Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Promulgation of final permanent regulation
Date this document prepared	November 20, 2006

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Emergency regulations,12 VAC 5-71, “Regulations Governing Virginia Newborn Screening Services) went into effect March 1, 2006 replacing the previous regulation 12 VAC 5-70 “Regulations Governing the Newborn Screening and Treatment Program”. The emergency regulation provides governance for the newborn screening program which substantially expanded services to screen for 29 (up from 12) genetic disorders and heritable diseases as mandated by legislative changes from the 2005 General Assembly.

The agency has been in the process to make this regulation permanent. Substantive changes between the emergency and proposed regulation text outline the available benefits for obtaining metabolic formula, low protein modified foods, and metabolic supplements for residents diagnosed with conditions listed in the regulation. Other changes made provide further definition and clarification to existing text.

One change has been made between the proposed and final permanent text addressing licensed nurse midwives redrawing unsatisfactory specimens.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On November 20, 2006, the State Health Commissioner approved the final regulation text as authorized by the State Board of Health at their October 20, 2006 meeting. The final regulation text was approved for 12 VAC 5-71 (Regulations Governing Newborn Screening Services). This regulation is currently in effect as an emergency regulation (from March 1, 2006 through February 28, 2007). The previous regulation 12 VAC 5-70 (Regulations Governing the Newborn Screening and Treatment Program), in effect prior to adoption of the emergency regulation, is being permanently repealed.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Chapter 721 of the 2005 Acts of Assembly amended and reenacted Sections 32.1-65 through 32.1-67.1 of the Code of Virginia to expand newborn screening effective March 1, 2006. As mandated under the Code, the Board of Health promulgated emergency regulations to implement provisions of the act to be effective within 280 days of the enactment. The final permanent regulation is now being promulgated.

In addition to the authority described in the previous section, the Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The final regulation is necessary to replace the emergency regulation currently in effect until February 28, 2007 and repeal the prior regulation (12 VAC 5-70). The regulation will provide governance for Virginia Newborn Screening Services, a state mandated program administered by the Department of Health.

Virginia Newborn Screening Services has implemented the most significant expansion in its history and now screens all infants born in the Commonwealth for 29 genetic disorders and heritable diseases. Previously the program had screened for 12 disorders (including hearing screening). The expansion was a result of legislation passed during the 2005 General Assembly as recommended by a Joint Commission on Health Care study completed the previous year. The expansion of services is consistent with newly released federal guidelines as outlined in the 2005 report “Newborn Screening: Toward a Uniform Screening Panel and System” commissioned by the US Department of Health and Human Services.

The final regulation, consistent with the emergency regulation, will provide official notice for the conditions that the Commonwealth tests blood spots of all newborns. Previously newborn screening conditions had been listed in the Code; however, with the breadth of the current expansion and possibilities for further

increases as technology continues to advance, conditions screened for under the program will be promulgated through the regulatory process.

The final regulation, consistent with the emergency regulation, provides greater details of responsibilities of parties involved in newborn services, such as hospitals, primary care providers, and the testing laboratory. These details are necessary to address the level of change in the services provided and assure equitable treatment of all infants. In addition, the federal report "Newborn Screening: Toward a Uniform Screening Panel and System," referenced previously provides guidance to states to develop minimum standards and model policies and procedures. This guidance is incorporated as applicable into the final proposed regulation.

The final proposed regulation addresses services available for infants and children who have selected heritable disorders and genetic diseases diagnosed through newborn screening services. The Code of Virginia previously had stipulated special formula and low protein food benefits for children and pregnant women. The Code change, in effect March 1, 2006, now states that all diagnosed individuals are eligible for the children with special health care needs program. The final proposed regulation specifies that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through newborn screening services will be automatically referred to the Care Coordination for Children network for care coordination services. The intent is to describe diagnostic, case management, and financial treatment assistance that the department will be responsible to provide or assure in a consistent format. The intent is to strengthen linkages to an umbrella of services routinely made available to all special needs children, including infants diagnosed through newborn screening. In addition, the final proposed regulation seeks to make available equitable assistance regardless of disorder or disease.

