MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	11/21/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/6/2017

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	10	13	02-.04, .12-.18, .20, .21, .23-.27
10	52	12	03-.15

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator **Telephone Number**
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6. Check applicable items:
_ New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: March 30 and June 16, 2016.

X- Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Kathleen A. Ellis, Assistant Attorney General, (telephone #410-767-1867) on November 18, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title	**Telephone No.**
Secretary	410-767-6500

Date

November 21, 2016

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 10 LABORATORIES
10.10.13 Medical Laboratories — Testing for Hereditary and Congenital Disorders in Newborn Infants
Subtitle 52 PREVENTIVE MEDICINE
10.52.12 Newborn Screening

Authority: See proposal.

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to :
(1) Amend Regulations .02—.04, .12—.18, .20, .21, .23— .27 under COMAR 10.10.13 Medical Laboratories – Testing for Hereditary and Congenital Disorders in Newborn Infants; and
(2) Amend Regulations .03—.07, .09—.13, and .15; and repeal Regulations .08 and .14 under COMAR 10.52.12 Newborn Screening.

Statement of Purpose

The purpose of this action is to :
(1) Align regulations with the addition of Severe Combined Immunodeficiency (SCID) to the Maryland Newborn Screening Program; and
(2) To make general clarifying changes to existing language.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.
The DHMH Newborn Screening and Childhood Division will not require additional funding to add SCID to the State's newborn screening panel (implementation began during the spring 2016). In 2015, the newborn screening and follow-up fee was increased from $100 to $106 specifically to cover the costs associated with incorporating SCID into the newborn screening program.

Since some well infants will incur abnormal SCID test results (false positives), additional testing will also be required to determine the underlying cause of the abnormal result. Therefore, abnormal results and the costs for follow-up testing will be covered by public resources (Medicaid) and/or private insurers.

The Newborn Screening and Childhood Division is further aided by the Department's

Newborn Screening Follow-up Unit which investigates each abnormal test result by contacting health care providers, parents and guardians (if necessary) regarding abnormal results and the need for follow-up testing and treatment. The Follow-up Unit can use existing staff to absorb required duties as a result of adding SCID to the newborn screening panel.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	NONE	
B. On other State agencies:	(E+)	Indeterminate
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
Insurance	(-)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

B. Expenditures will increase for Medicaid, as they will cover the costs of additional testing in the case of abnormal results for children insured by their program.

D. Insurers will cover the costs for follow-up testing performed in the case of abnormal results.

F. This change will benefit families and parents as they will receive SCID diagnosis information earlier.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to

dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 6, 2017. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
Yes
C. If 'yes', state whether general, special (exact name), or federal funds will be used:
The Newborn Screening and Childhood Division currently operates via a Special Fund as per Chapter 56 of 2015 (Newborn Screening Program Fund). This non-lapsing Special Fund is designed to provide funding for the screening of newborn infants for hereditary and congenital disorders. Fee revenues associated with the 2015 increase of the newborn screening and follow-up fee ($100 to $106) are consequently incorporated into the Special Fund and are specifically used to cover the costs associated with SCID screening. In addition, the Follow-up Unit is able to use existing staff to absorb required duties as a result of adding SCID to the DHMH newborn screening panel.
D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
The proposed amendments will not have an economic impact on small businesses as the amendments will not pose any duties or obligations on these entities.
G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 10 LABORATORIES

10.10.13 Medical Laboratories — Testing for Hereditary and Congenital Disorders in Newborn Infants

Authority: Health-General Article, §§13-102, 13-103, 13-108—13-110, Annotated Code of Maryland

COMAR 10.10.13 (June 16, 2016)

.02 Scope.

This chapter:

A. Identifies standards and requirements for a medical laboratory performing screening tests, diagnostic tests, or both, for hereditary and congenital disorders on *blood-spot* specimens from newborn infants; and

B. (text unchanged)

.03 Definitions

A. (text unchanged)

B. Terms Defined.

(1)—(4) (text unchanged)

[(5) "Blood-spot" means a specimen of blood taken by heel stick from a newborn infant and applied to a circle on a special filter paper collection test requisition card for use in testing for hereditary and congenital disorders.**]**

(5) Blood-spot Specimen.

(a) "Blood-spot specimen" means a whole-blood specimen collected from a newborn infant's heel and applied to the designated area on a blood-spot collection test requisition card for the purpose of performing screening tests.

(b) "Blood-spot specimen" includes:

(i) The first screening blood-spot specimen collected from a newborn infant, usually in the birthing facility or other place where the newborn infant was born, within 48 hours after the newborn infant's birth;

(ii) The second screening blood-spot specimen collected from a newborn infant, usually collected when the newborn infant is between 10 and 14 days of age; and

(iii) A blood-spot specimen collected subsequent to a blood-spot specimen specified in §B(5)(b)(i) and (ii) of this regulation as required to meet the medical needs and condition of the newborn infant and any additional specific screening blood-spot specimen collection and screening test requirements of this chapter and COMAR 10.52.12.

(6)—(9) (text unchanged)

(10) "Courier" means an entity employed by a person to convey a *blood-spot* specimen from the site of *blood-spot* specimen collection to the laboratory where *blood-spot* specimen will be tested.

