Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) 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	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	December 5, 2012

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.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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.

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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Severe combined immunodeficiency 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.

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. 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.

The addition of SCID to the core panel will result in an increase in the newborn screening fee. The VDH Office of Family Health Services has long partnered with the Department of General Services' Division of Consolidated Laboratory Services (DCLS) to provide blood spot newborn screening services. 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. It is estimated that an additional $15.00 per test will be assessed, bringing the total cost of the blood spot screening panel to $68.00. The fee increase will also cover the costs for additional VDH newborn screening follow-up personnel as well as other screening-related expenses such as test kits used for cystic fibrosis mutation analysis. The estimated fee of $68.00 is 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. According to DCLS, the proposed fee increase is expected to hold until at least 2018.

While newborn screening is a fee-for-service program, 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.

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 detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The changes proposed to 12 VAC 5-71 will revise the Section 30 listing of specific disorders for which screening is conducted by adding Severe Combined Immunodeficiency (SCID) to the state's core panel. Currently, the Division of Consolidated Laboratory Services (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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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. The Virginia Department of Health has 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 potential change and cost effectiveness.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the

alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Anne Massey, 109 Governor Street, 10th Floor, Richmond VA 23219, phone (804)864-7797, fax (804)864-7380, or email Anne.Massey@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 day of the public comment period.

Pursuant to 12 VAC 5-11, a regulatory advisory panel will be used to assist in the development of this regulatory proposal. If you are interested in serving on this panel, please contact Anne Massey, 109 Governor Street, 10th Floor, Richmond VA 23219, phone (804)864-7797, fax (804)864-7380, or email Anne.Massey@vdh.virginia.gov.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Family impact

Assess the potential 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.