Financial assistance to help pay for medical treatments through the children with special health care needs program is means tested and available for children of families and adults at or below 300% federal poverty level. The regulation outlines available assistance including the opportunity to purchase metabolic formula through the Virginia Department of Health for those who have incomes above 300% federal poverty level and no health insurance coverage for the products. A reimbursement benefit for modified low protein foods and metabolic supplements is also provided up to $1,500 annually for those with incomes at or below 300% federal poverty level. Adult clients previously receiving formula and who have incomes at or below 300% with no health insurance coverage for the product may also qualify to receive formula at no cost through the Department.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Substantive changes between the emergency and proposed regulation text are found in Section 160. This section outlines benefits available to persons diagnosed with conditions listed in the regulations. Resident children under the age of 21 will be referred to the Care Connection for Children program which is one component of the agency's Children with Special Health Care Needs Program. All resident children regardless of income will qualify to receive case management and family support services. Children in families who meet gross family income means testing (currently at or below 300% federal poverty level) may be able to use Pool of Funds to cover expenses for metabolic formula, hospitalizations, medications, durable medical equipment, and other diagnostic testing not related to the conditions which qualified them for the program. To access the Pool of Funds, applicants must demonstrate that they have applied for all available state and federal assistance and not have current insurance which covers their expenses. Resident adults (ages 21 and older) diagnosed with conditions listed in the regulation and with gross

incomes at or below 300% federal poverty level may qualify for metabolic formula provided to them at no cost. Adults must also demonstrate that they have applied for all available state and federal assistance and not have current insurance which covers metabolic formula. Children in families and adults above 300% federal poverty level and without insurance coverage for metabolic formula will have the opportunity to purchase metabolic formula through the Department of Health. Reimbursement of up to $1,500 annually may be available to children in families and adults whose incomes are at or below 300% federal poverty level for expenses of purchasing low protein modified foods and metabolic supplements These persons must also demonstrate that they have applied for all available state and federal assistance and not have current insurance covering low protein modified foods or metabolic supplements. Some sections have added clarifying definitions upon suggestion from the Department of Planning and Budget following their review of the emergency regulation text.

Definitions for care coordination, the Pool of Funds, metabolic formula, low protein modified foods, and metabolic supplements have been added or modified. All benefits are contingent upon available funding and the Commissioner reserves the right to suspend any part of the treatment assistance in order to maintain the financial integrity of the program. A section has been added which provides for the Commissioner to further interpret and administer the regulation through guidance documents. Testing services provided under the program have been further clarified as "confirmatory" testing services for abnormal screening results. Infants born in Virginia but who are residents of other states who need follow up will be referred back to their state of residence for follow up and confirmatory testing. Language has been added which authorizes the contracted lab to set the fee charged for purchase of newborn dried-blood-spot screening specimen collection kits by hospitals and providers in consultation with the department and in accordance with applicable statutes. Clarifying language about short-term follow up, education, regularly scheduled clinics, program responsibilities, and program evaluation has been added. The federal report, "Newborn Screening: Toward a Uniform Panel and System" by the American College of Medical Genetics in 2005, has been determined not necessary to incorporate by reference.

One change between the proposed permanent and final text has been made which addresses unsatisfactory specimens. Unsatisfactory specimens originally drawn by a licensed midwife will be redrawn by the licensed midwife should referral to a health care provider or facility result in a delay of specimen recollection and submission.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage of these regulations will be to identify infants at birth who may have life-threatening genetic and heritable diseases. The number of infants whose lives will be saved or identified before a disease crisis results in a permanent disability will be increased by expanding the number of conditions that all infants are screened for from 12 to 29 as of March 1, 2006. Early identification will provide cost savings to both families and the state. The State of Wisconsin has estimated that for every four dollars spent on newborn screening services, five dollars are saved. Children who are identified with these conditions after a medical crisis tend to have a poorer prognosis and require higher use of long-term medical and assistive care. Families, who have infants identified with these conditions, may also undergo genetic testing and counseling to help guide future reproductive decisions and medical management.

The primary disadvantage of these regulations will be an increase in the number of families who receive abnormal test results that ultimately do not result in a diagnosed disease. More families may experience stress related to further testing and contemplation of possible disease in their infant.

