Virginia Regulatory Town Hall

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Proposed 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	Make emergency regulation permanent
Date this document prepared	May 2, 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

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The emergency regulation, 12 VAC 5-71, “Regulations Governing Virginia Newborn Screening Services”, becomes effective March 1, 2006. The agency seeks to make this regulation permanent. The substantive changes between the emergency and proposed 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.

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 number(s), if applicable, and (2) promulgating entity, i.e., the 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 by 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 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 by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The proposed permanent regulation is necessary to replace the emergency regulation which will be in effect from March 1, 2006 through February 28, 2007. The regulation will provide governance for Virginia Newborn Screening Services, a state mandated program administered by the Department of Health.

Virginia Newborn Screening Services is undergoing the most significant expansion in its history from the current panel, which screens for 12 disorders (including hearing screening), to an expanded panel, which will screen for 29 disorders. In concurrence with a 2004 Joint Commission on Health Care study, legislation passed during the 2005 General Assembly directed the department to expand newborn screening. The expansion is to be consistent with the uniform core panel recently recommended in the 2005 report “Newborn Screening: Toward a Uniform Screening Panel and System” commissioned by the US Department of Health and Human Services. The proposed regulation, as 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, listing of conditions will be promulgated through the regulatory process.

The proposed regulation further details responsibilities of parties involved in newborn services, such as hospitals, primary care providers, and the testing laboratory. This is needed to address the level of change the services are undergoing 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 proposed regulation.

The proposed regulation addresses services available for infants and children who have selected heritable disorders and genetic diseases diagnosed through newborn screening services. Previously, the Code of Virginia stipulated special formula and low protein food benefits for children and pregnant women. The Code change, in effect March 1, 2006, states that all diagnosed individuals are eligible for

the children with special health care needs program. The 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 proposed regulation seeks to make available assistance equitable 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.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The 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 contigent 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.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so 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.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no federal requirements, only recommendations, related to newborn screening. Each year, the Department of Health reports data related to the number of screens performed and the positives identified to the U.S. Department of Health and Human Services, Maternal and Child Health Bureau, which administers Title V block grant funds. These data are required to receive block grant funds although the performance measure results do not currently effect the level of funding the state receives. Title V block grant funds are used to support state newborn screening services. The Commonwealth is using the most recent recommendations issued in the 2005 report "Newborn Screening: Toward a Uniform Screening Panel and System" commissioned by the US Department of Health and Human Services to guide the expansion of newborn screening. This approach was recommended by the Joint Commission on Health Care and codified in 2005.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No localities will be disproportionately affected by expanded newborn screening.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulation on farm or forest land preservation.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Nancy Ford, RN, MPH, Division of Child and Adolescent Health, Virginia Department of Health, 109 Governor Street, Richmond VA 23219, phone: (804) 864-7691, fax: (804) 864-7722, or e-mail: Nancy.Ford@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will not be held as indicated in the Notice of Intended Regulatory Action published November 14, 2005 in the Virginia Register.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a	Implementing newborn screening services will cost: $ 5.35 million in fees (Enterprise funds) paid to

delineation of one-time versus on-going expenditures	Division of Consolidated Laboratories by hospitals for newborn screening test kits. Of this total, $983,000 is transferred to Virginia Department of Health to support its program activities and the remainder supports the laboratory services. Virginia Department of Health contracts with the Division of Consolidated Laboratories to perform newborn screening. $1,006,253 in Maternal and Child Health federal block grant funds. These funds provide support to Virginia Newborn Screening Services for program administration, medical consultation by metabolic specialists on abnormal results (24/7), patient follow-up, confirmatory testing, medical and nutritional management through contracted metabolic treatment centers, and genetic counseling. Funds also support long term care coordination and provision of metabolic formulas and other dietary supplements for children meeting means testing at or below 300% Federal Poverty Level. These funds include genetic services under state contract provided for other reasons than newborn screening ($600,472). These expenses are on-going.
Projected cost of the regulation on localities	No projected cost to localities.
Description of the individuals, businesses or other entities likely to be affected by the regulation	All infants born in the Commonwealth will receive newborn screening. Hospitals, birthing centers, and health care providers have responsibilities for certain components of newborn screening including specimen collection. Contracted parties including Division of Consolidated Laboratories and metabolic treatment centers have some responsibilities defined in the regulation.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Approximately 101,000 infants are born in the Commonwealth each year in approximately 65 Virginia hospital or birthing center facilities. Over 3,800 licensed physicians and midwives may be the provider responsible for the health care of these infants with responsibilities related to newborn screening. None of the hospitals would be considered small businesses. Most of the health care providers might be considered small businesses.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	Costs to hospitals will be approximately $5.35 million statewide for purchase of newborn screening filter paper kits ($53 per kit for 101,000 births). This represents a $21 increase from the previous fee of $32 per kit. These costs can be recouped through third party payments for deliveries. Other hospital costs may be incurred for maintaining a trained workforce and recordkeeping. Training may require 2 hours annually per staff person. Training is provided at no cost by Virginia Newborn Screening Services. Staff persons who

