



Notice of Intent to Adopt Rules

A copy of the proposed rules may be obtained at <http://rules.wyo.gov>

Revised July 2019

1. General Information

a. Agency/Board Name*		
b. Agency/Board Address	c. City	d. Zip Code
e. Name of Agency Liaison		f. Agency Liaison Telephone Number
g. Agency Liaison Email Address		
h. Date of Public Notice		i. Comment Period End Date
j. Public Comment URL or Email Address:		
k. Program		

* By checking this box, the agency is indicating it is exempt from certain sections of the Administrative Procedure Act including public comment period requirements. Please contact the agency for details regarding these rules.

2. Legislative Enactment

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 regular rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

No. Yes. If the rules are new, please provide the Chapter Numbers and Years Enacted (e.g. 2015 Session Laws Chapter 154):

3. Rule Type and Information

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. Please use the "Additional Rule Information" form to identify additional rule chapters.

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 Repealed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 Repealed
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 Repealed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 Repealed
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 Repealed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 Repealed
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 Repealed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 provide the NEW chapter name in parenthesis following the OLD chapter name. Example: Old Chapter Name: General Provisions; New Chapter Name: General Provisions and Requirements. This would appear as "General Provisions (General Provisions and Requirements)."

4. Public Comments and Hearing Information

a. A public hearing on the proposed rules has been scheduled. No. Yes. Please complete the boxes below.

Date:	Time:	City:	Location:
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b. What is the manner in which interested persons may present their views on the rulemaking action?

By submitting written comments to the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: _____

A public hearing will be held if requested by 25 persons, a government subdivision, or by an association having not less than 25 members. Requests for a public hearing may be submitted:

To the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: _____

c. Any person may urge the Agency not to adopt the rules and request the Agency to state its reasons for overruling the consideration urged against adoption. Requests for an agency response must be made prior to, or within thirty (30) days after adoption, of the rule, addressed to the Agency and Agency Liaison listed in Section 1 above.

5. Federal Law Requirements

a. These rules are created/amended/revoked to comply with federal law or regulatory requirements. No. Yes. Please complete the boxes below.

Applicable Federal Law or Regulation Citation:
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Indicate one (1):

The proposed rules meet, but do not exceed, minimum federal requirements.

The proposed rules exceed minimum federal requirements.

Any person wishing to object to the accuracy of any information provided by the Agency under this item should submit their objections prior to final adoption to:

To the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: _____

6. State Statutory Requirements

a. Indicate one (1):

The proposed rule change *MEETS* minimum substantive statutory requirements.

The proposed rule change *EXCEEDS* minimum substantive statutory requirements. Please attach a statement explaining the reason that the rules exceed the requirements.

b. The Agency has completed a takings assessment as required by W.S. 9-5-304. A copy of the assessment used to evaluate the proposed rules may be obtained:

By contacting the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: _____

7. Additional APA Provisions

a. Complete all that apply in regards to uniform rules:

These rules are not impacted by the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j).

The following chapters do not differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j):

_____ (Provide chapter numbers)

These chapters differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j) (see Statement of Principal Reasons).

_____ (Provide chapter numbers)

b. Checklist

The Statement of Principal Reasons is attached to this Notice 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.

If applicable: In consultation with the Attorney General's Office, the Agency's Attorney General representative concurs that strike and underscore is not required as the proposed amendments are pervasive (Chapter 3, *Types of Rules Filings*, Section 1, Proposed Rules, of the Rules on Rules).

8. Authorization

a. I certify that the foregoing information is correct.

<i>Printed Name of Authorized Individual</i>	
<i>Title of Authorized Individual</i>	
<i>Date of Authorization</i>	

CHAPTER 1
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 (2019) pursuant to the provisions of Wyoming Statutes 35-4-801, -802. The Department states its reasons for amending chapter 1, as follows.