The roles of health care professionals attending births, primary care providers, hospitals, the screening laboratory, and the agency follow up and education program have been more clearly defined in the emergency and proposed permanent regulation. Time frames and responsibilities for assuring testing and follow up as well as provider and parent notification have been enhanced. This provides for more equitable and quality treatment of all infants born in the Commonwealth regardless of where they are born and receive care.

The fee levied for newborn screening by the contracted testing laboratory (Division of Consolidated Laboratories, Department of General Services) increased from $32 to $53 on November 1, 2005 to cover costs associated with expanded newborn screening. Hospitals pay this fee for each newborn screening filter paper, which is used to collect and submit screening specimens. The regulation authorizes the contracted lab to set the fee in consultation with the Department of Health.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

One change has been made to the final text following publication of the proposed text in response to public comment received by the Commonwealth Midwives Alliance.

The following text has been added to the end of 12VAC5-71-80-D3: "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."

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

One public comment was received by the Commonwealth Midwives Alliance on October 19, 2006.

The comment expressed concern that the requirement for infants to be taken to a primary care provider or health care facility to have a repeat specimen drawn in the case of unsatisfactory results when the first specimen was drawn by a licensed midwife may cause an unnecessary burden or delay in specimen collection and submission.

The agency responded by adding text at the end of 12VAC 5-71-80-D3 to require licensed midwives to redraw and submit unsatisfactory newborn blood spot specimens which they had originally submitted should referral of the infant to a primary care provider or health care facility result in a delay.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Changes between the pre-emergency regulation and proposed regulation			
12VAC5-70-10	12VAC5-71-10	Definitions	Definitions will be expanded considerably to explain services operating under expanded newborn screening panel. Several definitions no longer in use will be deleted.
12VAC5-70-20	12 VAC 5-71-20 and 120 through 150	General Information	The current section describes authority, purpose, administration, and application. In the proposed regulation, several of these sections are deleted because they may be considered obsolete by the Code Commission, as those sections do not convey an instruction. A proposed section does authorize the Commissioner to further implement the regulation through the use of guidance documents. Proposed sections outline general information on multiple department programs' responsibilities related to newborn screening services. These responsibilities are clarified by specific entity in the proposed sections and described below in detail.
12VAC5-70-30	12VAC5-71-30 through 100	Testing	The current section describes minimal provisions for who is tested, exemptions, laboratory services, and timing of testing. Proposed sections separate these provisions and are described below in detail.
12VAC5-70-40	12VAC5-71-40 through 110	Reports and notifications	The current section requires the reports be sent to hospitals and healthcare providers. It authorizes establishment of protocols by the department for other notifications. These responsibilities are clarified for each specific entity in the proposed sections and described below in detail.
12VAC5-70-50	12VAC5-71-50 through 160	Services and treatment provided	This current section requires the department to provide services of appropriate professionals to manage persons with diseases specified and to provide these services at no direct cost to medically indigent families. These responsibilities are clarified by specific entity in the proposed sections and described below in detail.
	12VAC5-71-	Core panel of heritable	This proposed section lists the conditions

	30	disorders and genetic diseases	(28) for which the newborn-dried-blood-spot testing is conducted. These conditions are based upon federal recommendations as mandated by Chapter 721 of 2005 Acts of Assembly. Previously listed individually in the Code, the disorders tested for will be maintained in the regulation, due to the scope of the expansion and the possibility for further change.
	12VAC5-71-40	Religious exemption	This proposed section provides for the refusal of testing and documentation due to religious beliefs as mandated by § 32.1-65 of the Code of Virginia.
	12VAC5-71-50	Responsibilities of the physician or midwife	This proposed section states that the physician, certified nurse midwife, or midwife who is licensed by the Board of Medicine in charge of the infant's care after delivery is responsible for causing the specimen for newborn screening to be collected and submitted as mandated in § 32.1-65 of the Code of Virginia.
	12VAC5-71-60	Responsibilities of the first attending healthcare provider	This proposed section clarifies that for infants born outside of the hospital, the first attending healthcare provider as defined in 12VAC5-71-10 has the responsibility to cause the specimen to be collected and submitted.
	12VAC5-71-70	Newborn dried blood-spot screening collection and submission and notification—hospital deliveries	This proposed section outlines appropriate time intervals for specimen collection and makes specific circumstantial provisions (e.g. premature infants) for infants who are born in hospitals. This section also assigns responsibility for collection of primary and necessary repeat specimens and communication responsibilities among multiple providers caring for the newborn.
	12VAC5-71-80	Newborn dried blood-spot screening collection and submission and notification—deliveries outside of the hospital	This proposed section outlines appropriate time intervals for specimen collection and makes specific circumstantial provisions (e.g. premature infants) for infants who not born in hospitals. This section also assigns responsibility for collection of primary and necessary repeat specimens and communication responsibilities among multiple providers of the newborn's care.
	12VAC5-71-90	Responsibilities of the chief executive officer	This proposed section assigns responsibility for hospitals to have policies and procedures for collection, notification, communication, and training related to newborn screening services.
	12VAC5-71-100	Responsibilities of the testing laboratory	This proposed section outlines responsibilities of the contract laboratory to

