PROPOSED RULE # _____.

Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" (CVR 04-000-001) adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms and enclosures with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted to the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of Proposed Filing Coversheet will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Newborn Screening Program Rule

/s/ Dawn O'Toole , on 8/27/2026

(signature) (date)

Printed Name and Title:

Dawn O'Toole, Chief Operating Officer
Agency of Human Services

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Filing Confirmed

1. TITLE OF RULE FILING:
   Newborn Screening Program Rule
2. ADOPTING AGENCY:
   Agency of Human Services - Vermont Department of Health
3. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: Jessica Schifano, Policy Director

Agency: Agency of Human Services - Vermont Department of Health

Mailing Address: 280 State Drive Waterbury, VT 05671-8300

Telephone: 802-798-6756 Fax:

E-Mail: AHS.VDHRules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:
https://www.healthvermont.gov/laws-regulations/laws/proposed-health-rules

4. SECONDARY CONTACT PERSON:

(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: Meg McCarthy, Policy Advisor

Agency: Agency of Human Services - Vermont Department of Health

Mailing Address: 280 State Drive Waterbury, VT 05671-8300

Telephone: 802-904-9319 Fax:

E-Mail: AHS.VDHRules@vermont.gov

5. RECORDS EXEMPTION INCLUDED WITHIN RULE:

(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) No

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

6. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

18 V.S.A. §§ 102, 115, and 991; 3 V.S.A. § 801(b)(11)

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

3 V.S.A. § 801(b)(11) states, "'Adopting authority' means, for agencies that are attached to the Agenc[y] of...Human Services...the secretaries of those agencies…"

18 V.S.A. § 115 (b)(5) states "The Commissioner of Health is authorized to adopt rules for the purpose of screening chronic diseases and developmental disabilities in newborns."

18 V.S.A. § 991 (a)-(b) states "The Commissioner of Health shall establish a statewide birth information network designed to identify newborns who have specified health conditions which may respond to early intervention and treatment by the health care system."

"The Department of Health is authorized to collect information for the birth information network for the purpose of preventing and controlling disease, injury, and disability."

18 V.S.A. § 991 states "…The Department of Health is authorized to amend the list of medical conditions through rulemaking pursuant to 3 V.S.A. chapter 25 to meet the objectives of this section."

8. CONCISE SUMMARY **(150 WORDS OR LESS)**:

The purpose of these regulations is to provide standards for screening for certain diseases in newborn children where early identification and treatment may significantly delay disease progression and reduce severity of complications and/or death by assuring timely initiation of treatment services. These screenings are part of the early case-finding program for chronic diseases. This rule applies to all health care providers for newborn infants. This rulemaking does the following:

1)Adds three new diseases (Mucopolysaccharidosis type II, Guanidinoacetate Methyltransferase Deficiency, Infantile Krabbe disease) to the condition list for

dried bloodspot testing to align with the Recommended Uniform Screening Panel (RUSP);

2)Non-substantively amends existing conditions on the conditions list for dried bloodspot testing to align with the RUSP;

3) Updates terminology and improves clarity;

4) Updates the Rule to align with current standards of practice among health care providers and the Department of Health.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

With early identification and treatment, disease progression, severe complications, disability and death can be prevented. The addition of these diseases does not require further testing of the child, it simply adds to the list of tests performed using the current dried blood spot test.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13)(A):

The Agency of Human Services determined that the proposed changes are within its authority under 18 V.S.A. § 991. 18 V.S.A. § 991 authorizes the Department of Health to amend the list of medical conditions to help identify newborns who have specified health conditions which may respond to early intervention and treatment and for the purpose of preventing and controlling disease, injury, and disability. Aligning Vermont's list with the federal RUSP will achieve those objectives given that the conditions on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Health care providers

Vermont newborns

Hospitals

Parents or legal guardians

12. BRIEF SUMMARY OF ECONOMIC IMPACT **(150 WORDS OR LESS)**:

The Department anticipates that this rulemaking will have a direct economic cost on hospitals due to expanding the newborn screening panel of conditions. The Department estimates that the cost incurred by hospitals from this rulemaking will be $25.50 per baby tested.

