Chapter 71.

Regulations Governing Virginia Newborn Screening Services

12 VAC 5-71-10. Definitions.

The following words and terms when used in this regulation, shall have the following meanings unless the context clearly indicates otherwise:

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday, from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN Pool of Funds, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

“Care Coordination” means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

“Certified nurse midwife” means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II 18 VAC 90-30-60 et seq. and 18 VAC 90-30-120 and 18 VAC 90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, and a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

“Confirmatory testing” means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

“Core panel conditions” means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (1) specific and sensitive screening tests, (2) a sufficiently well understood natural history, and, (3) available and efficacious treatments.

"Department" means the State Department of Health.

“Dried-blood-spot specimen” means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

“Guardian” means a parent-, court-, or clerk-appointed guardian of the person.

“Healthcare provider” means a person who is licensed to provide health care as part of their job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

“Heritable disorders and genetic diseases” means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means a medical care facility licensed as a hospital by the Virginia Department of

Health.

"Infant" means a child less than 12 months of age.

“Low protein modified foods” means foods that are: (1) specially formulated to have less than one gram of protein per serving; (2) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease; (3) not natural foods that are naturally low in protein; and, (4) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

“Metabolic formula” means nutritional substances that are (1) prescribed by a health professional with appropriate prescriptive authority; (2) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (3) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (4) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs

“Metabolic supplements” means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

“Midwife” means a person licensed as a nurse practitioner in the category of certified nurse

midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

“Newborn” means an infant who is 28 days old or less.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multi-state licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

“Parent” means a biological, adoptive, or stepparent.

“Pediatric Comprehensive Sickle Cell Clinic Network” means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support services for newborns and children living with sickle cell disease and other genetically-related Hemoglobinopathies.

“Physician" means a person holding a current license to practice medicine as a Doctor of Medicine and Surgery or Doctor of Osteopathic Medicine by the Virginia Board of Medicine or a current multi-state licensure privilege to practice in Virginia as a Doctor of Medicine and Surgery or Doctor of Osteopathic Medicine.

“Pool of Funds” means funds designated for payment of direct health care services. Access to

the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state match.

“Population-based” means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.

"Preterm infant" means a neonate whose birth occurs through the end of the last day of the 36th week following the onset of the last menstrual period.

“Repeat specimen” means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

“Resident” means an individual who resides within the geographical boundaries of the Commonwealth.

“Satisfactory specimen” means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

“Screened-abnormal” means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

“Testing laboratory” means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

“Total parenteral nutrition (TPN)” means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12 VAC 5-71-20 D.

“Unsatisfactory specimen” means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

“Virginia Genetics Advisory Committee” means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

“Virginia Newborn Screening System” means a coordinated and comprehensive group of services—education, screening, follow up, diagnosis, treatment and management, and program evaluation—managed by the department’s Virginia Newborn Screening Services and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born

in Virginia.

"Virginia Sickle Cell Awareness Program: means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or sickle cell trait and for such other genetically-related Hemoglobinopathies.

12 VAC 5-71-20. Administration of chapter.

This chapter is administered by the commissioner.

The commissioner may issue a guidance document that interprets these regulations and provides guidance for their implementation. Such a document shall be reviewed and revised whenever the regulations of this chapter are reviewed, and may also be amended or revised as needed to meet changing circumstances.

Guidance documents shall include procedures for accessing program services including available assistance when not otherwise addressed in these regulations or the Code of Virginia.

12 VAC 5-71-30. Core panel of heritable disorders and genetic diseases.

A. The Virginia Newborn Screening System, which includes Virginia Newborn Screening Services and the Virginia Early Hearing and Intervention Program, shall ensure that

the core panel of heritable disorders and genetic diseases, for which newborn screening is conducted, is consistent with but not necessarily identical to the recommendations for screening by the American College of Medical Genetics in its 2005 report Newborn Screening: Toward a Uniform Screening Panel and System.

