Complete Sections 1-3 and 5-6)

**Regular Rules**

<b>1. General Information</b>			
a. Agency/Board Name <b>Wyoming Department of Health</b>			
b. Agency/Board Address <b>401 Hathaway Building</b>		c. City <b>Cheyenne</b>	d. Zip Code <b>82002</b>
e. Name of Agency Liaison <b>Heather Canarecci</b>		f. Agency Liaison Telephone Number <b>307-777-8028</b>	
g. Agency Liaison Email Address <b>heather.canarecci2@wyo.gov</b>		h. Adoption Date <b>4/29/2020</b>	
i. Program <b>Mandatory Screening of Newborn Infants</b>			
<b>2. Legislative Enactment</b> For purposes of this Section 2, "new" only applies to regular (non-emergency) 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 non-emergency or regular rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?			
<input checked="" type="checkbox"/> <b>No.</b> <input type="checkbox"/> <b>Yes.</b> If the rules are new, please provide the Chapter Numbers and Years Enacted (e.g. 2015 Session Laws Chapter 154):			
<b>3. Rule Type and Information</b> For purposes of this Section 3, "New" means an emergency or regular rule that has never been previously created.			
a. Provide the Chapter Number, Title* and Proposed Action for Each Chapter. <i>Please use the "Additional Rule Information" form to identify additional rule chapters.</i>			
Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed	
<b>1</b>	Mandatory Screening of Newborns for Metabolic and Genetic Conditions		
Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed	
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Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed	
Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed	

\* If the name of a chapter of rules is changing, please only provide the NEW chapter name on this rules certification form.

**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:


**5. Checklist**

a.  For regular rules, the Statement of Principal Reasons is attached to this Certification and, in compliance with Tri-State Generation and Transmission Association, Inc. v. Environmental Quality Council, 590 P.2d 1324 (Wyo. 1979), includes a brief statement of the substance or terms of the rule and the basis and purpose of the rule

b.  For emergency rules, the Memorandum to the Governor documenting the emergency, which requires promulgation of these rules without providing notice or an opportunity for a public hearing, is attached to this Certification.

**6. Agency/Board Certification**

The undersigned certifies that the foregoing information is correct. By electronically submitting the emergency or regular rules into the Wyoming Administrative Rules System, the undersigned acknowledges that the Registrar of Rules will review the rules as to form and, if approved, the electronic filing system will electronically notify the Governor's Office, Attorney General's Office, and Legislative Service Office of the approval and electronically provide them with a copy of the complete rule packet on the date approved by the Registrar of Rules. The complete rules packet includes this signed certification page; the Statement of Principal Reasons or, if emergency rules, the Memorandum to the Governor documenting the emergency; and a strike and underscore copy and clean copy of each chapter of rules.

Signature of Authorized Individual	
Printed Name of Signatory	Michael A. Ceballos
Signatory Title	Director, Wyoming Department of Health
Date of Signature	04/01/2020

**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	



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Michael A. Ceballos  
Director

Mark Gordon  
Governor

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## MEMORANDUM

**Date:** March 25, 2020

**To:** Governor Mark Gordon

**From:** Michael A. Ceballos, Director  
Wyoming Department of Health

**Subject:** Proposed Extension of Emergency Rules for the Wyoming Department of Health Rules, Chapter 1, Emergency Rule for Mandatory Screening of Newborns for Metabolic and Genetic Conditions

**Ref:** C-2020-102

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**Priority:** High. Deadline for Response is April 28, 2020.

**Summary:** The Department of Health seeks to extend the emergency amendment of *Rules, Wyoming Department of Health, Mandatory Screening of Newborn Infants*, chapter 1 (2017), which regulate the mandatory screening of newborns for metabolic and genetic disorders pursuant to Wyo. Stat. Ann. §§ 35-4-801 and -802.