13. A HEARING WILL BE SCHEDULED.

IF A HEARING WILL NOT BE SCHEDULED, PLEASE EXPLAIN WHY.

14. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING, PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:

Zip Code:
URL for Virtual:

---

15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):
16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Newborn screening

Chronic diseases

Disease identification

Dried bloodspot

Hearing screening

Hospitals

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

---

1. TITLE OF RULE FILING:
   Newborn Screening Program Rule
2. ADOPTING AGENCY:
   Agency of Human Services – Vermont Department of Health
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT -** Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment if the rule is replaced with other text.
   - **NEW RULE -** A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **AN AMENDMENT OF AN EXISTING RULE .**

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE)*:

   Newborn Screening Program Rule, 5/1/2019, Secretary of State Rule Log #19-012

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

---

1. TITLE OF RULE FILING:

   Newborn Screening Program Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Vermont newborns: There are potential benefits to children from early intervention to address the conditions identified in screening.

   Parents and guardians of newborns: There are potential benefits to parents and guardians of newborns should their children receive early intervention to address the conditions identified in screening.

Hospitals: The Department anticipates that this rulemaking will have a direct economic cost on hospitals due to expanding the newborn screening panel of conditions. Screening for Mucopolysaccharidosis type II is estimated to cost $16.70 per baby, Guanidinoacetate Methyltransferase Deficiency is estimated to cost $4.40 per baby, and Infantile Krabbe disease is estimated to cost $4.40 per baby. The Department estimates that the cost incurred by hospitals from this rulemaking will be $25.50 per baby tested.

Healthcare providers: The Department does not anticipate any impact on healthcare providers as this rulemaking aligns with current standards of practice.

4. IMPACT ON SCHOOLS:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

This rulemaking would not have any direct costs on schools. There may be potential benefits to schools due to children with less severe and debilitating chronic conditions.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

Since the rulemaking does not have any direct costs for schools, the Department did not consider alternatives. However, any potential benefits to schools would not be realized if the three diseases are not added since children will go without the screening, would be less likely to receive prompt diagnosis of their conditions, and as a result, may not receive early interventions to reduce the severity of the chronic conditions that could have been identified during screening.

6. IMPACT ON SMALL BUSINESSES:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

There are no anticipated impacts to small businesses.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

   There are no anticipated impacts to small businesses.

8. COMPARISON:

   COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

   The alternative to this rulemaking is not adding the three additional diseases to the newborn screening panel. This would eliminate the additional cost of screening charged to hospitals. However, disorders on the newborn screening panel are chosen based on evidence that supports the potential net benefit of early intervention. If the conditions are not added, children will go without the screening, would be less likely to receive prompt diagnosis of their conditions, and as a result, may not receive early interventions to address the conditions that could have been identified during screening.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

   The Department has consulted with laboratories to determine the actual cost of the new tests. Determining the long-term benefits of debilitating chronic conditions avoided is not feasible at this time.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

---

1. TITLE OF RULE FILING:

   Newborn Screening Program Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   No impact is anticipated.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   No impact is anticipated.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   No impact is anticipated.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   No impact is anticipated.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   No impact is anticipated.
8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   No impact is anticipated.
9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The rule does not impact any of the areas listed above, and therefore, this analysis sufficiently captures that there will be no environmental impact.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

---

1. TITLE OF RULE FILING:

   Newborn Screening Program Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   The Department engaged stakeholders in developing the proposed rule and plans to conduct targeted outreach to the parties listed below. Additionally, there will be public notice, a public comment period, and a public hearing. The rule will be posted on the Department of Health website: https://www.healthvermont.gov/laws-regulations/laws/proposed-health-rules.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   The Department will conduct targeted outreach to the following:

   Hospitals and healthcare administrators(all Vermont hospitals, Dartmouth Hitchcock Medical Center, Champlain Valley Physicians Hospital, and other regional referral hospitals)

   Vermont Association of Hospitals and Health Systems

Health care providers (specialists, hospitalists, primary care providers, nurses, laboratories, OB/GYNs, midwives, audiologists, etc.)