(11)—(13) (text unchanged)

(14) "First screening" means a screening performed on the first blood-*spot* specimen collected from a newborn after birth.

(15) "First–tier test" means a blood test performed on a new infant's **[**blood**]** *blood-spot* specimen that:

(a)—(b) (text unchanged)

(16) "Follow-Up Unit" means the follow-up component and staff of the Department's Newborn Screening Program, which carries out the duties set forth in COMAR **[**10.52.12.13**]** *10.52.12.12*.

(17) (text unchanged)

(18) "Home birth" means the birth of an infant which occurs intentionally outside of a birthing facility.

(19) "Home birth attendant" means a physician who is licensed to practice under Health Occupations Article, Title 14, Annotated Code of Maryland, a nurse midwife who is licensed and certified under Health Occupations Article, Title 8, Annotated Code of Maryland, or a direct-entry midwife who is licensed under Health Occupations Article, Title 8, Subtitle 6C, Annotated Code of Maryland, who is caring for the mother and infant at delivery during a home birth as defined in §B(18) of this regulation.

[(18)**]** *(20)* (text unchanged)

[(19)**]** *(21)* "Newborn" or "newborn infant" means an infant:

(a)—(c) (text unchanged)

(d) From whom a **[**blood**]** *blood-spot* specimen was collected and submitted to the Department's public health laboratory for newborn screening by a birthing facility or other health care provider located in Maryland, regardless of the infant's place of birth;

(e)—(f) (text unchanged)

[(20)**]** *(22)* Newborn Screening or Screening.

(a) (text unchanged)

(b) "Newborn Screening" or "screening" includes:

(i) First-tier testing on a first, second, or subsequent *blood-spot* specimen; and

(ii) text unchanged)

[(21**]** *(23)* Newborn Screening Program.

(a) (text unchanged)

(b) "Newborn Screening Program" includes:

(i)—(iii) (text unchanged)

(iv) The **[**Department's Newborn Screening**]** Follow-up Unit; and

(v) (text unchanged)

[(22)**]** *(24)*—**[**(26)**]** *(28)* (text unchanged)

[(27) Screening Specimen.

(a) "Screening specimen" means a whole-blood specimen collected from a newborn infant's heel and applied to the designated area on a blood-spot collection test requisition card for the purpose of performing screening tests.

(b) "Screening specimen" includes:

(i) The first screening specimen collected from a newborn infant, usually in the birthing facility or other place where the newborn was born, within 7 days after the newborn infant's birth;

(ii) The second screening specimen collected from a newborn infant, usually during a well-baby visit in a physician's office, between 1 and 4 weeks after the infant's birth; and

(iii) A specimen collected subsequent to the specimens specified in §B(27)(b)(i) and (ii) of this regulation as required to meet the medical needs and condition of the newborn infant and any additional specific specimen collection and screening test requirements of this chapter and COMAR 10.52.12.**]**

[(28)**]** *(29)* Screening Test.

(a) (text unchanged)

(b) "Screening test" includes a test performed on a:

(i) First screening *blood-spot* specimen;

(ii) Second screening *blood-spot* specimen; or

(iii) Subsequent screening *blood-spot* specimen.

(c) (text unchanged)

[(29)**]** *(30)* "Second screening" means a test performed on a routine second *blood-spot* specimen collected when the newborn infant is between **[**1 week and 4 weeks**]** *10 and 14 days* old even though the test results from the newborn's first specimen were normal.

[(30)**]** *(31)* Second-Tier Test.

(a) "Second-Tier test" means a test performed on a newborn screening *blood-spot* specimen when a first-tier test provides an abnormal screening test result or a borderline abnormal screening test result.

(b) (text unchanged)

[(31)**]** *(32)* (text unchanged)

[(32)**]** *(33)* "Supplemental test" means a test performed on a *blood-spot* specimen collected from a newborn infant that is:

(a)—(b) (text unchanged)

[(33)**]** *(34)* "Unsatisfactory *blood-spot* specimen" means a blood-spot *specimen* that may produce an inaccurate or unreliable test result because the blood-spot *specimen* exhibits one of the problems of collection as specified in Regulation .21B and C of this chapter.

.04 Permit.

A. (text unchanged)

B. Requirements. Before offering to perform or performing a first-tier, supplemental, or second-tier test on a blood-spot *specimen* collected from a newborn infant, a person shall:

(1)—(2) (text unchanged)

.12 First-Tier, Supplemental, and Second-Tier Tests.

A. First-Tier Tests; Requirement. The Department's public health laboratory shall perform first-tier tests on all screening *blood-spot* specimens collected from a newborn infant.

B. (text unchanged)

C. First-Tier Tests. The Department's public health laboratory shall perform a first-tier test on a newborn infant to screen for the following metabolic or hereditary disorders, which are approved for screening by the Council and the Secretary:

(1)—(51) (text unchanged)

(52) **[**Dienoyl CoA**]** *2,4-dienoyl-CoA* reductase deficiency (DE RED); **[**and**]**

(53) Cystic fibrosis*; and*

(54) Severe Combined Immunodeficiency (SCID).

