Dear Senators VANORDEN, Wintrow, and
Representatives VANDER WOUDE, Erickson, Rubel:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Department of Health and Welfare:

IDAPA 16.02.12 - Newborn Screening (ZBR Chapter Rewrite) - Proposed Rule (Docket No. 16-0212-2401).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 12/03/2024. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 12/31/2024.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4854, or send a written request to the address on the memorandum attached below.

Terri Kondeff
Director

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Legislative Drafter - Kyle Slominski

DATE: November 14, 2024

SUBJECT: Department of Health and Welfare

IDAPA 16.02.12 - Newborn Screening (ZBR Chapter Rewrite) - Proposed Rule (Docket No. 16-0212-2401)

Summary and Stated Reasons for the Rule

The Department of Health and Welfare submits notice of proposed rulemaking at IDAPA 16.02.12, regarding newborn screening. The Department states that this is a Zero Based Regulation chapter rewrite pursuant to Executive Order 2020-01. The Department states that the proposed rule specifies tests and procedures that must be performed on newborn infants for early detection of various disorders and conditions and to prevent infant blindness. The proposed rule makes revisions to these procedures and updates incorporation by reference material.

Negotiated Rulemaking / Fiscal Impact

The Department states that negotiated rulemaking was not conducted. The Department notes that two public meetings were posted on Townhall Idaho and received public responses. The Department states that there is no anticipated negative fiscal impact.

Statutory Authority

The rulemaking appears to be authorized pursuant to Sections 39-906, 39-909, 39-910, and 56-202, Idaho Code

cc: Department of Health and Welfare
Jared Larsen

***** PLEASE NOTE *****

Per the Idaho Constitution, all administrative rules may be reviewed by the Legislature during the next legislative session. The Legislature has 3 options with this rulemaking docket: **1)** Approve the docket in its entirety; **2)** Reject the docket in its entirety; or **3)** Reject the docket in part.

IDAPA 16 – DEPARTMENT OF HEALTH AND WELFARE

16.02.12 – NEWBORN SCREENING

DOCKET NO. 16-0212-2401 (ZBR CHAPTER REWRITE)

NOTICE OF RULEMAKING – PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-202, Idaho Code, and Sections 39-906, 39-909, and 39-910, Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

VIRTUAL TELECONFERENCE Via WebEx
Wednesday, September 18, 2024 **12:00-1:00 p.m. (MT)**
Join from the meeting link **https://idhw.webex.com/idhw/j.php?MTID=mca1c94cd6d168f5453c5de6efd5a03bb** **Join by meeting number** **Meeting number (access code): 2821 229 7212** **Meeting password: njSjbpUC695 (65752782 when dialing from a phone or video system)** **Join by phone** **+1-415-527-5035 United States Toll** **+1-303-498-7536 United States Toll (Denver)**

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: Executive Order 2020-01, Zero Based Regulation, requires agencies to review and rewrite chapters every five (5) years on an approved schedule. The purpose of this proposed rulemaking is to comply with this mandate and is scheduled for presentation to the 2025 Legislature. The rule specifies the tests and procedures that must be performed on newborn infants for early detection of metabolic disorders, endocrine disorders, hemoglobin disorders, cystic fibrosis, critical congenital heart disease, and prevention of infant blindness.

FEE SUMMARY: There will not be a change to the fee structure for newborn screening.

FISCAL IMPACT: There is no anticipated negative fiscal impact with this rule rewrite.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted. However, two public meetings were posted on Townhall Idaho and received public responses on March 14th, 2024, and April 11th, 2024.

INCORPORATION BY REFERENCE: The materials cited are being incorporated by reference as they provide details on industry standards associated with specimen collection, the filter paper collection device, application of blood to the filter paper, and uniform techniques for collecting the best possible specimen for use in dried blood spot specimen screening, and industry standards associated with appropriate pulse-oximetry equipment and uniform screening algorithms to obtain the most accurate results for critical congenital heart disease screening.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Jared Larsen at 208-334-5500.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before September 25th, 2024.

DATED this 30th day of July, 2024.

