Virginia

Regulatory Town Hall
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Final Regulation
Agency Background Document

Agency name	State Board of Health (Virginia Department of Health)
Virginia Administrative Code (VAC) citation	12VAC5-71 *et seq.*
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	November 10, 2014

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

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The final 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.

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 or board taking the action, and (3) the title of the regulation.

The Virginia State Board of Health approved the final amendments for the Regulations Governing Virginia Newborn Screening Services, 12VAC5-71 on December 4, 2014.

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 Section 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 Section 32.1-65.

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.

All newborns in Virginia would be screened for SCID as a result of this final 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 opportunity for 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 2015.

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.

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 29 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 there are 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 is estimated to be $8.50 per sample. (This is higher than the original estimate from June, 2013 that the cost would be $7.50 a sample.)

The $8.50 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 $16.50 per panel. As a result, the total cost of the blood spot screening panel increased from $53.00 to $78.00. (This cost increase went into effect on January 1, 2014.) This cost is less than the national average fee of $89.75 among 22 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.

The Division of Consolidated Laboratory Services (DCLS) at the Department of General Services, which conducts the tests, is installing the last of the SCID screening instrumentation now. Once in place, DCLS will run a complete validation study to insure all testing processes are in control and will consistently provide accurate and reproducible results across all instruments. At the same time, DCLS is stocking up on supplies and is recruiting for three additional scientists needed to test all newborn screening samples for SCID.

DCLS is also working with VDH staff to provide support for the educational materials that will be developed and distributed to parents and the healthcare community relate to SCID screening.

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.

No changes have been made to the text of the proposed regulation since the publication of the proposed stage.

Section number	Requirement at proposed stage	What has changed	Rationale for change
N/A	N/A	N/A	N/A

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.

Commenter	Comment	Agency response
Nataly Jouseph	Wonderful	Comment noted.
Melba Atkinson	"Please add SCID Newborn Screening to the routine testing done in the state of Virginia for infants."	Comment noted.
Virginia Rodriguez	"Please pass the necessary legislation to test for this disease."	Comment noted.
Kristen Klaaren	"I am writing to urge you to add SCID testing to the list of routine testing done for newborns."	Comment noted.
Paige Rannigan	"Please add SCID to newborn screening tests so that children's lives can be saved."	Comment noted.
Gail Mattocks	"Please vote for SCID screening for newborns."	Comment noted.

Alexandra Brunst	This is an affordable test that will save the lives of affected babies through newborn screening.	Comment noted.
Jasey Snead	"This screening should be mandatory in the state of Va. It would save lives and I personally see no reason to NOT do this screening!"	Comment noted.
Kerri Madden	"I am in favor of SCID Newborn Screening. Early detection is key."	Comment noted.
Mary Cail	"If the parents of newborns who suffer this disease are recommending that it be added to newborn screenings, I suggest that we listen to them."	Comment noted.
Anne Gould	"Please add SCID to routine newborn screenings - it can save lives."	Comment noted.
Diana Bower	"Please amend this law to save lives and families. It will help keep medical costs down as well with early screening and treatment."	Comment noted.
Stephen Sielinski	"Getting regulations passed to test for Severe combined immunodeficiency (SCID) in newborns is critical."	Comment noted.
Jayne P Hollar	"I support the adding of SCID to newborn screenings."	Comment noted.
Jenny Dimasi	"This is a devastating condition and could be helped by infant screening. For minimal cost devastation could be possibly avoided."	Comment noted.
Charlotte Hisey	It is of vital importance to pass this in order to start screening for SCID."	Comment noted.
Patricia M. Rannigan	"Please pass this bill, as no one needs to go through the horror of losing a child."	Comment noted.
Marsha Meeks	"Please include SCID testing as a mandatory newborn test!"	Comment noted.
Kay Ferguson	Seems a simple matter to add testing for SCIDS to newborn screening and it has the potential to avert great suffering for affected infants and their families.	Comment noted.
Cheryl Hughes	"My heart breaks to think about the parents out there who could lose a child due to ignorance of their child's propensity for this condition, when screening could easily educate them."	Comment noted.
Judith Miller	"Every child deserves a chance."	Comment noted.
Clare Rannigan	"As the grandmother of a beautiful grandson who lost his	Comment noted.

	battle with SCID at 5 months of age I implore you to add this test to newborn screenings in Virginia."	
Donna Varela	"I'm strongly in favor of SCID screening. It saves lives!"	Comment noted.
Laura Lilley-Bell	"This must be amended. Even 1 child lost to SCID is 1 too many."	Comment noted.
Crystal Simmons	"If it could save 1 life it should be done."	Comment noted.
Tammy Wood	"Our children NEED this screening."	Comment noted.
Edward Rodriguez	"The test costs so little and can save so many lives. The sooner SCID is diagnosed, the easier it is to treat. This is a 100% no brainer that must, must, MUST, occur!!"	Comment noted.
Robert C Rannigan	"In favor of SCID testing."	Comment noted.
Immune Deficiency Foundation	"Your approval of the pending regulations will save the lives of babies in Virginia. We hope that Virginia will join the 21 other states that are currently screening for SCID."	Comment noted.
Barb Ballard	"This test makes sense as a health initiative, as a budgetary issue, and as an ethical issue."	Comment noted.

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-71-30	N/A	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.