The emergency amendment of these rules took effect December 31, 2019, and is set to expire on April 29, 2020. The purpose of the emergency amendment was to add Spinal Muscular Atrophy (SMA) to the Wyoming Newborn Screening Panel. SMA is a rare genetic condition affecting 1 in 10,000 live births. Early identification, diagnosis, and treatment improves motor outcomes and lowers the risk of death or needing a ventilator in people with SMA. An emergency amendment was necessary to add SMA to the Wyoming Newborn Screening Panel due to events out of the Department's control at the Colorado Department of Public Health and Environment (CDPHE), who performs laboratory analysis for Wyoming newborn screening specimens. The CDPHE lab implemented screening for SMA effective January 1, 2020, for both Colorado and Wyoming, however, the CDPHE lab acted before the Department could formally prescribe the manner for performing SMA screening in rule as required by W.S. 35-4-801(a).

The Department now seeks to extend the emergency amendment due to time spent finalizing additional content to be proposed with the formal amendment of these rules; increased workload

during the 2020 legislative session; and unforeseen circumstances resulting from the COVID-19 state of emergency and public health emergency.

To ensure there is no lapse between the expiration of the emergency amendments to these rules, as extended, and the formal promulgation of amendments through the regular rulemaking process, the proposed rules packet is being submitted concurrently with this emergency rules extension packet.

Enclosed is the emergency rules extension packet.

**Agency Contact Name:** Carleigh Soule, Newborn Screening and Genetics Coordinator

**Agency Contact Phone:** 307-777-6297

**Agency Contact Email:** carleigh.soule@wyo.gov

MAC/cs

c: Stephanie Pyle, MBA, Senior Administrator, Public Health Division

## CHAPTER 1

### Mandatory Screening of Newborns for Metabolic and Genetic Conditions

#### Intent to Create Emergency Rule

#### **Statement of Reasons**

The Wyoming Department of Health (Department) proposes to create an emergency amendment to *Rules, Wyoming Department of Health, Mandatory Screening of Newborn Infants*, Chapter 1 (2017).

Wyoming Statute 35-4-801(a) requires the mandatory screening of newborns for metabolic and genetic disorders to be performed in the manner prescribed in rule by the Wyoming Department of Health. This Fall, the Wyoming Newborn Screening Advisory Committee, the committee established under W.S. 35-4-801(b), decided to add a new screen to the newborn screening panel for spinal muscular atrophy. Spinal muscular atrophy (SMA) is a rare genetic condition affecting 1 in 10,000 live births. Early identification, diagnosis, and treatment improves motor outcomes and lowers the risk of death or needing a ventilator in people with SMA.

The Department intends to prescribe the manner for performing SMA screening, as required under W.S. 35-4-801(a), through the regular rulemaking process, however, recent developments require an emergency amendment to immediately add SMA to the Wyoming Newborn Screening Panel.

The Department contracts with the Colorado Department of Public Health and Environment (CDPHE) to perform laboratory analysis for Wyoming newborn screening specimens. The CDPHE lab plans to implement SMA screening beginning January 1, 2020, for both Colorado and Wyoming newborn samples. And, due to how screening is performed, the CDPHE lab will be unable to refrain from SMA screening while administering the Wyoming Newborn Screening Panel. This presents the following legal and ethical dilemma to the Department:

1. Legally, this means that SMA screening will not be performed in a manner prescribed in rule as required by W.S. 35-4-801(a), because a regular rule change would not be effective by January 1, 2020.
2. Ethically, this means that the Department would still have to notify parents that their newborn has screened positive for SMA, regardless if the screening was performed pursuant to W.S. 35-4-801(a).

Accordingly, the Department now seeks the emergency amendment of *Rules, Wyoming Department of Health, Mandatory Screening of Newborn Infants*, chapter 1 (2017) to account for SMA screening, effective as close to January 1, 2020, as possible. Shortly after the filing of this emergency rule, the Department will promulgate a permanent rule through the regular rulemaking process.

## CHAPTER 1

### MANDATORY SCREENING OF NEWBORNS FOR METABOLIC AND GENETIC CONDITIONS

#### Emergency rules are in effect no longer than 120 days after filing with the Registrar of Rules

**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) 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. 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, organic acid disorders, and other metabolic and genetic disorders.

(ii) Pulse oximetry screening performed according to § 6 of this Chapter,

which screens for critical congenital heart disease (CCHD).

(c) The Wyoming Newborn Screening Panel is found at <https://health.wyo.gov/publichealth/mch/newbornscreening/> and made available by the Department upon 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.

(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.

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