Alex J. Adams, PharmD, MPH
Director
Idaho Department of Health & Welfare
450 W. State Street, 10th Floor
P.O. Box 83720
Boise, ID 83720-0036
(208) 334-5500 phone; (208) 334-6558 fax
Alex.Adams@dhw.idaho.gov

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0212-2401
(ZBR Chapter Rewrite)

16.02.12 – NEWBORN SCREENING

000. LEGAL AUTHORITY.
~~The Idaho Legislature has given the Board of Health and Welfare and the Director of the Department authority to promulgate rules governing the testing of newborn infants for phenylketonuria and other preventable diseases and governing the instillation of an ophthalmic preparation in the eyes of the newborn to prevent Ophthalmia Neonatorum, under~~ Sections 39-906, 39-909, and 39-910, Idaho Code. ~~(3-17-22)~~( )

~~**001. TITLE AND SCOPE.**~~

~~**01. Title**. These rules are titled IDAPA 16.02.12, "Newborn Screening." (3-17-22)~~

~~**02. Scope**. These rules specify the tests and procedures that must be performed on newborn infants for early detection of metabolic disorders, endocrine disorders, hemoglobin disorders, cystic fibrosis, critical congenital heart disease, and prevention of infant blindness.~~ ~~(3-17-22)~~

001. (RESERVED)

002. INCORPORATION BY REFERENCE.
The Department has incorporated by reference the following documents: (3-17-22)

01. Dried Blood Spot Specimen Collection ~~on Filter Paper~~ for Newborn Screening ~~Programs; Approved Standard, Fifth~~ Seventh Edition. The Department has adopted Clinical Laboratory Standards Institute's "Dried Blood Spot Specimen Collection ~~on Filter Paper~~ for Newborn Screening ~~Programs; Approved Standard~~," ~~Fifth Edition, Clinical and Laboratory Standards Institute. 2007 (ISBN 1-56238-644-1)~~ Seventh Edition, 2021 (ISBN 978-68440-108-6), and hereby incorporates this standard by reference. A copy is available for review at the Department, or through the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, telephone 1-610-688-0100. ~~(3-17-22)~~( )

02. Critical Congenital Heart Defects (CCHDs). The Department has adopted the Critical ~~CHD~~

Congenital Heart Defect Screening Methods as recommended by the American Academy of Pediatrics~~, from "Strategies of Implementing Screening for Critical Congenital Heart Diseases," Kemper, et al., 2011,~~ online resource, and hereby incorporates this material by reference. Copies may be obtained from the Department, see online at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html. ~~(3-17-22)~~( )

003. -- 009. (RESERVED)

010. DEFINITIONS.
The following definitions will apply in the interpretation and enforcement of this chapter: (3-17-22)

01. Critical Congenital Heart Disease (CCHD). CCHD, also known as critical congenital heart defects, is a term that refers to a group of serious heart defects, as defined by the Centers for Disease Control and Prevention (CDC), that are present from birth. (3-17-22)

02. Department. The Idaho Department of Health and Welfare. (3-17-22)

03. Dried Blood Specimen. A blood specimen obtained from an infant by means of skin puncture, not by means of venipuncture or any other method, that is placed on special filter paper and allowed to dry. (3-17-22)

04. Hyperalimentation. The administration of an amount of nutrients beyond minimum normal requirements of the appetite, in an attempt to replace nutritional deficiencies. (3-17-22)

05. Laboratory. A medical or diagnostic laboratory certified according to the provisions of the Clinical Laboratory Improvement Amendments of 1988 by the United States Department of Health and Human Services. (3-17-22)

06. Newborn Screening. Newborn screening means a laboratory procedure performed on dried blood specimens from newborns to detect those at risk for the diseases specified in Subsection 100.01 of these rules. (3-17-22)

07. Person Responsible for Registering Birth of Child. The person responsible for preparing and filing the certificate of birth is defined in Section 39-255, Idaho Code. (3-17-22)

08. Pulse Oximetry. A non-invasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen using equipment approved by the U.S. Food and Drug Administration for use with newborn infants. (3-17-22)

09. Test Kit. The materials provided by the laboratory for the purposes of dried blood specimen collection and submission of specimens for newborn screening laboratory procedures. (3-17-22)

