Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Amend regulations to add Severe Combined Immunodeficiency (SCID) to the Virginia Newborn Screening System core panel of heritable disorders and genetic diseases.
Date this document prepared	May 2, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The proposed regulatory action would add Severe Combined Immunodeficiency (SCID) to the newborn screening panel. Blood spot newborn screening services are provided by the Department of General Services' Division of Consolidated Laboratory Services in partnership with the Virginia Department of Health. SCID is a primary immunodeficiency disease that is estimated to occur in approximately 1 out of every 50,000 live births. Effective treatment for SCID is available if it is detected early. Screening is necessary as this disease cannot be detected through physical examinations. The addition of SCID to the newborn screening panel has been recommended by the Virginia Genetics Advisory Committee and on a national level, this disease has been added to the core panel of 31 genetic disorders included in the Recommended Uniform Screening Panel of the US Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

SCID means Severe Combined Immunodeficiency.
DCLS means Division of Consolidated Laboratory Services.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by § 32.1-12 of the Code of Virginia.

Section 32.1-65 of the Code of Virginia requires newborn screening to be conducted on every infant born in the Commonwealth of Virginia.

Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services. The regulations are required to include a list of newborn screening tests pursuant to § 32.1-65.

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.

All newborns in Virginia would be screened for SCID as a result of this proposed regulatory action. SCID is currently estimated to occur in approximately 1 out of every 50,000 live births and some data suggest that figure could be higher. SCID is a term applied to a group of inherited disorders characterized by defects in both T and B cell responses. The defining characteristic of SCID is the absence of T-cells and, as a result, lack of B-cell function, the specialized white blood cells made in the bone marrow to fight infection. Neonates with SCID appear healthy at birth, but without early treatment, most often by bone marrow transplant from a healthy donor, these infants cannot survive or if they do, have significant morbidities. In addition, the success of the bone marrow transplantation decreases with delayed diagnosis, mostly due to underlying infections. All these factors also add to the cost of care of these patients. Undiagnosed cases are 100% fatal.

Screening for SCID gives affected infants the advances of early diagnosis and treatment. Early identification results in a higher survival rate, better outcomes and lower healthcare costs. Screening for SCID is an imperative diagnostic tool since SCID cannot be detected by a physical examination. Laboratory screening is available for high volume testing at a reasonable cost.

SCID was added to the Recommended Uniform Screening Panel (RUSP) by the US Health and Human Services Secretary Kathleen Sebelius following extensive study and recommendation from the Secretary's Advisory Panel on Heritable Disorders in Newborns and Children. The Virginia Genetics Advisory Committee also unanimously voted to recommend to the State Health Commissioner that SCID be added to the state newborn screening panel. A Virginia SCID Planning Workgroup met September 20-

21, 2012 to formulate a plan and discuss issues surrounding the possible addition of this condition to the Virginia panel. It is anticipated that Virginia would begin screening for SCID in 2014.

Substance

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

The changes proposed to 12VAC5-71 will revise the Section 30 listing of specific disorders for which screening is conducted by adding SCID to the state's core panel. Currently, the DCLS analyzes biological markers that may be indicative of 28 certain disorders that constitute the core panel. Section 32.1-67 of the Code of Virginia requires that this list of screened disorders be in the regulation. Section 32.1-65 of the Code requires that Virginia's screening tests are consistent with the panel recommended by the U.S. Secretary of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

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 indicate.

The primary advantage of this regulatory action to the public and to the Commonwealth is universal access to early diagnosis and treatment of SCID. Screening for SCID allows for early identification of the disease, which then leads to higher survival rates, better health outcomes and lower costs.

A pertinent matter of interest to the regulated community, government officials, and the public is the projected increase in the cost of the blood spot screening panel. Newborn screening is a fee-for-service program, and the fee is paid by hospitals and other screeners who must purchase the filter paper kits used for blood spot collection. Most screening is performed in hospitals, with about 10-15% of screening performed by private physicians and military facilities. Hospitals do not generally pass on these costs to patients because third party payers usually pay a negotiated bundled amount per delivery, and Medicaid-reimbursed delivery payment is set by the state. Self-pay patients may be responsible to pay the screening fee themselves if they have the resources to do so.

Since the SCID screening assay is based on new highly sensitive, specific molecular detection methodology not previously employed by the newborn screening laboratory, the DCLS requires additional capital equipment, staff and some laboratory renovation to conduct SCID screening. Based on current cost estimates and the current number of samples being tested annually, the cost to add SCID screening will be $7.50 per sample. Adjustments to this estimate are possible if DCLS receives a grant for two-year funding from the Centers for Disease Control and Prevention. This funding source could potentially contribute up to $300,000 in both FY 2014 and FY 2015 towards lab related costs associated with adding SCID to the panel.