D. Approved Methods:

(1) A permittee shall use:

(a)—(d) (text unchanged)

(e) Tandem mass-spectrometry when testing for the hereditary or congenital disorders listed in §C(11)—(52) *and (54)* of this regulation; and

(f) (text unchanged)

(2) (text unchanged)

.13 Screening Test *Blood-spot* Specimens — Collection and Test Requisition.

A. *Blood-spot* Specimen Collection

(1) A person shall collect a newborn infant's **[**blood**]** *blood-spot* specimen for testing under this chapter by using only the special blood-spot *specimen* collection test requisition card provided by the Department.

(2) The Department shall provide the special blood-spot *specimen* collection test requisition card to the:

[(a) Birthing facility to collect a *blood-spot* specimen on a newborn infant born in an institution; and

(b) Person responsible for having newborn screening administered to a newborn infant born outside a birthing facility.**]**

(a) Individual in charge of a birthing facility or the individual's designated representative; or

(b) Home birth attendant.

(3) **[**A birthing facility or person responsible for having newborn screening administered to a newborn infant born outside a birthing facility**]** *The individual in charge of a birthing facility or the individual's designated representative, or the home birth attendant* shall collect a *blood-spot* specimen consisting of heel-stick whole blood obtained:

(a) When a newborn infant is 24 to **[**(72)**]** *48* hours old;

(b) On a blood-spot *specimen* collection test requisition card provided by the Department; and

(c) (text unchanged)

B. Blood-Spot *Specimen* Collection Test Requisition Card Information. **[**A person**]** *An individual* shall record the following information as specified on the Department-supplied blood-spot *specimen* collection test requisition card:

(1) (text unchanged)

(2) Blood-spot specimen information including:

(a)—(b) (text unchanged)

(c) Initials or other identifier of the individual who collected the *blood-spot* specimen;

(3)—(5) (text unchanged)

.14 Screening *Blood-spot* Test Specimens — Procedures, Submission, and Delivery Requirements.

A. Standard Operating Procedure. **[**A birthing facility or person responsible for having blood collected from a newborn infant born outside a birthing facility**]** *The individual in charge of a birthing facility or the individual's designated representative, or the home birth attendant* shall maintain written standard operating procedures for the collection, handling, storage, and transport of newborn infant blood-spot *specimen* collection test requisition cards, including instructions for staff to:

(1) Ensure and maintain *blood-spot* specimen integrity, quality, and acceptability;

(2) (text unchanged)

(3) Identify precautions against:

(a) Milking or squeezing the *blood-spot specimen* collection site;

(b) Layering successive drops of blood on the same circle on the blood-spot *specimen* collection test requisition card;

(c) (text unchanged)

(d) Touching or smearing a blood-spot *specimen* before it is fully air-dried;

(e) Scratching or abrading the blood-spot *specimen*;

(f) Not allowing a blood-spot *specimen* to dry thoroughly before sending the blood-spot *specimen* collection test requisition card to a laboratory; and

(g) Damaging, stretching, or wrinkling the filter paper before, during or after *blood-spot* specimen collection;

(4) (text unchanged)

(5) Handle and temporarily store a blood-spot *specimen* collection test requisition card, including the procedures and techniques for:

(a) (text unchanged)

(b) Stacking of blood-spot *specimen* collection test requisition cards; and

(c) Temporarily storing blood-spot *specimen* collection test requisition cards.

B. Submission and Delivery Requirements. **[**A birthing facility or person responsible for having newborn screening administered to a newborn infant born outside a birthing facility**]** *The individual in charge of a birthing facility or the individual's designated representative, or the home birth attendant* shall transport and deliver to the Department's public health laboratory a newborn infant blood-spot *specimen* collection test requisition card using:

(1)—(4) (text unchanged)

15. Test *Blood-spot* Specimens — Use, Research, Storage, and Retention.

A. Use. A permittee may use a newborn infant blood-spot *specimen* from a newborn infant to test for only the conditions listed in Regulation .12C of this chapter.

B. Research. A researcher may not use a Maryland newborn infant's blood spot *specimen* or test results for research purposes unless the:

(1) (text unchanged)

(2) The researcher acknowledges in writing that the researcher will return all untested **[**blood-spots**]** *blood-spot specimens* to the Department's public health laboratory within 6 months of completing the approved research.

C. Storage. A permittee or researcher shall store a newborn infant blood-spot *specimen* in a sealed, moisture-proof container at between **[**2º**]** *2ºC* and **[**32ºC**]** *6ºC.*

D. Retention. A permittee shall:

(1) Retain a newborn infant's**[**:

(a) Gel,**]** *gel,* produced when testing for hemoglobin disorders, for at least 90 days after testing is complete; and

[(b) Blood-spot for 25 years after the blood-spot is received for screening, supplemental, or diagnostic testing; and**]**

[(2)**]** *(b)* Return to the State's public health laboratory all untested **[**blood-spots**]** *blood-spot specimens* received from the Department's public health laboratory for supplemental or diagnostic testing within 90 days after testing is completed by the permittee.

(2) The Department's public health laboratory shall retain and maintain for 25 years a newborn infant's blood-spot specimen after the blood-spot specimen is received for screening, supplemental testing, or diagnostic testing.

.16 Test Records — Retention.