B. The department shall review, at least biennially, national recommendations and guidelines and may propose changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the commissioner on proposed changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

D. Infants under 6 months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:

1. Argininosuccinic acidemia (ASA);
2. Beta-Ketothiolase deficiency (βKT);
3. Biotinidase deficiency (BIOT);
4. Carnitine uptake defect (CUD);
5. Citrullinemia (CIT);

6. Congenital adrenal hyperplasia (CAH);

7. Congenital hypothyroidism (CH);

8. Cystic fibrosis (CF);

9. Galactosemia (GALT);

10. Glutaric acidemia type I (GA I);

11. Hemoglobin Sickle/Beta-thalassemia (Hb S/βTh);

12. Hemoglobin Sickle/C disease (Hb S/C);

13. Homocystinuria (HCY);

14. Isovaleric acidemia (IVA);

15. Long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);

16. Maple syrup urine disease (MSUD);

17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);

18. Methylmalonic acidemia (mutase deficiency) (MUT);

19. Methylmalonic acidemia (Cbl A,B);

20. Multiple carboxylase deficiency (MCD);

21. Phenylketonuria (PKU);

22. Propionic acidemia (PROP);

23. Sickle cell anemia (Hb SS disease) (Hb SS);

24. Tyrosinemia type I (TYR I);

25. Trifunctional protein deficiency (TFP);

26. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);

27. 3-hydroxy 3-methyl glutaric aciduria (HMG), and

28. 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC).

E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set forth in §§ 32.1-64.1 and 32.1-64.2. of the Code of Virginia and as governed by 12 VAC 5-80 et seq.

12 VAC 5-71-40. Religious exemption from newborn dried-blood-spot screening requirements.

Refusal by the infant's parent or guardian to consent to the collection and submission of a newborn dried-blood-spot screening specimen because the test conflicts with his religious practices or tenets shall be documented in the medical record and communicated to the department.

12 VAC 5-71-50. Responsibilities of the physician or midwife.

For every live birth in the Commonwealth, the physician or midwife in charge of the infant's care after delivery shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12 VAC 5-71-30 D and in accordance with 12 VAC 5-71-70 or 12 VAC 5-71-80.

12 VAC 5-71-60. Responsibilities of the first attending healthcare provider.

In the event that a physician or midwife does not attend the birth and newborn dried-blood-spot screening tests have not been performed, the first attending healthcare provider shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12 VAC 5-71-30 D in accordance with 12 VAC 5-71-110.

12 VAC 5-71-70. Newborn dried-blood-spot screening specimen collection, specimen submission, and notification—hospital deliveries.

A. Newborn dried-blood-spot specimen collection and submission shall be done in accordance with requirements that are determined by the department's designated testing laboratory.

B. Newborn dried-blood-spot specimen collection shall occur after 24 hours of age or immediately before the newborn's discharge, whichever comes first.

C. If the initial newborn dried-blood-spot specimen is collected before 24 hours of age, a repeat specimen shall be collected at the time of discharge or no later than 14 days of age, regardless of earlier test results.

D. If the newborn is a preterm infant, the newborn dried-blood-spot specimen shall be collected at 7 days of age or at the time of discharge from the hospital, whichever occurs first.

E. If the newborn requires a blood transfusion or total parenteral nutrition (TPN) or if the newborn is suspected of having a heritable disorder or genetic disease that is listed in 12 VAC 5-71-30 D:

1. The newborn dried-blood-spot specimen may be collected before 24 hours of age and subsequently submitted; and

2. A repeat newborn dried-blood-spot specimen shall be collected at the time of discharge or no later than 14 days of age, regardless of earlier test results, and subsequently submitted.

F. On notification by the hospital that the infant was discharged before a newborn dried-blood-spot specimen was collected, the healthcare provider in charge of the infant's care or their designee shall:

1. Notify the infant's parent that the infant was discharged before a newborn dried-blood-spot specimen was collected;

2. Cause the collection of a specimen within 48 hours of that parental notification; and

3. Cause the submission of the specimen.

G. If the newborn is to be transferred to another hospital and is less than 24 hours of age:

1. The physician or certified nurse midwife in charge of the infant's care at the hospital of birth shall:

a. Cause the collection a newborn dried-blood-spot specimen before the newborn is transferred to another hospital;

b. Cause the submission of the specimen; and

c. Notify the receiving physician or healthcare provider that a newborn dried-blood-spot specimen was collected before 24 hours of age.

2. The receiving physician or healthcare provider shall:

a. Cause the collection of a repeat specimen at the time of discharge or no later than 14 days of age, regardless of earlier test results; and

b. Cause the submission of the specimen.

H. If the infant is transferred to another hospital and is 24 hours of age or older, the physician in charge of the infant's care at the hospital of birth shall:

1. Cause the initial collection and submission of a newborn dried-blood-spot specimen for the infant who is being transferred;

2. Notify the receiving physician or physician of record on transfer that the infant's specimen has been collected; and

3. Notify the receiving physician or physician of record if a newborn dried-blood-spot specimen needs to be repeated or if confirmatory testing is required.