011. -- 049. (RESERVED)

050. USE AND STORAGE OF DRIED BLOOD SPECIMENS.

01. Use and Storage of Dried Blood Specimens. Dried blood specimens will be used only for the purpose of testing or re-testing, when necessary, the infant from whom the specimen was taken, and for congenital birth defects. Limited use of specimens for routine calibration of newborn screening laboratory equipment and quality assurance is permissible. ~~(3-17-22)~~( )

~~**02. Prohibited Use of Dried Blood Specimens**. Dried blood specimens may not be used for any purpose other than those described in Subsection 050.01 of this rule without the express written consent of the parent(s) or guardian(s) of the infant from whom the specimen was collected.~~ ~~(3-17-22)~~

~~**03. Storage of Dried Blood Specimens**. Dried blood specimens may be stored at the testing facility for a period not to exceed eighteen (18) months. Acceptable use of stored specimens will be for re-testing the specimen in the event of a symptomatic diagnosis or death of the infant during the storage period.~~ ~~(3-17-22)~~

051. -- 099. (RESERVED)

100. DUTIES OF THE ADMINISTRATOR OF THE RESPONSIBLE INSTITUTION AND THE PERSON REQUIRED TO REGISTER THE BIRTH OF A CHILD.

01. Conditions for Which Infants Will Be Tested. All infants born in Idaho must be tested for at least the following conditions: (3-17-22)

a. Biotinidase deficiency; (3-17-22)

b. Congenital hypothyroidism; (3-17-22)

c. Galactosemia; (3-17-22)

d. Maple syrup urine disease; (3-17-22)

e. Phenylketonuria; and (3-17-22)

f. Critical congenital heart disease. (3-17-22)

02. Blood Specimen Collection. (3-17-22)

~~**a.** The dried blood specimen collection procedures must follow the document listed in Subsection 004.01 of these rules. (3-17-22)~~

~~**b.** For infants admitted to the neonatal intensive care unit (NICU), the initial dried blood specimen for newborn screening must be obtained upon admission to the NICU. (3-17-22)~~

~~e~~**a.** For ~~non-premature~~ healthy infants, ~~in hospital,~~ the initial dried blood specimen for newborn screening must be obtained between twenty-four (24) and forty-eight (48) hours of age. ~~(3-17-22)~~( )

b. All infants must be retested. A test kit should be given to the parents or responsible party at the time of discharge from the institution where initial newborn care was rendered, with instructions to have a second dried blood specimen collected. The preferred time for sample collection for healthy infants is between ten (10) and fifteen (15) days of age. ( )

c. For infants admitted to the neonatal intensive care unit (NICU), the initial dried blood specimen for newborn screening must be obtained upon admission to the NICU. Newborns who require a blood transfusion, hyperalimentation, or dialysis should have a dried blood specimen collected for screening prior to these procedures. ( )

d. For low birth weight, sick infants (requiring three (3) or more weeks of hospitalization) and/or NICU infants, the first newborn screen specimen should be collected upon admission to the NICU, the second at twenty-four (24) to forty-eight (48) hours of age, and the third at twenty-eight (28) days or four (4) weeks of age. ( )

~~d~~**e.** For newborns transferred from one hospital to another, the originating hospital must assure that the dried blood specimen is drawn. If the newborn is ~~too premature or~~ too sick to have a dried blood specimen drawn for screening prior to transfer and a dried blood specimen is not obtained, the originating hospital must document this, and notify the hospital to which the newborn is being transferred that a dried blood specimen for newborn screening has not been obtained. ~~(3-17-22)~~( )

~~e~~**f.** Prior to the discharge of an infant from the institution where initial newborn care or specialized medical care was rendered, the Administrator of the institution must assure that an adequate dried blood specimen has been collected regardless of the time the infant is discharged from the institution. (3-17-22)

~~f~~**g.** For births occurring outside of a hospital, the birth attendant is responsible for assuring that an

acceptable dried blood specimen is properly collected for newborn screening as stipulated in Section 100 of this rule. (3-17-22)

~~g. Newborns who require a blood transfusion, hyperalimentation, or dialysis must have a dried blood specimen collected for screening prior to these procedures. (3-17-22)~~