The Department's public health laboratory shall retain and maintain electronically or as a hard copy for 25 years the:

A. Top copy of the requisition portion of the blood-spot *specimen* collection test requisition card;

B.—D. (text unchanged)

.17 Testing — First-Tier.

A. The Department's public health laboratory shall test, using first-tier tests, appropriately timed and collected blood-spot **[**screening specimens**]** *specimen* of a newborn infant's blood for the disorders listed in Regulation .12C of this chapter.

B. Full-Term Healthy Newborn Infants.

(1) If a newborn infant is born at term and is healthy, the Department's public health laboratory shall conduct a**[**:

(a) First**]** *first* screening using first-tier tests to detect the disorders listed in Regulation .12C of this chapter on a *blood-spot* specimen collected when the full-term healthy newborn infant is between 24 *and 48* hours **[**and 7 days**]** old; and

[(a) Second**]** *(2) conduct a second* screening using first-tier tests on a *blood-spot* specimen collected when the full-term healthy infant is between **[**1 and 4 weeks**]** *10 and 14* days old.

[(2) If the first *blood-spot* specimen is collected when a full term healthy newborn infant is younger than 24 hours old, the Department's public health laboratory shall conduct a:

(a) Second screening using first-tier tests to detect the disorders listed in Regulation .12C of this chapter on a *blood-spot* specimen collected when the newborn infant is between 24 hours and 7 days old; and

(b) Third screening using first-tier tests on a *blood-spot* specimen collected when the full-term healthy infant is between 1 and 4 weeks old.

C. Premature or Ill Newborn Infant.

(1) If a newborn infant who is born prematurely or **[**is**]** expected to be ill for more than 14 days was younger than 24 hours old when the *blood-spot* specimen was collected for a first screening, the Department's public health laboratory shall conduct a:

(a)—(b) (text unchanged)

(2) If a newborn infant who is born prematurely or **[**is**]** expected to be ill for more than 14 days was 24 hours old or older at the time the newborn infant's blood-*spot specimen* was collected for a first screening, the Department's public health laboratory shall perform a second screening **[**using first-tier tests on a *blood-spot* specimen collected when the newborn infant is between 7 days and 14 days old**]** to screen for:

(a)—(b) (text unchanged)

(3) If a newborn infant was transfused before the *blood-spot* specimen was collected for a first screening, the Department's public health laboratory shall conduct, in addition to any other screenings specified in §B(1) and (2) of this regulation, a fourth screening using first-tier tests on a *blood-spot* specimen collected 4 months after a newborn infant's last transfusion to screen for:

(a)—(c) (text unchanged)

.18 Testing — Second-Tier and Supplemental.

A. (text unchanged)

B. A permittee:

(1) (text unchanged)

(2) Shall complete a second-tier or supplemental test on a *blood-spot* specimen within 3 working days after the *blood-spot* specimen arrives at the laboratory; and

(3) (text unchanged)

.20 Quality Control.

A. Quality Control Program.

(1) A permittee shall develop, establish, implement, maintain and follow written quality control policies, procedures, and techniques that provide and ensure accurate, reliable, and valid test results and reports.

[(1)**]** *(2)* (text unchanged)

[(3)**]** *(3)* A permittee's quality control procedures and practices shall include, but are not limited to, the use of:

(a)—(e) (text unchanged)

B. (text unchanged)

C. Supplies, Reagents, and Materials.

(1) A permittee shall ensure that supplies, reagents, and other materials used in the collected, handling, testing, and storing of newborn **[**blood-spots**]** *blood-spot specimens* are stored, labeled, checked for proper reactivity, and used according to the provisions of this chapter.

(2) A permittee shall:

(a)—(b) (text unchanged)

(c) Test representative samples of each lot of materials used for or in the process of testing *blood-spot* specimens on a regularly scheduled basis to determine that each lot of test material is capable of performing as required; and

(d) (text unchanged)

(3) (text unchanged)

.21 Quality Assessment and Quality Assurance.

A. A permittee shall:

(1)—(2) (text unchanged)

(3) Have an accessioning mechanism or system that:

(a) Tracks *blood-spot* specimens and allows first and subsequent *blood-spot* specimens and test results from the same newborn infant to be linked for testing and analysis; and

(b) (text unchanged)

B. A permittee may not test a blood-spot *specimen* exhibiting:

(1)—(6) (text unchanged)

C. A permittee may not test a *blood-spot* specimen:

(1) (text unchanged)

(2) That is unaccompanied by information necessary for the testing to be meaningful, including the:

(a)—(b) (text unchanged)

(c) Date and time of *blood-spot* specimen collection;

(d)**—**(f) (text unchanged)

(3) If an infant was transfused before the first screening and the repeat *blood-spot* specimen collected to test for hemoglobin was drawn earlier than 4 months after the last transfusion; or

(4) (text unchanged)

D. Within 24 hours of receipt of an unsatisfactory *blood-spot* specimen, the permittee shall notify the submitter of the unsatisfactory *blood-spot* specimen by telephone, facsimilie, or electronic mail:

(1) That the *blood-spot* specimen cannot be tested; and

(2) To submit another *blood-spot* specimen as soon as possible.