			the department. Section 32.1-65 of the Code of Virginia authorizes the tests to be performed by the Division of Consolidated Laboratory Services. This section also authorizes the contracted lab to set the fee charged for newborn dried-blood-spot screening specimen collection kits purchased by hospitals and providers.
	12VAC5-71-110	Reporting to the commissioner	This proposed section outlines reporting duties as specified in § 32.1-66
	12VAC5-71-120	Scope and content of Virginia Newborn Screening Services	This proposed section outlines the responsibilities of the department with regard to follow up, diagnosis, data collection, education, referrals, and treatment services available.
	12VAC5-71-130	Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network	This proposed section outlines the responsibilities of this program with regard to consultation to primary care providers, family counseling and support, scheduled clinics, and referral to inpatient care facilities.
	12VAC5-71-140	Responsibilities of metabolic treatment and genetic centers facilities	This proposed section outlines the responsibilities of department-contracted centers with regard to clinical services, including consultation to health care providers, family counseling and support, schedule clinics, inpatient care facilities, clinical genetic services, and nutritional counseling.
	12VAC5-71-150	Responsibilities of the Care Connection for Children network	This proposed section outlines the responsibilities of this program with regard to care coordination services for those cases referred by newborn screening services.
	12VAC5-71-160	Availability of assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements	This proposed section outlines assistance which may available to individuals diagnosed with conditions listed in the regulation in obtaining medically necessary metabolic formula, low protein modified foods, and metabolic supplements.
	12VAC5-71-170	Emergency suspension of assistance	This proposed section authorizes the commissioner to suspend any part of the treatment assistance program to maintain financial integrity of the program.
	12VAC5-71-180	Use of federal, state, or other resources	This proposed section authorizes use of federal Title V maternal and child health block grant funds and other funds as sought and received to provide newborn screening services.
	12VAC5-71-190	Confidentiality of information	This proposed section states newborn screening record maintenance, storage and safeguard requirements.
Changes made since the publication of the emergency regulation			

12VAC5-71-10		Definitions	Definitions for care coordination, metabolic formula, low protein modified foods, and metabolic supplements added. Definition of Pool of Funds modified to add funding source.
12VAC5-71-20		Administration of chapter	Authorizes commissioner to issue guidance documents to interpret and administer regulations
12VAC5-71-20	12VAC5-71-30	Core panel of heritable disorders and genetic diseases	Same text.
12VAC5-71-30	12VAC5-71-40	Religious exemption from newborn dried-blood-spot screening requirements	Same text.
12VAC5-71-40	12VAC5-71-50	Responsibilities of the physician or midwife	Same text.
12VAC5-71-50	12VAC5-71-60	Responsibilities of the first attending healthcare provider	Requirements for infants on antibiotics deleted as it is no longer standard medical practice.
12VAC5-71-60	12VAC5-71-70	Newborn dried blood-spot screening collection and submission and notification—hospital deliveries	Same text.
12VAC5-71-70	12VAC5-71-80	Newborn dried blood-spot screening collection and submission and notification—deliveries outside of the hospital	Addition of requirement for licensed midwives to redraw unsatisfactory specimens should referral to a health care provider or facility result in a delay of recollection.
12VAC5-71-80	12VAC5-71-90	Responsibilities of the chief executive officer	Same text.
12VAC5-71-90	12 VAC5-71-100	Responsibilities of the testing laboratory	Adds text authorizing the testing laboratory to set the fee charged for purchase of newborn dried-blood-spot screening specimen collection kits in consultation with the department. Kits are purchased by birthing hospitals and physicians.
12VAC5-71-100	12VAC5-71-110	Reporting to the commissioner	Same text.
12VAC5-71-110	12VAC5-71-120	Scope and content of Virginia Newborn Screening Services	“Confirmatory” was added to clarify testing done after screening. Clarifies that out of state residents born in Virginia will receive screening but will be referred back to their state of residence for confirmatory testing and follow up services. Further clarification of scope of newborn screening services related to follow up, evaluation of services, education, provision of information regarding treatment assistance and entry into care also added.