I. The healthcare provider in charge of the infant's care, on receiving notice from the testing laboratory that the infant's newborn dried-blood-spot specimen is unsatisfactory, shall:

1. Cause the collection of a repeat specimen as soon as possible but no later than two business days after notice; and

2. Cause the submission of the specimen.

J. The healthcare provider in charge of the infant's care, on receiving notice of the results of the infant's newborn dried-blood-spot screening test, shall place or cause to be placed the results in the infant's medical record and cause parental notification of test results.

K. The healthcare provider in charge of the infant's care, on receiving notice of the infant's screened-abnormal result, shall:

1. Cause the collection of a repeat newborn dried-blood-spot specimen for repeat or confirmatory testing as soon as possible but no later than two business days after notice;

2. Cause the submission of the specimen; and

3. Take immediate action, as instructed, when notified of a critically-abnormal screening result.

12 VAC 5-71-80. Newborn dried-blood-spot screening specimen collection, specimen submission, and notification—deliveries outside of the hospital.

A. In the event that the infant is born outside of a hospital, the attending physician or midwife shall ensure that

1. Newborn dried-blood-spot specimen collection and submission is done in accordance with requirements that are determined by the department's designated testing laboratory.

2. Newborn dried-blood-spot specimen collection occurs after 24 hours of age.

3. If the initial newborn dried-blood-spot specimen is collected before 24 hours of age, a repeat specimen shall be collected no later than 14 days of age, regardless of earlier test results.

4. If the newborn is hospitalized, the infant's healthcare provider shall cause the newborn dried-blood-spot screening specimen collection and submission in accordance with 12 VAC 5-71-70.

B. The healthcare provider in charge of the infant's care, on receiving notice of the results of the infant's newborn dried-blood-spot screening test, shall place or cause to be placed the results in the infant's medical record and cause parental notification of test results.

C. The healthcare provider in charge of the infant's care, on receiving notice from the testing laboratory that the infant's newborn dried-blood-spot specimen is unsatisfactory, shall:

1. Cause the collection of a repeat specimen as soon as possible but no later than two business days after notice; and

2. Cause the submission of the specimen.

D. The healthcare provider in charge of the infant's care, on receiving notice of the infant's screened-abnormal result, shall:

1. Cause the collection of a repeat newborn dried-blood-spot specimen for repeat or confirmatory testing as soon as possible but no later than two business days after notice;

2. Cause the submission of the specimen; and

3. Take immediate action, as instructed, when notified of a critically-abnormal screening result.

If a licensed midwife has ordered the newborn-dried-blood-spot screening test and is notified that the results are unsatisfactory or abnormal, the infant shall be immediately referred to a physician or health care facility for repeat collection and submission and for care and treatment as necessary.

The licensed midwife shall cause the collection and submission of a repeat newborn dried-blood-spot specimen if the specimen is unsatisfactory and referring the infant to a physician or health care facility for repeat collection will result in a delay of more than two business days.

12 VAC 5-71-90. Responsibilities of the chief executive officer.

The chief executive officer shall assure that the hospital providing birthing services develops and implements policies and procedures to make certain that the following steps take place:

A. Collection of newborn dried-blood-spot screening specimens shall occur after 24 hours of birth, and collection and submission of the specimens shall meet the standards required by the testing laboratory;

B. Notification of the newborn's physician of record or designee shall occur within one business day in the event that the infant is discharged before the newborn dried-blood-spot screening specimen has been collected;

C. Communication of the newborn dried-blood-spot screening test results to the newborn's physician of record or designee shall occur so that test results may become part of the infant's medical record on file with the physician;

D. Information relative to newborn screening dried-blood-spot results and treatment shall be recorded in the patient's medical record, and retention of the information shall comply with applicable medical record retention requirements; and

E. Training of staff on newborn dried-blood-spot screening specimen collection and submission and parental notification shall be implemented in a way that ensures an adequately trained and knowledgeable workforce is maintained for implementing specimen collection and submission and parental notification according to standards required by the testing laboratory and guidance from the department.

12 VAC 5-71-100. Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests.

A. Newborn dried-blood-spot screening tests shall be performed by the Division of Consolidated Laboratory Services or other laboratory the department has contracted with to provide this service in accordance § 32.1-65 the Code of Virginia.