E. If a permittee reports a test result on a newborn infant and later discovers that the test result was erroneous or questionable, the permittee shall:

(1) Give prompt notice of the erroneous or questionable patient test result to the:

(a)—(b) (text unchanged)

(c) **[**Newborn Screening**]** Follow-up Unit;

(2)—(5) (text unchanged)

(6) Take any additional measures necessary to reduce or eliminate the threat to the health and safety of the patient including:

(a) (text unchanged)

(b) Retesting the same blood-spot *specimen*;

(c) Testing a new blood-spot *specimen*; and

(d) Retesting the same blood-spot *specimen* and testing a new blood-spot *specimen*.

.23 Reporting Test Results.

A. All Test Results. For a newborn infant, a permittee shall:

(1) Report all first-tier, supplemental, and second-tier results to:

(a) (text unchanged)

(b) **[**A person**]** *An individual* who will use the test results in identifying, tracking, caring for, and treating the newborn infant, including:

(i) (text unchanged)

(ii) Personnel in the **[**Department's Newborn Screening**]** Follow-up Unit;

(2) Report to the persons listed in §A(1) of this regulation within 3 working days after the laboratory obtains the *blood-spot* specimen, all test results that are within normal limits;

(3) (text unchanged)

(4) Include with each report the following information:

(a) Date the *blood-spot* specimen was received in the laboratory;

(b)—(c) (text unchanged)

(5) Report all abnormal test results to the **[**Department's Newborn Screening**]** Follow-up Unit on the same day that a test result is obtained and reviewed.

B. Specific Test results. A permittee may not report a test result as being within normal limits for:

(1) Amino acid levels for disorders specified in Regulation .12C(11)—(24) of this chapter and for a total galactose level for galactosemia as specified in Regulation .12C(3) of this chapter if:

(a) A newborn infant was not on milk or formula feeding at least 24 hours before the *blood-spot* specimen was collected; or

(b) (text unchanged)

(2) (text unchanged)

.24 Reporting Abnormal Test Results to the [Newborn Screening] Follow-up Unit.

A. Reporting Requirements. A permittee shall immediately report an abnormal or diagnostic test result to the **[**Newborn Screening**]** Follow-up Unit by:

(1)—(3) (text unchanged)

B.—C. (text unchanged)

D. Reporting Requirements; Sickle Cell Disease Hemoglobin **[**Requirements**]**. A permittee shall report results for hemoglobin disorders as specified in Regulation .12C(7)—(10) of this chapter for sickle cell disease in terminology that includes:

(1)—(2) (text unchanged)

.25 Reporting System and Communication Software

A permittee shall:

A. Have available and use a reliable and accurate electronic information system that is capable of collecting, compiling, transferring, and communicating all normal and abnormal test results to the **[**Newborn Screening**]** Follow-up Unit; and

B. Provide the **[**Newborn Screening**]** Follow-up Unit, where applicable, with:

(1) The necessary information system and electronic communications software or interface to be used by the **[**Newborn Screening**]** Follow-up Unit to receive from the permittee the newborn screening test results and reports required in this chapter; and

(2) (text unchanged)

.26 Availability of Statistical and Scientific Data.

A. Statistical Reports. The State's public health laboratory, the **[**Newborn Screening**]** Follow-up Unit, or both, on request, shall provide Newborn Screening Program statistical data for official State and national reports to:

(1)—(3) (text unchanged)

B. (text unchanged)

.27 Sanctions

A.—B. (text unchanged)

C. The Secretary may impose a directed plan of correction, limit testing, deny a permit renewal, or suspend or revoke a current permit if a permittee has:

(1) (text unchanged)

(2) Conducted research on newborn infant *blood-spot* specimens within the Newborn Screening Program's approval as required in Regulation .15 of this chapter; or

(3) (text unchanged)

D.—F. (text unchanged)

Subtitle 52 PREVENTIVE MEDICINE

10.52.12 Newborn Screening

Authority: Health-General Article, §§13-109 and 13-111, Annotated Code of Maryland

10.52.12 (March 30, 2016)

.03 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) Birthing Facility.

(a) (text unchanged)

(b) "Birthing facility" includes a:

(i)—(ii) (text unchanged)

(2) Blood-spot Specimen.

(a) "Blood-spot specimen" means a whole-blood specimen collected from a newborn infant's heel and applied to the designated area on a blood-spot specimen collection test requisition card for the purpose of performing screening tests.

(b) "Blood-spot specimen" includes:

(i) The first screening blood-spot specimen collected from a newborn infant, usually in the birthing facility or other place where the newborn infant was born, within 48 hours after the newborn infant's birth;

(ii) The second screening blood-spot specimen collected from a newborn infant, usually collected when the newborn infant is between 10 and 14 days of age; and

(iii) A blood-spot specimen collected subsequent to a specimen specified in §B(2)(b)(i) and (ii) of this regulation as required to meet the medical needs and condition of the newborn infant and any additional specific screening blood-spot specimen collection and screening test requirements of this chapter and COMAR 10.10.13.

[(2)**]** *(3)*—**[**(3)**]** *(4)* (text unchanged)

[(4)**]** *(5)* "Courier" means an entity employed by a person to convey a *blood-spot* specimen from the site of *blood-spot* specimen collection to the laboratory where the *blood-spot* specimen will be tested.