~~h. If a dried blood specimen cannot be obtained for newborn screening before transfusion, hyperalimentation, or dialysis, the hospital must ensure that a repeat dried blood specimen is obtained at the appropriate time when the specimen will reflect the infant's own metabolic processes and phenotype. (3-17-22)~~

~~i. All infants must be retested. A test kit must be given to the parents or responsible party at the time of discharge from the institution where initial newborn care was rendered, with instructions to have a second dried blood specimen collected. The preferred time for sample collection is between ten (10) and fifteen (15) days of age. (3-17-22)~~

03. Specimen Data Card. The person obtaining the newborn screening specimen ~~must~~ should complete ~~the~~ all demographic information requested on the specimen collection card ~~attached to the sample kit. The First Specimen Card must include the infant's mother's date of birth, address, and phone number. Both the First and Second Specimen's Card must include the items listed in 100.03.a. through 100.03.k. of this rule, optional fields may be completed as needed~~. ~~(3-17-22)~~( )

~~a. Name of the infant; (3-17-22)~~

~~b. Whether the birth was a single or multiple-infant birth; (3-17-22)~~

~~c. Name of the infant's mother; (3-17-22)~~

~~d. Gender of the infant; (3-17-22)~~

~~e. Method of feeding the infant; (3-17-22)~~

~~f. Name of the birthing facility; (3-17-22)~~

~~g. Date and time of the birth; (3-17-22)~~

~~h. Date and time the specimen was obtained; (3-17-22)~~

~~i. Name of the attending physician or other attendant; (3-17-22)~~

~~j. Date specimen was collected; and (3-17-22)~~

~~k. Name of person collecting the specimen. (3-17-22)~~

04. Specimen Mailing. Within twenty-four (24) hours after collection, the dried blood specimen ~~must~~ should be mailed to the laboratory by first class mail or its equivalent, except when mailing service is not available. When mailing service is not available on weekends and holidays, dried blood specimens ~~must~~ should be mailed to the laboratory on the first available mail pick-up day. The preferred method of mailing, following a weekend or holiday, is by expedited mail service. ~~(3-17-22)~~( )

05. Record Keeping. Maintain a record of all dried blood specimens collected for newborn screening. This record ~~must~~ should indicate: ~~(3-17-22)~~( )

a. Name of the infant; (3-17-22)

b. Name of the attending physician or other attendant; (3-17-22)

c. Date specimen was collected; ~~and~~ ~~(3-17-22)~~( )

d. Name of person collecting specimen~~.~~; and ~~(3-17-22)~~( )

e. Tracking number if courier service is used. ( )

06. Collection Protocol. Ensure that a protocol for collection and submission for newborn screening of adequate dried blood specimens has been developed, documented, and implemented. Individual responsibilities must be clearly defined and documented. The attending physician ~~must~~ or birth attendant should request that the test be done. The ~~hospital~~ facility may make an appropriate charge for this service and should seek reimbursement when available. ~~(3-17-22)~~( )

07. Responsibility for Recording Specimen Collection. (3-17-22)

a. The administrator of the responsible institution, or their designee, must record on the birth certificate whether the dried blood specimen for newborn screening has been collected. (3-17-22)

b. When a birth occurs outside a hospital, the person responsible for registering the birth of the child must record on the birth certificate whether the dried blood specimen for newborn screening has been collected and submitted within twenty-four (24) hours following collection. (3-17-22)

08. Fees. The Department will provide access to newborn screening laboratory services. If the administration of the responsible institution or the person required to register the birth of a child chooses to utilize this service, the Department will collect a fee equal to the cost of the test kit, analytical, and ~~diagnostic~~ follow-up services provided by the laboratory. The fees must be remitted to the Department before the laboratory provides the test kit to those responsible for ensuring the infant is tested according to these rules. ~~(3-17-22)~~( )

101. -- 199. (RESERVED)

200. LABORATORY DUTIES.

01. Participation in Centers for Disease Control and Prevention (CDC) Newborn Screening Quality Assurance Program. All laboratories receiving dried blood specimens for newborn screening on infants born in Idaho ~~must~~ should participate in the Newborn Screening Quality Assurance Program operated by the CDC. ~~(3-17-22)~~( )