Vermont Medical Society

UVM Medical Center Educational Services Practice - Vermont Parent Infant Program

Medicaid/Insurers

Pharmacy groups

New England Regional Genetics Group

New England Consortium of Metabolic Programs

Advocacy groups (Association for Creatine Deficiencies, Krabbe Connect, Hunter's Hope, National MPS Society, Project Alive, Expecting Health/Baby's First Test, Vermont Hands & Voices, National Organization for Rare Disorders)

Regional Newborn Screening Programs

American Academy of Pediatrics

Association of Public Health Laboratories (NewSTEPs)

Vermont Family Network

Vermont Department of Health's Children with Special Health Needs Program

Vermont Department for Children and Families Children's Integrated Services

Newborn Screening Program Rule

1. Authority

1.1. This rule is adopted pursuant to 18 V.S.A. §§ 102, 115 and 991.

2. Purpose and Scope

2.1. The purpose of this rule is to provide standards for screening for certain diseases in newborn children where early identification and treatment may prevent severe disability and/or death by assuring timely initiation of treatment services. These screenings are part of the early case-finding program for chronic diseases. This rule applies to all health care providers for newborn infants.

3. Definitions

3.1. "Department" means the Vermont Department of Health.

3.2. "Dried bloodspot" means the blood specimen drawn for the purpose of screening newborns for certain serious disorders not readily apparent at birth and which require early diagnosis and treatment.

3.3. "Newborn Screening Program" means the Department of Health's program to assure that infants born in the state are tested for certain diseases and conditions for which early identification and treatment will prevent severe disability and/or death, and, for those affected, to assure timely initiation of treatment services.

3.4. "Newborn screening test" means the screening for certain rare and serious diseases and conditions which may not be apparent at birth. Newborn screening tests are conducted through a laboratory analysis of dried bloodspots obtained from newborn infants and point-of-care testing.

3.5. "Point-of-care testing" means physiologic tests that are administered to newborns and interpreted at the bedside, the site of direct delivery of health care, such as hearing screening to detect hearing loss, or pulse oximetry to detect possible Critical Congenital Heart Disease.

4. Testing of Newborns

4.1. Dried bloodspot testing:

4.1.1. The health care provider should inform the parent or guardian of the reasons for and the procedures used in the newborn screening tests as well as the potential health consequences of declining screening. Health care providers shall perform screening tests on newborn infants unless the parent, guardian or custodian of the newborn declines screening.

4.1.2. The laboratory designated by the Department shall test for the following diseases from the dried bloodspots:

- 3-Hydroxy-3-methylglutaric aciduria
- 3-Methylcrotonyl-CoA carboxylase deficiency
- Argininosuccinic aciduria
- β-Ketothiolase deficiency
- Biotinidase deficiency
- Carnitine uptake defect/carnitine transport defect
- Citrullinemia, type I
- Classic galactosemia
- Classic phenylketonuria
- Congenital adrenal hyperplasia
- Cystic fibrosis
- Glutaric acidemia type I
- Glycogen storage disease type II (Pompe)
- Guanidinoacetate Methyltransferase Deficiency
- Holocarboxylase synthase deficiency
- Homocystinuria
- Infantile Krabbe disease
- Isovaleric acidemia
- Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency
- Maple syrup urine disease
- Medium-chain acyl-CoA dehydrogenase deficiency
- Methylmalonic acidemia (cobalamin disorders)
- Methylmalonic acidemia (methylmalonyl-CoA mutase)
- Mucopolysaccharidosis type I
- Mucopolysaccharidosis type II
- Primary congenital hypothyroidism
- Propionic acidemia
- Severe combined immunodeficiencies
- S, βeta-thalassemia
- S,C disease
- S,S disease (Sickle cell anemia)

- Spinal muscular atrophy due to homozygous deletion of exon 7 in SMN1
- Trifunctional protein deficiency
- Tyrosinemia, type I
- Very long-chain acyl-CoA dehydrogenase deficiency
- X-Linked adrenoleukodystrophy

4.2. Point-of-care testing:

4.2.1. Health care providers shall perform a hearing screening test on newborn infants unless the parent, guardian or custodian of the newborn declines screening.