[(5)**]** *(6)*—**[**(6)**]** *(7)* (text unchanged)

[(7)**]** *(8)* "First screening" means a screening performed on the first **[**blood**]** *blood-spot* specimen collected from a newborn infant after birth.

[(8)**]** *(9)* (text unchanged)

[(9)**]** *(10)* "Follow-Up Unit" means the follow-up component and staff of the Department's Newborn Screening Program, which carries out the duties set forth in Regulation **[**.13**]** *.12* of this chapter.

[(10)**]** *(11)* (text unchanged)

(12)"Home birth" means the birth of an infant which occurs intentionally outside of a birthing facility.

(13) "Home birth attendant" means a physician who is licensed to practice under Health Occupations Article, Title 14, Annotated Code of Maryland, a nurse midwife who is licensed and certified to practice under Health Occupations Article, Title 8, Annotated Code of Maryland, or a direct-entry midwife who is licensed under Health Occupations Article, Title 8, Subtitle 6C, Annotated Code of Maryland, who is caring for the mother and infant at delivery during a home birth as defined in §B(12) of this regulation.

[(11)**]** *(14)*—**[**(12)**]** *(15)* (text unchanged)

[(13)**]** *(16)* "Newborn" or "newborn infant" means an infant:

(a)—(c) (text unchanged)

(d) From whom a **[**blood**]** *blood-spot* specimen was collected and submitted to the State's public health laboratory for newborn screening by a birthing facility or other health care provider located in Maryland, regardless of the infant's place of birth;

(e)—(f) (text unchanged)

[(14)**]** *(17)* Newborn Screening or Screening.

(a) (text unchanged)

(b) "Newborn screening" or "screening" includes:

(i) First-tier testing on a first, second, or subsequent *blood-spot* specimen; and

(ii) (text unchanged)

[(15)**]** *(18)* Newborn Screening Program.

(a) (text unchanged)

(b) "Newborn Screening Program" includes:

(i)—(iii) (text unchanged)

(iv) The **[**Department's Newborn Screening**]** Follow-up Unit; and

(v) (text unchanged)

[(16) Screening Specimen.

(a) "Screening specimen" means a whole-blood specimen collected from a newborn infant's heel and applied to the designated area on a blood-spot collection test requisition card for the purpose of performing screening tests.

(b) "Screening specimen" includes:

(i) The first screening specimen collected from a newborn infant, usually in the birthing facility or other place where the newborn infant was born, within 7 days after the newborn infant's birth;

(ii) The second screening specimen collected from a newborn infant, usually collected when the newborn infant is between 1 and 4 weeks of age; and

(iii) A specimen collected subsequent to a specimen specified in §B(16)(b)(i) and (ii) of this regulation as required to meet the medical needs and condition of the newborn infant and any additional specific screening specimen collection and screening test requirements of this chapter and COMAR 10.10.13.**]**

[(17)**]** *(19)* "Second screening" means a test performed on a routine second *blood-spot* specimen collected when the newborn infant is between **[**1 week and 4 weeks**]** *10 and 14 days* old even though the test results from the newborn's first *blood-spot* specimen were normal.

[(18)**]** *(20)* Second-Tier Test.

(a) "Second-tier test" means a test performed on a newborn screening *blood-spot* specimen when a first-tier test provides an abnormal screening test result or a borderline abnormal screening test result.

(b) (text unchanged)

[(19)**]** *(21)* "Supplemental test" means a test performed on a *blood-spot* specimen collected from a newborn infant that is:

(a)—(b) (text unchanged)

[(20)**]** *(22)* "Unsatisfactory *blood-spot* specimen" means a blood-spot *specimen* that may produce an inaccurate or unreliable test result because the blood-spot *specimen* exhibits one of the problems of collection as specified in COMAR 10.10.13.21B and C.

.04 Responsibilities of the Department.

A.—B. (text unchanged)

C. Notification. The Department shall notify the parents and guardians of newborn infants that laboratories other than the Department's public health laboratory may perform postscreening confirmatory or diagnostic tests on newborn infants for hereditary and congenital disorders.

.05 Selection of Disorders for Screening.

A. (text unchanged)

B. The selected disorders are:

(1)—(51) (text unchanged)

(52) **[**Dienoyl CoA**]** *2,4-dienoyl-CoA* reductase deficiency (DE RED); **[**and**]**

(53) Cystic fibrosis*; and*

(54) Severe Combined Immunodeficiency (SCID).

C. Supplemental Tests. The State's Newborn Screening Program may not request or perform a supplemental test until the public health laboratory has confirmed there is sufficient *blood-spot* specimen to test for the required panel of disorders set forth in §B of this regulation.

.06 Pre-Test Information.