12VAC5-71-120	12VAC5-71-130	Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network	Definition of regularly scheduled clinics further clarified.
12VAC5-71-130	12VAC5-71-140	Responsibilities of metabolic treatment and genetic centers facilities	Appropriate Code reference to newborn screening added.
12VAC5-71-140	12VAC5-71-150	Responsibilities of the Care Connection for Children network	Same text.
12VAC5-71-150	12VAC5-71-180	Use of federal, state, or other resources	Same text
12VAC5-71-160	12VAC5-71-190	Confidentiality of information	Same text.
12VAC5-71-170		Documents incorporated by reference	The document, "Newborn Screening: Toward a Uniform Panel and System" by the American College of Medical Genetics in 2005, has been determined not necessary to incorporate by reference.
	12VAC5-71-160	Availability of assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements	New section provides that the department will maintain a procedure to assist eligible persons and that expenditures are limited to available funding. Specific benefits for metabolic formula, low protein modified foods, and metabolic supplements are detailed by age group and means testing.
	12VAC5-71-170	Emergency suspension of assistance	Authorizes the commissioner to suspend any portion of the treatment assistance plan to ensure financial integrity of the program.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The Virginia Newborn Screening Regulations Advisory Group analyzed the previous regulation while considering development of the current emergency and proposed final regulation. With the magnitude of the current expansion and since the regulation involves the delivery of a population-based service to all

infants born in the Commonwealth, it was deemed necessary to further clarify responsibilities and specific timelines for specimen collection, reporting, and follow up for the new regulation. Less stringent requirements could impact the quality of services provided and result in poorer health outcomes if infants do not receive testing and appropriate follow up within a prescribed timely manner. There are no other applicable regulations to consolidate which impact newborn screening. Small businesses may not be exempted as a category because screening for all infants must be managed equitably by their providers, regardless of business size, to assure optimal outcomes.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulation provides for expanded testing of newborns for selected heritable disorders and genetic diseases. Expanded testing will facilitate early identification of such disorders. Conditions were added to the testing panel based on a 2005 federal study and report entitled "Newborn Screening: Toward a Uniform Screening Panel and System." The recommended conditions were selected based on the following criteria: (1) clinical characteristics (e.g., incidence, burden of disease if not treated, phenotype (observable characteristics) in the newborn); (2) analytical characteristics of the screening test (e.g., availability and features); and (3) diagnosis, treatment, and management of the condition in both the acute and chronic forms, including the availability of health professionals experienced in diagnosis, treatment, and management. Expanded testing should improve the health of newborns, reduce morbidity and mortality from these conditions, and contribute to an overall positive impact on families.

In some cases, families will receive screening results that require further testing. Families whose infants will be found not to have these diseases after further testing may experience some distress during the diagnostic testing phases and may incur financial costs associated with such testing. National studies, however, have found an overall positive cost benefit when weighing the stresses that may be caused by initial false positives, versus the benefits of identification and early treatment for infants who have these diseases.

Although the testing is mandated by the Code of Virginia, provisions remain in the statute for parents to refuse newborn screening if the test conflicts with his religious practices or tenets. Because parents retain the right to refuse testing, the regulation does not erode the authority or rights of parents.