4.2.2. Health care providers shall perform on every newborn a screening for critical congenital heart disease (CCHD) that reflects the standard of care unless the parent, guardian or custodian of the newborn declines screening.

5. Reporting

5.1. All results of dried bloodspot testing shall be sent by the designated laboratory to the Department.

5.2. Health care providers shall provide CCHD screening data or newborn dried bloodspot testing follow-up data (e.g., rescreens, diagnostic evaluations, referrals) to the Department upon request.

5.3. Health care providers shall report results of newborn hearing screens, rescreens, and diagnostic evaluations to the Department.

5.4. Providers who implement services for children birth to 3 years of age who are Deaf and Hard of Hearing (e.g., Teachers of the Deaf and Hard of Hearing, Speech and Language Pathologists, Audiologists, Early Intervention Providers) shall report referrals and enrollments into early intervention services to the Department.

5.5. The screening health care provider shall send documentation of a parent or guardian's declination for newborn dried bloodspot testing and hearing screening to the Department.

6. Quality Assurance

6.1. The Department of Health will provide training and technical assistance to hospitals and health care providers in the implementation of the newborn screening program to assure that the program operates according to current standards of practice as established by the American Academy of Pediatrics, the Centers for Disease Control and Prevention, or other such recognized experts in the field of newborn screening.

7. Retention and Use of Dried Bloodspot Specimens

7.1. After testing is complete, the testing laboratory shall store residual dried bloodspots for one year and then destroy the samples. Storage and destruction shall be consistent with nationally recognized laboratory standards and applicable federal requirements relating to the disposal of human blood and body fluids.

7.2. If the storage environment of any dried bloodspot specimen is found to have deviated from the required conditions, such that the stability of the specimen is likely to have been affected, the testing laboratory shall first notify the Vermont Newborn Screening Program and then shall destroy the dried bloodspot specimen in a manner consistent with applicable federal requirements relating to the disposal of human blood and body fluids.

7.3. Dried bloodspot specimens may be destroyed earlier than one year at the written request of the infant's parent(s) or legal guardian(s).

7.4. During the one-year period, at the request of the attending physician, and with written consent of the infant's parent(s) or guardian(s), stored dried bloodspot specimens may be retrieved and used for further testing which would assist in the interpretation of screening results or clinical findings for the infant.

7.5. Dried bloodspots may be used without parental consent by the testing laboratory only for the purpose of quality assurance and quality control for routine maintenance and function checks.

7.6. Dried bloodspots shall not be used for any other purposes without written consent from a parent or guardian.

Newborn Screening Program Rule

1. Authority

1.1. This rule is adopted pursuant to ~~3 V.S.A. § 3003;~~ 18 V.S.A. §§ 102, 115 and 9915~~5087~~.

2. Purpose and Scope

2.1. The purpose of this rule is to provide standards for screening for certain diseases in newborn children where early identification and treatment may prevent severe disability and/or death by assuring timely initiation of treatment services. These screenings are part of the early case-finding program for chronic diseases. This rule applies to all health care providers for newborn infants.

3. Definitions

3.1. "Department" means the Vermont Department of Health.

3.2. "Dried bloodspot" means the blood specimen drawn for the purpose of screening newborns for certain serious disorders not readily apparent at birth and which require early diagnosis and treatment.

3.3. "Newborn Screening Program" means the Department of Health's program to assure that infants born in the state are tested for certain diseases and conditions for which early identification and treatment will prevent severe disability and/or death, and, for those affected, to assure timely initiation of treatment services.

3.4. "Newborn screening test" means the screening for certain rare and serious diseases and conditions which may not be apparent at birth. Newborn screening tests are conducted through a laboratory analysis of dried bloodspots obtained from newborn infants and point-of-care testing.