Before a *blood-spot* specimen is sent for newborn screening, a health care provider *or the individual's designated representative* shall provide to the newborn infant's parent or guardian an explanation of newborn screening that includes:

A.—B. (text unchanged)

.07 [Births in a Birthing Facility.] *Initial Screening.*

The individual in charge of a birthing facility or the individual's designated representative, or the home birth attendant shall:

A. **[**Specimen Collection and Screening.**]** If the parent or guardian of the newborn infant does not object to newborn screening**[**, the individual in charge of a birthing facility or the individual's designated representative shall**]**:

(1) Collect a **[**blood**]** *blood-spot* specimen:

(a)—(b) (text unchanged)

(2) Submit the collected **[**blood**]** *blood-spot* specimen to the Department's public health laboratory**[.]***;*

B. **[**Parental Objection.**]** When a parent or guardian objects to newborn screening**[**, the individual in charge of a birthing facility or the individual's designated representative shall**]**:

(1) (text unchanged)

(2) Inform the **[**Department's**]** Follow-Up Unit by telephone, fax, or email of the objection within 12 hours after the objection**[.]***;*

C. **[**Full-Term Healthy Newborn Infants.**]** *For full-term healthy newborn infants:*

(1) **[**The individual in charge of a birthing facility or the individual's designated representative shall collect from each full-term healthy newborn infant to be tested**]** *Collect* a *blood-spot* specimen to test for the disorders set forth in Regulation .05 of this chapter not sooner than 24 hours after the onset of milk feeding, regardless of whether the newborn is breast-fed or formula-fed**[.]***; and*

(2) If the newborn infant is discharged before 24 hours after the onset of milk feeding, **[**the individual in charge of the birthing facility or the individual's designated representative shall**]** collect the *blood-spot* specimen as late as practical before the newborn infant is discharged from the birthing facility**[.]***; and*

D. **[**Ill or Premature Newborn Infants. If**]** *For* a newborn infant **[**to be tested is**]** born prematurely or **[**is**]** expected to be ill for longer than 14 days, **[**the individual in charge of the birthing facility or the individual's designated representative shall**]** *if the newborn infant's medical condition permits,* collect:

(1) A **[**blood**]** *blood-spot* specimen for the newborn screening test *upon admission*, before the administration of blood products**[,** if the newborn infant's medical condition permits**]** *or antibiotics*;

(2) A subsequent *blood-spot* specimen **[**24**]** *48* to 72 hours after birth, regardless of milk feeding status;

(3) A subsequent *blood-spot* specimen *by 10 days of age* when milk feeding**[**, as set forth on §C(2) of this regulation,**]** is established *or the infant has been receiving additional protein through intravenous fluids*; and

(4) An additional subsequent specimen *at one month of age or* at discharge, *whichever comes first*.

[E. Hearing Screening. The individual in charge of the birthing facility or the individual's representative shall:

(1) Record results of a newborn infant's hearing screening test;

(2) Record any risk factors for hearing loss;

(3) Record demographic, clinical, and health care provider information required by the Early Hearing Detection and Intervention Program in the Maternal and Child Health Bureau; and

(4) Transmit the information recorded in §E(1)—(3) of this regulation to the Early Hearing Detection and Intervention Program in the Maternal and Child Health Bureau in the format specified by the Early Hearing Detection and Intervention Program**]**.

[.09] *.08* Second Screening.

A health care provider shall have a **[**blood**]** *blood-spot* specimen collected for a second screening for the disorders set forth in Regulation .05 of this chapter when the newborn is between **[**1 week and 4 weeks**]** *10 and 14 days* old.

[.10] *.09* Transport of *Blood-spot* Specimens to a Licensed Laboratory.

A. A birthing facility representative, physician, or other health care provider or, in the case when a birth occurs outside a birthing facility, the individual required to prepare and file the certificate of birth, shall send newborn screening *blood-spot* specimens only to the Department's public health laboratory for the performance of newborn screening, as set forth in COMAR 10.10.13.14B.

B. The individual responsible for collecting and submitting a *blood-spot* specimen for a newborn screening test shall ensure that**[**:

(1) Specimens**]** *blood-spot specimens* are forwarded by courier to the Department's public health laboratory within 24 hours after collection**[**; and

(2) Couriers deliver specimens to the Department's public health laboratory within 24 hours after the courier receives the specimen**]**.

[.11] *.10* Results.

A. Normal Screening Results.

(1) The Department's public health laboratory shall report normal newborn screening test results to the submitter of the *blood-spot* specimen **[**and to the Department's Newborn Screening Follow-Up Unit**]** within 3 business days after receipt of the *blood-spot* specimen.

(2) A birthing facility representative, health care provider, or the individual who is responsible for filing the certificate of birth if the birth occurs outside a birthing facility, or other submitter of the *blood-spot* specimen shall:

(a)—(b) (text unchanged)

B. Abnormal Screening Results.

(1) The Department's public health laboratory shall immediately report abnormal newborn screening test results to the **[**Department's Newborn Screening**]** Follow-Up Unit.

(2) The Department's public health laboratory shall report to the **[**Department's Newborn Screening**]** Follow-Up Unit all known demographic and clinical data on the newborn infant in an electronic format compatible with the Department's information system databases operated by the Department's public health laboratory, as set forth at COMAR 10.10.13.25.

(3) The **[**Department's Newborn Screening**]** Follow-Up Unit shall enter results in the Department's database and initiate follow-up procedures as specified in Regulation **[**.13**]** *.12* of this chapter.

(4) The submitter of the *blood-spot* specimen shall:

(a)—(b) (text unchanged)

[.12] *.11* Referral Procedures

The individual in charge of a birthing facility or the individual's designated representative, or the home birth attendant shall:

[A. Newborn Infants Born in a Birthing Facility.**]**

[(1) The individual in charge of a birthing facility or the individual's designated representative shall develop**]**

A. Develop collection and transport procedures to ensure against collecting and submitting unsatisfactory *blood-spot* specimens for each of the categories of newborn infant listed in **[**§A(2)—(4)**]** *§§B—E* of this regulation.