	may need training include laboratory and nursery personnel. Health care providers may realize cost savings of a minimum of $424,000 with the expansion. Currently over 8,000 specimens have collection issues, which may cause them to be repeated. Often the primary care physician collects the repeat specimen and incurs costs for purchasing the filter paper. Under the expansion, specimens which need to be repeated will be performed at no additional cost. Providers will have costs associated with reporting and recordkeeping. The projected number of additional abnormal results may be up to 1900 with the expansion. Each abnormal may require from 1 up to 4 hours per case in staff time for patient contact, office visit, consultation, and reporting confirmatory testing results back to VDH if applicable. Some of this cost, however, may be recouped through third party payors. Given the number of health care providers, however, the increase in volume per provider should be minimal.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No alternatives to promulgating this regulation exist. The regulation is mandated by the third enactment of Sections 32.1-65 through 32.1-67.1 of the Code of Virginia from the 2005 Acts of Assembly (Chapter 721).

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 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.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

No comments were received following publication of the Notice of Intended Regulatory Action.

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.

Providing special metabolic formulas through this model will result in changes to the current formula program, which is now centrally and separately administered. As of October 2005, 99 participants receive metabolic formulas through the central program. Of these persons, 68 are children under the age 21 who would qualify for the services of the children with special health care needs program. All families of these children would receive care coordination services and family-to-family support services. In this group, 11 are known to be covered under Medicaid and would continue to have medical services and

metabolic formulas covered under Medicaid. In addition, 30 persons would qualify under the current Pool of Funds guidelines to have their metabolic formulas covered. VDH would be increasing its costs over the current program by $16,000. In this group, however, 19 appear to be at 200% or below federal poverty level and may be eligible for FAMIS Plus (Medicaid) or FAMIS. Care coordinators would help these families pursue enrollment in applicable programs. Of the 68 children currently receiving formula through the centrally administered program, 27 appear to have family incomes above 300% federal poverty level, which would make them ineligible for coverage for metabolic formulas through the Pool of Funds. Twelve of these families have incomes exceeding $100,000 annually. The 27 families with incomes above 300% federal poverty level would no longer receive a formula subsidy as in the current system. VDH would be reducing its costs by $66,000 for this cohort. The average family would be paying an additional $ 1,740 annually out of pocket for metabolic formulas. However, of the 27 families in this group, 17 have private insurance and care coordinators would help them further explore coverage through their health insurer. The resulting change in management of the metabolic formula program may cause a hardship for a small number of families no longer receiving assistance. VDH, however, is planning to allow these families to purchase formula at-cost plus shipping through the state discounted contract.

Of the 31 adults currently receiving formula payment assistance, 9 have Medicaid and may be able to receive benefits through Medicaid. VDH plans to grandfather adults at or belowr 300% federal poverty level and provide these adults with the same benefit that will be provided to children. Currently 20 adults are at this income level might receive formula at a cost to VDH of approximately $41,000. These adults would be realizing a cost savings. Eleven adults have incomes over 300% federal poverty level. Five of these have private health insurance, which may be an option for coverage. These adults may pay an average of $4,820 annually for formula. Currently, seven of these eleven adults are already paying the total cost for their formulas through the department due to their income levels.

It is estimated that approximately half of the children in Virginia live in families at or below 300% federal poverty level. Children from families in this income bracket who currently have conditions that will be identified under the expanded screening panel may now qualify for formula assistance. This is estimated to be an additional 28 children. These families would experience an increase in disposable family income and VDH costs would increase by $155,400 annually for those transitioning into formula coverage under the Pool of Funds. Of the anticipated 23 newly identified infants that may be diagnosed with a condition requiring metabolic formula under the revised screening panel, approximately 11 may qualify for Pool of Funds assistance. Some families who receive a diagnosis through newborn screening services will not have access to financial assistance due to their income.

The department plans to provide a low protein modified food benefit of $1,500 annually to families with incomes at or below 300% federal poverty level. This would be a $500 reduction from the previous benefit and only available to those passing the means test. Of the current 28 families using this benefit, 12 would qualify due to their incomes, 12 families would not qualify, and 4 families have unknown income. In the past year the average reimbursement per participant was $399. No one utilized the full $2,000 benefit, however two participants had expenses over $1,500. These two participants may experience a reduction in their reimbursement of $236 and $122, respectively.

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.

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

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-	12VAC5-71-	Services and treatment	This current section requires the department

70-50	50 through 160	provided	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.
	12VAC5-71-30	Core panel of heritable disorders and genetic diseases	This proposed section lists the conditions (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	Same text.
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.

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