3.5. "Point-of-care testing" means physiologic tests that are administered to newborns and interpreted at the bedside, the site of direct delivery of health care, such as hearing screening to detect hearing loss, or pulse oximetry to detect possible Critical Congenital Heart Disease.

4. Testing of Newborns

4.1. Dried bloodspot testing:

4.1.1. The health care provider should inform the parent or guardian of the reasons for and the procedures used in the newborn screening tests as well as the potential health consequences of declining~~refusing~~ screening. Health care providers ~~should~~ shall perform screening tests on newborn infants unless the parent, guardian or custodian of the newborn ~~refuses~~ declines screening.

4.1.2. The laboratory designated by the Department shall test for the following diseases from the dried bloodspots:

- ~~3-Methylcrotonyl-CoA carboxylase deficiency (3MCC)~~
- ~~3-OH 3-CH3~~3-Hydroxy-3-methyl-glutaric aciduria ~~(HMG)~~
- 3-Methylcrotonyl-CoA carboxylase deficiency ~~(3MCC)~~
- Argininosuccinic aciduria~~emia~~ ~~(ASA)~~
- β~~Beta~~-K~~k~~etothiolase deficiency ~~(BKT)~~
- Biotinidase deficiency ~~(BIOT)~~
- Carnitine uptake defect/carnitine transport defect ~~(CUD)~~
- Citrullinemia, type I ~~(CIT)~~
- Classic g~~G~~alactosemia ~~(Classical) (GALT)~~
- Classic ~~P~~phenylketonuria ~~(PKU)~~
- Congenital adrenal hyperplasia ~~(CAH)~~
- ~~Congenital hypothyroidism (CH)~~
- Cystic fibrosis ~~(CF)~~
- ~~Galactosemia (Classical) (GALT)~~
- Glutaric acidemia type I ~~(GA I)~~
- Glycogen storage disease type II (Pompe) ~~Disease~~
- Guanidinoacetate Methyltransferase Deficiency
- ~~Multiple~~ Holocarboxylase synthase deficiency ~~(MCD)~~
- ~~Hb S/Beta-thalassemia (Hb S/BTh)~~
- ~~Hb S/C disease (Hb S/C)~~
- Homocystinuria ~~(HCY)~~
- Infantile Krabbe disease
- Isovaleric acidemia ~~(IVA)~~
- Long-chain L-3 -hydroxy~~OH~~ acyl-CoA dehydrogenase deficiency ~~(LCHAD)~~
- Maple syrup urine disease ~~(MSUD)~~
- Medium-chain acyl-CoA dehydrogenase deficiency ~~(MCAD)~~
- Methylmalonic acidemia (cobalamin disorders~~Cbl A, B~~)
- Methylmalonic acidemia (methylmalonyl-CoA mutase ~~deficiency~~) ~~(MUT)~~
- Mucopolysaccharidosis t~~T~~ype I ~~(MPS 1)~~
- Mucopolysaccharidosis type II

- Primary c~~C~~ongenital hypothyroidism ~~(CH)~~
- ~~Multiple carboxylase deficiency (MCD)~~
- ~~Phenylketonuria (PKU)~~
- Propionic acidemia ~~(PROP)~~
- Severe combined immunodeficiencies~~y~~ ~~(SCID)~~
- ~~Hb S, /β~~Beta-thalassemia ~~(Hb S/BTh)~~
- ~~Hb S,/~~C disease ~~(Hb S/C)~~
- S,S disease (Sickle cell anemia) ~~(Hb SS disease) (SS)~~
- Spinal ~~M~~muscular ~~A~~atrophy due to homozygous deletion of exon 7 in SMN1~~(SMA)~~
- Trifunctional protein deficiency ~~(TFP)~~
- Tyrosinemia, type I ~~(TYR I)~~
- Very long-chain acyl-CoA dehydrogenase deficiency ~~(VLCAD)~~
- X-Linked a~~A~~drenoleukodystrophy~~(X ALD)~~

4.2. Point-of-care testing:

4.2.1. Health care providers ~~should~~ shall perform a hearing ~~loss~~ screening test on newborn infants unless the parent, guardian or custodian of the newborn declines~~refuses~~ screening.