B. Collect or otherwise have collected:

[(2) Newborn Infants Discharged Before 24 hours of Milk Feeding. In**]**

(1) An additional blood-spot specimen before the newborn is 7 days old for newborn infants discharged before 24 hours of milk feeding in addition to the *blood-spot* specimen collected before discharge, as set forth in Regulation .07C(2) of this chapter**[**, the individual in charge of a birthing facility or the individual's designated representative shall collect an additional specimen before the newborn is 7 days old**]**.

[(3) Newborn Infants Discharged Before a Specimen is Collected. If**]**

(2) The blood-spot specimen before the newborn is 7 days old if a newborn infant is discharged from a birthing facility before a newborn screening *blood-spot* specimen is collected**[**, the individual in charge of the birthing facility or the individual's designated representative shall collect the specimen before the newborn is 7 days old**]**.

[(4) Newborn Infants with an Unsatisfactory Specimen. If**]**

(3) An additional blood-spot specimen within 7 days after notification if the laboratory reports to a birthing facility *or a home birth attendant* that the **[**laboratory has received an unsatisfactory specimen, the individual in charge of a birthing facility or the individual's designated representative, within 7 days after notification that the initial specimen was unsatisfactory, shall collect or otherwise have collected an additional specimen**]** *initial blood-spot specimen was unsatisfactory*.

[(5) Newborn Infants Who are Transfused Before Specimen Collection. If**]**

(4) A blood-spot specimen to be tested for hemoglobins, biotinidase, and galastose -1 phosphate uridyl transferase (GALT) only, four months after the last transfusion if the initial *blood-spot* specimen was not collected until after the infant was transfused**[**, the individual in charge of the birthing facility or individual's designated representative shall collect a specimen to be tested for hemoglobins, biotinidase, and galactose -1 phosphate uridyl transferase (GALT) only, 4 months after the last transfusion**]**.

[B. Newborn Infants Born Outside a Birthing Facility. If the birth of a newborn infant occurs outside a birthing facility**,** the individual required to prepare and file the certificate of birth shall:

(1) Collect and submit an additional specimen to the State's public health laboratory for each newborn infant reported by the public health laboratory to have an unsatisfactory specimen; and

(2) Submit the additional specimen within 7 days after notification that the initial specimen was unsatisfactory.**]**

[.13] .*12* Follow-Up Procedures.

A. Department's Responsibilities.

(1) The **[**Department's Newborn Screening**]** Follow-Up Unit shall investigate each abnormal result indicative of increased risk for an hereditary or congenital disorder by contacting the infant's health care provider, or other appropriate individual to notify the parent or guardian, or if the health care provider cannot be contacted, by contacting the infant's parent or guardian directly **[**or directing the designated representative of the appropriate birthing facility, the infant's health care provider, or other appropriate individual to notify the parent or guardian**]** regarding:

(a)—(d) (text unchanged)

(2) If the parent or guardian fails to respond to the birthing facility, health care provider, or other responsible individual acting as set forth in §B(1) of this regulation, the individual in charge of the birthing facility or the individual's designated representative, health care provider, or other responsible individual shall notify the **[**Department's Newborn Screening**]** Follow-Up Unit, which shall then try to notify the parent or guardian of the need for follow-up by using at least one of the following means, in the indicated order of priority:

(a)—(d) (text unchanged)

(3) The **[**Department's Newborn Screening**]** Follow-Up Unit shall provide recommendations to the responsible birthing facility, health care provider, and the parent or guardian, as appropriate, regarding the appropriate follow-up and diagnostic evaluation of the newborn infant.

(4) The **[**Department's Newborn Screening**]** Follow-Up Unit shall recommend:

(a) (text unchanged)

(b) That no treatment be administered to the newborn infant until the results of the follow-up evaluation have established that the infant has a *hereditary or congenital* disorder.

(5) The **[**Department's Newborn Screening**]** Follow-Up Unit shall inform health care personnel and parents or guardians of:

(a)—(b) (text unchanged)

B. Responsibilities of the Birthing Facility or Health Care Provider. The individual in charge of the birthing facility or individual's designated representative or health care provider shall:

(1) Evaluate the infant for signs, symptoms, and biochemical evidence of a *hereditary or congenital* disorder;

(2) (text unchanged)

(3) Collect and submit any required **[**blood**]** *blood-spot* specimens for repeat screening or diagnostic testing; and

(4) Report the results of diagnostic testing to the **[**Department's Newborn Screening**]** Follow-Up Unit.

[.15] .*13* Records.

A. (text unchanged)

B. **[**Upon**]** *On* request, a laboratory or health care provider shall make available to the **[**Department's Newborn Screening**]** Follow-Up Unit medical records, records of laboratory tests, and any other medical information the **[**Department's Newborn Screening**]** Follow-Up Unit considers necessary to:

(1)—(3) (text unchanged)

C. (text unchanged)

VAN T. MITCHELL

Secretary of Health and Mental Hygiene