02. Specimen Processing. Dried blood specimens for newborn screening ~~must~~ should be processed within twenty-four (24) hours of receipt by the laboratory or before the close of the next business day. ~~(3-17-22)~~( )

03. Result Notification. Normal test results may be reported by mail to the submitter. Other results ~~must~~ should be reported in accordance with Section 300 of these rules. ~~(3-17-22)~~( )

201. -- 299. (RESERVED)

300. FOLLOW-UP FOR UNSATISFACTORY SPECIMENS, PRESUMPTIVE POSITIVE RESULTS AND POSITIVE CASES.

01. Follow-Up for Unsatisfactory Specimens. (3-17-22)

a. The laboratory will immediately report any unsatisfactory dried blood specimens to the submitting institution that originated the dried blood specimen or to the healthcare provider responsible for the newborn's care, with an explanation of the results. The laboratory will request a repeat dried blood specimen for newborn screening from the institution or individual submitting the original sample, or from the responsible provider as instructed by the program. ~~(3-17-22)~~( )

b. Upon notification from the laboratory and as instructed by the program, the health care provider responsible for the newborn's care at the time of the report ~~will cause another~~ should collect a repeat dried blood

specimen to be appropriately forwarded to the laboratory for screening. ~~(3-17-22)~~( )

02. Follow-Up of Presumptive Positive Results. The laboratory will report positive or suspicious results on an infant's dried blood specimen to the attending physician or midwife, or, if there is none or the physician or midwife is unknown, to the person who registered the infant's birth, and make recommendations on the necessity of follow-up testing. (3-17-22)

03. Positive Case Notification. Confirmed positive cases of biotinidase deficiency, congenital hypothyroidism, galactosemia, maple syrup urine disease, and phenylketonuria must be reported as described in IDAPA 16.02.10, "Idaho Reportable Diseases." (3-17-22)

301. NEWBORN CRITICAL CONGENITAL HEART DISEASE (CCHD) SCREENING.

01. Pulse Oximetry for the Screening of CCHD. ~~(3-17-22)~~

~~**a.** For births occurring in a hospital, the administrator of the institution or their designee must assure that all infants who meet the CDC criteria for CCHD screening are screened following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html.~~ ~~(3-17-22)~~

~~**b.**~~ For births occurring outside of a hospital, the birth attendant must assure that screening for congenital heart disease is conducted through the use of pulse oximetry ~~no sooner than~~ between twenty-four (24) hours after birth and no later than forty-eight (48) hours after birth following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html. ~~(3-17-22)~~( )

02. Responsibility of Recording CCHD Screening Results. (3-17-22)

a. For births occurring in a hospital, the administrator of the responsible institution or their designee must record the pulse oximetry results on the birth certificate and whether the CCHD screening was determined as "passed" or "failed" following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html, or "not screened." (3-17-22)

b. For births occurring outside of a hospital, the birth attendant or their designee must record the pulse oximetry results on the birth certificate and whether the CCHD screening was determined as "passed" or "failed" following the algorithm on the CDC website at: https://www.cdc.gov/ncbddd/heartdefects/hcp.html, or "not screened." (3-17-22)

03. Follow Up for Abnormal CCHD Screening Results. (3-17-22)

a. For births occurring in a hospital, the administrator of the responsible institution or their designee must make a referral for further evaluation of the newborn whose CCHD results are abnormal and inform the parent or legal guardian of the need for appropriate intervention. (3-17-22)

b. For births occurring outside of a hospital, the person performing the screening is responsible for making an immediate referral for further evaluation of the newborn whose CCHD results are abnormal and informing the parent or legal guardian of the need for appropriate intervention. (3-17-22)

302. -- 399. (RESERVED)