4.2.2. Health care providers shall perform on every newborn a screening for critical congenital heart disease (CCHD) ~~on every newborn~~ that reflects the standard of care unless the parent, ~~or~~ guardian or custodian of the newborn declines screening.~~, unless a congenital heart defect was detected prenatally. This screening may include pulse oximetry or other methodologies that reflect the standard of care.~~

5. Reporting

5.1. All results of dried bloodspot~~s~~ testing shall be sent by the designated laboratory to the Department ~~for surveillance of chronic diseases~~.

5.2. Health care providers shall provide CCHD screening data or newborn dried bloodspot testing follow-up data (e.g., rescreens, diagnostic evaluations, referrals) to the Department~~'s Newborn Screening Program~~ upon request.

5.3. Health care providers ~~may~~ shall report results of ~~point of care~~ newborn ~~and early periodic~~ hearing screens, rescreens, and diagnostic evaluations ~~ings~~ to the Department ~~for surveillance of chronic diseases~~.

~~5.3.~~5.4. Providers who implement services for children birth to 3 years of age who are Deaf and Hard of Hearing (e.g., Teachers of the Deaf and Hard of Hearing, Speech and Language Pathologists, Audiologists, Early Intervention Providers) shall report referrals and enrollments into early intervention services to the Department.

~~5.4.~~5.5. The screening health care provider ~~will~~ shall send documentation of a parent or guardian's declination~~refusal~~ for newborn dried bloodspot testing and hearing screening~~s~~ to the ~~Vermont~~ Department ~~of Health,, Vermont Newborn Screening Program~~.

6. Quality Assurance

6.1. The Department of Health will provide training and technical assistance to hospitals and health care providers in the implementation of the newborn screening program to assure that the program operates according to current standards of practice as established by the American Academy of Pediatrics, the Centers for Disease Control and Prevention, or~~and~~ other such recognized experts in the field of newborn screening.

7. Retention and Use of Dried Bloodspot Specimens

7.1. After testing is complete, the testing laboratory shall store residual dried bloodspots for one year and then destroy the samples. Storage and destruction shall be ~~done~~ consistent with nationally recognized laboratory standards and applicable federal requirements relating to the disposal of human blood and body fluids.

~~7.2. All existing dried bloodspot samples held by the Department at the time of adoption of this rule will be stored for one year and then destroyed in a manner consistent with applicable federal requirements relating to the disposal of human blood and body fluids.~~

~~7.3.~~7.2. If the storage environment of any dried bloodspot specimen is found to have deviated from the required conditions, such that the stability of the specimen is likely to have been affected, the testing laboratory shall first notify the Vermont Newborn Screening Program and then shall destroy the dried bloodspot specimen in a manner consistent with applicable federal requirements relating to the disposal of human blood and body fluids.

~~7.4.~~7.3. Dried bloodspot specimens may be destroyed earlier than one year at the written request of the infant's parent(s) or legal guardian(s).

~~7.5.~~7.4. During the one-year period, at the request of the attending physician, and with written consent of the infant's parent(s) or guardian(s), stored dried bloodspot specimens may be retrieved and used for further testing which would assist in the interpretation of screening results or clinical findings for the infant.

~~7.6.~~7.5. Dried bloodspots may be used without parental consent by the testing laboratory only for the purpose of quality assurance and quality control for routine maintenance and function checks.

~~7.7.~~7.6. Dried bloodspots shall not be used for any other purposes without written consent from a parent or guardian.

280 State Drive – Center Building
Waterbury, VT 05671-1000

OFFICE OF THE SECRETARY
TEL: (802) 241-0440
FAX: (802) 241-0450

JENNEY SAMUELSON
SECRETARY

TODD W. DALOZ
DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

DATE: June 29, 2026

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

---

I hereby designate Dawn O'Toole, Chief Operating Officer, Agency of Human Services as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedures Act, 3. V.S.A § 801 et seq.

CC: Dawn O'Toole via Dawn.OToole@vermont.gov