Early identification of infants with these selected genetic diseases and heritable disorders should have a positive impact on self-sufficiency. When identified early and properly managed, persons with these conditions can often live productive lives. Infants and children who are not identified early with these conditions are more likely to have permanent disabilities such as mental retardation that would lead to decreased dependency on state resources.

Implementing expanded newborn screening should not have an impact on marital commitment.

Implementing expanded newborn screening will likely result in some increased disposable family income for families who have incomes at or below 300% federal poverty level and have infants or children with one of the screened conditions. For families and adults above 300% federal poverty level, there may be a

decrease in disposable family income because the agency is moving to implement financial support for metabolic formulas to those who first meet a means test.

Chapter 721 of the 2005 Acts of Assembly mandates that all infants diagnosed through newborn screening services become eligible for the department's children with special health care needs program. Benefits for special metabolic formulas and low protein modified foods had previously been limited to specific diseases in the Code; until now Code language provided that families of children and pregnant women with phenylketonuria could purchase metabolic formulas at no more than 2% if their gross annual income. In addition, these families were eligible for financial reimbursement from the department of up to $2,000 annually for purchase of low protein modified foods. With the expansion of newborn screening services, these specific provisions were removed and treatment was mandated to be addressed in regulation. This provides the department the ability to address the full array of services that may be required by various conditions.

By facilitating entry into the children with special health care needs program, families will be better linked with available care coordination services, which includes the services of an insurance benefits specialist to help them apply for available health insurance or other applicable programs and fully utilize the health benefits they have.

In addition, the children with special health care needs program currently provides a Pool of Funds to help families at or below 300% federal poverty level whose children are uninsured or underinsured to help pay for medical services. Such payment currently may cover costs related to hospitalizations, medications, further diagnostic testing, durable medical equipment, and nutritional therapies including metabolic formulas.

Adults with diagnosed conditions under the expanded panel whose incomes are at or below 300% federal poverty level may qualify to receive metabolic formula at no cost. Both children and adults who meet means testing must also demonstrate that they have applied for all available state and federal assistance and have no current insurance which covers the medically necessary treatment.

Persons diagnosed with conditions listed in the regulation who have incomes above 300% federal poverty level may be able to purchase metabolic formula through the Department of Health if they do not have current health insurance coverage for the medically necessary product.

Both children and adults with diagnosed conditions under the expanded panel may also qualify for up to $1,500 annual reimbursement for the purchase of low protein modified foods and metabolic supplements used to treat the diagnosed condition. This benefit may be available to those whose gross family income is at or below 300% federal poverty level. Applicants will have to demonstrate that they have applied for all available state and federal assistance and that they do not have current insurance which covers the items for which they are seeking reimbursement.

Changing the program model by which formula benefits are administered connects families to a broader service network through Care Connection for Children. It further facilitates financial assistance for not only metabolic formula, but also for other medically necessary services such as medication, hospitalizations, nutritional supplements, and durable medical equipment. Shifting payment assistance for metabolic formula to the same standard used by the children with special health care needs program for other types of assistance applies an equal test to all families with need, regardless of diagnosis. By linking the financial assistance to income, VDH provides financial assistance to those considered medically indigent and does not subsidize families with moderate to high incomes. This is consistent with how VDH provides basic clinical services (sliding scale for those up to 250% federal poverty level) and how most other assistance programs in the Commonwealth are administered. This model establishes VDH as the payor of last resort.

Under the emergency regulation, transition to the new model has begun. The Departments of Health and Medical Assistance Services have partnered to assure a seamless transition for Medicaid clients who will

now receive metabolic formula through Medicaid participating DME vendors. Children under age 5 on Medicaid will be able to receive the full annual supply of metabolic formula through WIC services.

Approximately 25 clients (13 pediatric and 12 adults) will receive metabolic formula at no charge either through accessing the Children with Special Health Care Needs Program Pool of Funds (under 21 years of age) or through the Department distribution program (previous clients who qualify and are 21 years of age and older). These families of low to moderate incomes will likely experience an increase in disposable family income.

Other previous formula clients with incomes over 300% federal poverty level have been transitioned to receive metabolic formula through their health insurance coverage or have the opportunity to purchase metabolic formula at cost through the Department. These families may experience an increase or decrease in disposable family income depending on the individual circumstances.