B. The testing laboratory shall maintain accreditation under the Clinical Laboratory Improvement Amendments as defined in 42 CFR 493.

C. The testing laboratory shall perform required initial and secondary tests using validated analytical test methods, and establish normal ranges and notification protocols as

defined in the contract with the department. The testing laboratory may seek the advice of the Newborn Screening Subcommittee of the Virginia Genetics Advisory Committee.

D. On completion of newborn dried-blood-spot screening tests for the infant, the testing laboratory shall provide the completed test results to the submitting facility and to the infant's healthcare provider, as indicated on the newborn screening sample.

E. The testing laboratory shall provide the department's newborn screening services with the newborn dried-blood-spot screening test data that are necessary to carry out follow-up services.

F. The testing laboratory shall manage the distribution of newborn dried-blood-spot screening specimen collection kits.

G. The testing laboratory is authorized to set the fee charged to birthing hospitals and physicians for purchase of newborn dried-blood-spot screening specimen collection kits in consultation with the department and in accordance with applicable state statutes and regulations.

H. The testing laboratory shall maintain an information management system capable of electronic data exchange between the laboratory and the department's newborn screening services.

12 VAC 5-71-110. Reporting to the commissioner.

A. Physicians, midwives, public health nurses and other nurses who receive newborn dried-blood-spot screening test results, and administrators of hospitals in the Commonwealth shall make or cause to be made a report to the commissioner of a person under the age of 2 diagnosed as having a heritable disorder or genetic disease for which newborn dried-blood-spot screening tests are conducted.

B. The diagnosed cases shall be reported in accordance with § 32.1-69.1 of the Code of Virginia.

12 VAC 5-71-120. Scope and content of Virginia Newborn Screening Services.

A. The mission of Virginia Newborn Screening Services is to prevent mental retardation, permanent disability, or death through early identification and treatment of infants who are affected by those heritable disorders and genetic diseases listed in 12 VAC 5-71-30 D.

B. The scope of newborn screening services shall include the following:

1. Ensure that infants born in the Commonwealth receive newborn dried-blood-spot screening, confirmatory testing, and follow-up services for selected heritable disorders or genetic diseases;

2. Locate and track infants with screened-abnormal results or unsatisfactory results—a short-term process of ensuring that the identified healthcare provider is informed of results—in a timely matter, by at least 6 months of age, to determine if the infant has a selected heritable disorder or genetic disease;

3. Ensure that the department receives all diagnostic test results, both normal and screened-abnormal results, from healthcare providers;

4. Ensure that appropriate diagnostic data are collected, stored, and organized in a secure data management information system that allows for efficient extraction of appropriate data from the testing laboratory to newborn screening services in accordance with federal and state laws and regulations;

5. Assess and evaluate newborn screening services follow-up activities by collecting and reporting data required annually for Title V national performance measures that address how well the system functions;

6. Educate healthcare providers, parents, and the general public by electronic or written materials and educations sessions, as deemed necessary by the department;

7. Facilitate the entry of infants with screened-abnormal results into medical and dietary management services as needed upon receiving notification from the contracted lab of such results; and

8. Ensure that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through newborn screening services are referred to the Care Connection for Children network for care coordination services.

9. Provide information to residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through newborn screening services regarding available assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements which are medically necessary to manage their diagnosed heritable disorder or genetic disease listed in 12 VAC 5 71-30-D.

C. To ensure full implementation of newborn screening services, the department may establish contracts with, but not be limited to, the following entities, and the established contracts shall comply with all federal assurances:

1. A designated testing laboratory;

2. Medical facilities to provide metabolic treatment and genetic services; and

3. Other entities as needed.

D. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Public Law 103-62), shall be used to establish newborn screening services goals. The following goals shall change as needed to be consistent with applicable Title V national performance measures: All infants who are born in the Commonwealth and who are residents of Virginia will receive appropriate newborn dried-blood-spot screening, confirmatory testing, and follow-up services. All infants who are born in the Commonwealth and who are not residents of Virginia will receive appropriate newborn dried-blood-spot screening and be referred to their state of residence for confirmatory testing and follow-up services.

12 VAC 5-71-130. Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network.

A. Upon notification by Virginia Newborn Screening Services of an infant diagnosed with sickle cell disease, the Virginia Sickle Cell Awareness Program shall track infants identified with sickle cell disease and related hemoglobinopathies to ensure that they receive care and refer the infants to the Pediatric Comprehensive Sickle Cell Clinic Network.