The $7.50 fee for SCID testing is part of a more comprehensive fee increase for the newborn screening panel that will also cover costs for additional VDH follow-up personnel and other screening-related

expenses such as test kits used for cystic fibrosis mutation analysis. These other screening-related expenses will have an estimated fiscal impact of an additional $15.50-$17.50 per panel. As a result, the total cost of the blood spot screening panel is estimated to increase from $53.00 to between $76.00 and $78.00. This estimate reflects a cost that would be at or below the national average fee of $78.00 among seven fee-based newborn screening programs that have implemented SCID testing. It should also be noted that the Virginia newborn screening program has not had a fee increase since 2006.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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 requirements of this proposal that are more restrictive than federal requirements.

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 are particularly affected by the proposed regulation or bear any identified disproportionate material impact.

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 regulated community.

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 may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Dev Nair, Virginia Department of Health, 109 Governor Street, Richmond, Virginia 23219, (804) 864-7662, dev.nair@vdh.virginia.gov**.** Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	Projected costs to the state to implement the addition of SCID to the newborn screening panel will be incurred by DCLS. Costs related to capital equipment, staff, and laboratory renovation to conduct SCID screening are estimated to cost $950,000 in the first year and $750,000 in the second year, with on-going, annual costs thereafter. Two potential funding sources may help offset these costs, including the Centers for Disease Control and Prevention (CDC) and the Jeffrey Modell Foundation. Possible two-year grant funding available through CDC could contribute up to $300,000 for DCLS costs in both FY 2014 and FY 2015. Modell Foundation funding could provide $1 to DCLS for each newborn screened for SCID during the first twelve months of implementation. The remainder of the projected costs will be funded through the fee increase of the blood spot screening panel resulting from the addition of SCID to the core panel.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no projected costs on localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Hospitals, birth centers, and midwives
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.	There are sixty three birth hospitals and birth centers in Virginia; all of these institutions will be affected by the increased fee associated with the blood spot screening panel. Midwives who collect newborn screening samples will also be affected. Currently, there are sixty seven licensed midwives in Virginia.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The current cost of the newborn screening panel is $53.00. It is estimated that adding SCID to the newborn screening panel will result in an increase of $7.50 per sample. The $7.50 fee for SCID testing is part of a more comprehensive newborn screening panel fee increase that will also cover costs not specifically related to SCID testing. Those costs include additional VDH newborn screening follow-up personnel and other screening-related expenses including test kits used for cystic fibrosis mutation analysis. It is estimated that the total cost of the blood spot screening panel will increase from $53.00 to

	between $76.00 and $78.00. This cost reflects both the $7.50 for SCID testing and an additional $15.50-$17.50 for other screening-related expenses.
Beneficial impact the regulation is designed to produce.	Better health outcomes and higher survival rates for infants through SCID screening.

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.

The alternative to this proposed regulatory action is to not add Severe Combined Immunodeficiency (SCID) to the core panel of disorders for which newborns are screened. However this option would be in direct conflict with both the nationally Recommended Uniform Screening Panel (RUSP) and the recommendation of the Virginia Genetics Advisory Committee.

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 Department of Health convened a SCID workgroup comprised of internal and external stakeholders including pediatric immunologists and Centers for Disease Control and Prevention SCID experts as well as representatives from the Immune Deficiency Foundation and the Hospital and Healthcare Association to evaluate and consider this proposed regulatory change and cost effectiveness. The addition of SCID to the newborn screening panel cannot be achieved by an alternative regulatory method or less stringent requirements. 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 the public comment period following the publication of the NOIRA, and provide the agency response.

Twenty six comments were received during the public comment period following the publication of the NOIRA. All comments expressed support of adding SCID to the core panel of heritable disorders and genetic diseases. Several comments reflected personal experience with a family member diagnosed with

SCID in the explanation of support. Comments also referenced the importance of early diagnosis and treatment that would result from screening. VDH notes the support; no response is required.

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 proposed amendment to the regulation will not strengthen or erode the rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The proposed amendment will not encourage or discourage economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one's spouse, one's children and/or elderly parents.

The proposed amendment will not strengthen or erode marital commitment.

The proposed amendment will not increase or decrease disposable family income.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

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

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-71-30		Core panel of heritable disorders and genetic diseases	This section lists the conditions of the core panel of heritable disorders and genetic diseases for which the newborn-dried-blood-spot testing is conducted. The proposed change would add SCID to the core panel.