1. Section 3 is revised to add a definition for “Wyoming Newborn Screening Panel,” as designated by W.S. 35-4-801(a). The URL for the Wyoming Newborn Screening Program website was added to make the list of conditions on the Wyoming Newborn Screening Panel publicly accessible.
2. Section 4 is revised to add language pertaining to required collection of the second newborn screen by a qualified healthcare professional, also referenced in section 6.
3. Section 5 is revised to establish that the outlined requirements by which bloodspot specimens must be collected only apply to the initial bloodspot specimen collection. The word ‘initial’ is added throughout, as appropriate.
4. Section 6 is added. This section prescribes the process by which a second bloodspot must be collected between seven (7) and fourteen (14) days after birth. To include collection timeliness, collection procedures, delivery, and documentation. Collection of a second bloodspot specimen is important in identifying certain conditions that may be missed in the initial bloodspot specimen collection. The Wyoming Department of Health contracts with the Colorado Department of Public Health and Environment (CDPHE) for laboratory services for Wyoming newborn screening specimens. Colorado is a two-screen state. CDPHE laboratory equipment is calibrated assuming babies receive an initial and second bloodspot screen. This rule change will align rules and processes between the Wyoming Department of Health and CPDHE, its contracted laboratory.
5. Section 8 is revised to add language to ensure informed consent is obtained by the qualified healthcare professional performing the screen for both the initial and second screen. Edits to this section include:
 - a. At Section 8(a), adding the words “initial” and “second” to encompass both screens, and clarification that the qualified healthcare professional performing the initial bloodspot specimen collection shall inform parents about the importance of a second bloodspot specimen collection between approximately seven (7) and fourteen (14) days of age; and
 - b. At Section 8(c)(i)-(ii), adding language specific to procedures when parents or guardians objects to a second bloodspot specimen collection.
6. Section 9 is revised to increase the fee schedule. This program is self-funded, and covers the laboratory services for first and second screens, courier services for initial screens, and specialty follow-up services. On August 30, 2019, the Wyoming Newborn Screening Panel Advisory Committee, the committee designated by W.S. 35-4-801(b), voted to increase the newborn screening fee billed to hospitals and providers who perform the initial newborn screen. Accordingly, pursuant to W.S. 35-4-801(d), edits to this section include:
 - a. At Section 9(a), increasing the fee per initial bloodspot specimen from \$84.00 to \$97.32 for hospitals; and
 - b. At Section 9(b), increasing the fee per initial bloodspot specimen from \$84.00 to \$97.32 for qualified healthcare professionals in a non-hospital setting.

7. Further, at Section 9(c), language is added to give the program authority to increase the fee by twenty-five percent (25%) if the program necessitates it and it is voted on by the Wyoming Newborn Screening Panel Advisory Committee pursuant to W.S. 35-4-801(d). Similar authority already exists for a sister program: the mandatory screening of newborn infants for inborn errors in hearing. *See Rules, Wyo. Dep't of Health, Mandatory Screening of Newborn Infants*, ch. 2, § 10 (2017).

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.

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. §§~~ Wyoming Statutes 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. §§~~ W.S. 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.

(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 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)(a)~~ As determined by the committee established under ~~Wyo. Stat. Ann. §~~ 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, ~~and~~ organic acid disorders, and other metabolic and genetic

disorders; and

(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 ~~§ 6~~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 ~~§ 5(e) 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 initial bloodspot specimen collected and delivered according to subsection (c) of this section ~~§ 5(e) of this Chapter.~~

(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) ~~A~~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) ~~A~~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) ~~A~~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) ~~A~~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 5(c)(iv)(A) of this section~~Chapter~~.

(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 67. 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 78. Informed Consent.

(a) Before performing a the initial or 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 ~~Wyo. Stat. Ann. §§ W.S. 35-4-801(c). As part of the informed consent process,~~ The qualified healthcare professional performing the initial bloodspot specimen collection shall educate inform the child's parent or guardian about the importance of a second bloodspot specimen collection between approximately ~~ten (10)~~ seven (7) days and ~~two (2)~~ fourteen (14) days weeks 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 89. **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~~ 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 ~~84.00~~ 97.32 per initial bloodspot specimen collection performed.

(c) The fees assessed under ~~this section §§ 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.

(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.