B. The Pediatric Comprehensive Sickle Cell Clinic Network shall provide the following services:

1. Consultation on screened-abnormal results to primary care providers and parents;

2. Family counseling and support;

3. Regularly scheduled clinics, which meet the needs of the population served; and

4. Referral to appropriate inpatient care facilities.

C. The Pediatric Comprehensive Sickle Cell Clinic Network shall provide data as needed by the department's newborn screening services.

12 VAC 5-71-140. Responsibilities of metabolic treatment and genetic centers facilities.

A. The department's contracted metabolic treatment and genetic centers facilities shall collaborate with a specialized testing laboratory or laboratories for performing diagnostic testing on infants referred by the department's newborn screening services, in accordance to Section 32.1 - 65 of the Code.

B. The department's contracted metabolic treatment and genetic centers facilities shall provide the following clinical services:

1. Consultation on screened-abnormal results to healthcare providers;

2. Family counseling and support;

3. Regularly scheduled clinics;

4. Appropriate inpatient care facilities;

5. Clinical genetic services; and

6. Nutritional counseling and support.

C. The department's contracted metabolic treatment and genetic centers facilities shall provide written diagnostic and other related case information to the department's newborn screening services.

12 VAC 5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases and are referred to the network by Virginia Newborn Screening Services.

2. Other network services for eligible individuals in accordance with the § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening services.

12 VAC 5-71-160. Availability of assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements.

A. The department shall maintain a procedure to assist eligible persons in obtaining metabolic formula, low protein modified foods, and metabolic supplements.

B. Expenditures shall be limited to available funding.

C. Resident children under the age of 21 who have a diagnosis of a heritable disorder or genetic disease listed in 12 VAC 5 71-30-D and meet financial eligibility criteria for the Children with Special Health Care Needs Program Pool of Funds in accordance with the State Board of Health "Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals, 12VAC5-200-10 et seq.," § 10 – 210 may qualify to receive metabolic formula at

no cost. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have insurance coverage for metabolic formula.

D. Resident children under the age of 21 who have a diagnosis of a heritable disorder or genetic disease listed in 12 VAC 5 71-30-D and do not meet financial eligibility criteria for the Children with Special Health Care Needs Program Pool of Funds in accordance with the State Board of Health "Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals, 12VAC5-200-10 et seq.," § 10 – 210 may be eligible to purchase metabolic formula through the Virginia Department of Health.

E. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12 VAC 5 71-30-D and who have a gross family income at or below 300% Federal Poverty Level in accordance with the State Board of Health "Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals, 12VAC5-200-10 et seq.," § 10 – 210 may qualify to receive metabolic formula at no cost. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for metabolic formula.

F. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12 VAC 5 71-30-D and who do not meet financial criteria or other

eligibility criteria in accordance with the State Board of Health "Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals, 12VAC5-200-10 et seq.," § 10 – 210 may qualify to purchase metabolic formula through the Virginia Department of Health.

G. Residents who have a diagnosis of a heritable disorder or genetic disease listed in 12 VAC 5 71-30-D and who have a gross family income at or below of 300% Federal Poverty Level in accordance with the State Board of Health "Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals, 12VAC5-200-10 et seq.," § 10 – 210 may be eligible to receive reimbursement from the department up to $1,500 per year for purchase of low protein modified foods and metabolic supplements. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for low protein modified foods or metabolic supplements for which they are seeking reimbursement.

12 VAC 5-71-170. Emergency suspension of assistance.

The commissioner may suspend any portion of the assistance plan to ensure the financial integrity of Virginia Newborn Screening Services. The commissioner shall report any action taken under the provisions of this section to the Board of Health at its next scheduled meeting.

12 VAC 5-71-180. Use of federal, state, or other resources.

A. The commissioner or his designee may seek, receive, and expend federal, state general, or other non-general funds for the department necessary to administer newborn screening services.

B. Federal Title V funds received for the Children with Special Health Care Needs Program, authorized by § 32.1-77 of the Code of Virginia, may be used to support the department's newborn screening services, in accordance with applicable federal and state laws and regulations.

12 VAC 5-71-190. Confidentiality of information.

The department's newborn screening services and its contractors shall maintain, store, and safeguard client records from unauthorized access as required by law.