400. SUBSTANCES THAT FULFILL REQUIREMENTS FOR OPHTHALMIC PREPARATION.
Only those germicides ~~proven to be~~ effective in preventing ophthalmia neonatorum and recommended for use in its prevention by the ~~U.S. Department of Health and Human Services (including the U.S. Public Health Service, the Center for Disease Control and Prevention, and the U.S. Food and Drug Administration)~~ Centers for Disease Control and Prevention, the American Academy of Pediatrics, or the U.S. Preventative Services Task Force will satisfy the requirements established herein, under Section 39-903, Idaho Code. ~~(3-17-22)~~( )

401. -- 999. (RESERVED)

SYNOPSIS FOR INCORPORATION BY REFERENCE

INCORPORATION BY REFERENCE SYNOPSIS

In compliance with Section 67-5223(4), Idaho Code, the following is a synopsis of the differences between the materials previously incorporated by reference in this rule that are currently of full force and effect and newly revised or amended versions of these same materials that are being proposed for incorporation by reference under this rulemaking.

The following agency of the state of Idaho has prepared this synopsis as part of the proposed rulemaking for the chapter cited here under the docket number specified:

IDAHO DEPARTMENT OF HEALTH AND WELFARE
IDAPA 16.02.12 - Rules Governing NEWBORN SCREENING
Proposed Rulemaking - Docket No. 16-0212-2401

The Dried Blood Spot Specimen Collection for Newborn Screening 5th edition has been previously incorporated by reference in chapter 16.02.12. This rule change proposes incorporating the 7th edition of the same document, which is the most recent version of the publication. There have been several changes between the 5th edition, published in 2007, and the 7th edition, published in 2021. Those changes include:

From the 5th Edition to the 6th, these items were revised:

- Procedures for applying blood that was collected by different techniques in the preprinted circles on the specimen collection card
- Collection of blood with transfer devices
- The analysis of poor-quality and less-than-ideal specimens
- Pain management strategies during skin puncture
- Interfering substances
- Recommendations on the sources of blood
- Minimal and optional information captured with the collected specimen
- Specifications for the filter paper portion of the specimen collection device
- Procedures for handling, shipping/mailing of specimens
- Handling of blood spot specimens for DNA analysis
- Short- and long- term storage of specimens
- Appendix C, which focuses on filter paper evaluation and protocol, was rewritten and updated with a table and figure
- New Appendix D regarding patient conditions and treatments affecting NBS results

From the 6th Edition to the 7th, these items were revised:

- Title
- Introduced easy-to-follow step-action tables that include comments for each action (as applicable), consistent with CLSI's goal to make standards and guidelines more user friendly
- Added definitions for check sum character, collection device//specimen collection device (for newborn screening), dried blood spot, expected range, false-negative screening result, false-positive screening result, incision, in-range result, medical device, newborn screening program, newborn screening system, out-of-range result, puncture, re-collection, and specimen acceptability
- Added information clarifying the use of the term "filter paper"
- Updated filter paper considerations and shelf life
- Added information on identifying the patient and verifying patient and specimen identification at the time of collection
- Added information and references for acceptable blood specimen sources and collection sites
- Added discussion on preventing specimen contamination and preanalytical DNA analysis considerations
- Added information regarding proper documentation, which includes using a procedures manual, confirming patient identification, documenting consent or refusal, and confirming the demographic data and the expiration date on the collection device
- Added alternative for warming the newborn's heel
- Clarifying the benefits of single-use permanently retractable puncture devices for both the newborn and worker safety
- Added comment on making a single puncture that the specimen collector must not perform immediate repeat puncture at the same site
- Added instructions on post collection care
- Added information about anticoagulants to heel stick with capillary tube collection and application
- Updated information on DBS specimen acceptability and added image of good-quality DBS specimen
- Indicated records should include documentation showing delivery date and time, as well as the individual who received the specimen
- Revised Appendix A to maintain consistency with update collection method instruction
- Revised title of Appendix B and replaced previously used figures with new images of individual DBS, each with an explanation of the specimen quality issue shown
- Updated Appendix C per its source document and clarified the scope and purpose of this protocol for testing the absorption characteristics of filter paper
- Added interferences affecting NBS results to table in Appendix D
- Moved filter paper specifications formerly in Appendix E to Chapter 3

- Updated Appendix F by adding “repeat analysis to validate previous NBS results” to list of possible uses for residual DBS specimens that need prioritization