Virginia Department of Planning and Budget

Economic Impact Analysis

12 VAC 5-71 Regulations Governing Virginia Newborn Screening Services
Virginia Department of Health
Town Hall Action/Stage: 5259/8965
July 31, 2020 Revised September 1, 2020 to clarify technical details.

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) seeks to amend the existing newborn screening regulation to add spinal muscular atrophy (SMA) and X-linked adrenoleukodystrophy (X-ALD) to the newborn screening panel (NSP). The additions of SMA and X-ALD to the NSP have been recommended by the Virginia Genetics Advisory Committee. Blood spot newborn screening services are provided by the Department of General Services' Division of Consolidated Laboratory Services (DCLS) in partnership with the Virginia Department of Health (VDH) Office of Family Health Services, and as required by section 100 of these regulations (12 VAC 5-71-100).

Background

The Board proposes to amend section 30 "Core Panel of Heritable Disorders and Genetic Diseases," to add SMA and X-ALD. VDH reports that SMA is estimated to occur in approximately 9.1 out of every 100,000 live births and X-ALD is estimated to occur in approximately 6 out of every 100,000 live births. If these disorders progress undetected, they are known to cause severe disabilities and/or a severely shortened lifespan.[1] However, treatment for both these genetic disorders are available if they are detected early. Blood spot tests are necessary to detect these disorders as they cannot be detected at birth through physical

[1] Page 3 of the Agency Background Document includes further details about each disorder, including the various sub-types, symptoms, and typical outcomes. See https://townhall.virginia.gov/l/GetFile.cfm?File=58\5259\8965\AgencyStatement_VDH_8965_v1.pdf.

examinations. Virginia currently screens for 33 genetic disorders: 31 genetic disorders by dried blood spot screening along with critical congenital heart disease and hearing loss by point of care testing. With the addition of X-ALD and SMA, Virginia will be in alignment with the 35 disorders on the Secretary of the U.S. Department of Health and Human Services' Recommended Uniform Screening Panel.

Estimated Benefits and Costs

In Virginia, DCLS conducts roughly 99,000 newborn screening tests per year. Thus, the proposed amendments would result in the screening of all newborns in Virginia for these disorders; this would potentially benefit approximately 15 newborns each year who might be born with SMA or X-ALD, as well as their families. The benefits of early detection and treatment include not only the avoidance of disability but also the associated costs and other detrimental effects. These benefits would accrue over the entire lifespan of individuals having these genetic disorders.

However, laboratory screening comes at a cost. The Virginia Newborn Screening Program is solely funded through enterprise funding, which is generated from the collection of fees from dried blood spot specimen kits sold to submitting birthing facilities and health care providers statewide. VDH notes that in order to implement these two screenings statewide, DCLS would require infrastructure investment that includes additional laboratory equipment, programmatic staff, application development to incorporate screening results, incorporation of new education modules, identification of specialized medical support systems for infants and their families, and family support and case management services for infants diagnosed with SMA or X-ALD.

Specifically, adding SMA to the newborn screening panel results in an increase of $2.16, and adding X-ALD to the newborn screening results in an increase of $10.84 per sample, for a total of $13 for both of these disorders per sample. Further, the Board anticipates VDH costs to include one full-time employee for follow-up activities and education, and incurring outreach costs. The Board estimates DCLS costs related to capital equipment, staff, application development and education modules to be $389,631 in start-up costs and $192,262 annually for SMA screenings, and $1,101,568 in start-up costs and $1,073,422 annually for X-ALD screenings. These costs amount to an additional $13-$15 per test, since DCLS conducts roughly 99,000 tests a year.

These projected costs would be funded through a fee increase for the blood spot screening panel, which would need to go into effect 12 months prior to implementation to accrue start-up costs. Therefore, in order to begin including tests for SMA and X-ALD in the NSP in the 2020-21 fiscal year, DCLS increased the fee for the blood spot specimen kit from $101.20 to $138 effective October 1, 2019. As explained previously, an estimated $26-28 of this increase can be attributed directly to the changes proposed by the Board in this action. The overall fee increase would cover the cost of the two tests as well as other costs DCLS seeks to recoup for the expected addition of other tests in fiscal year 2021. Since the fees for the blood spot screening panel are set by DCLS and not the Board, this action does not directly lead to the introduction of new costs per se.

Businesses and Other Entities Affected

The increased fee directly affects hospitals, birth centers, and midwives who purchase the dried blood spot specimen kits from DCLS, as well as health insurance companies. VDH estimates that there are 58 hospitals, 10-15 birth centers, and an unknown number of midwives who would be affected by the fee increase.[2] Most private health insurance plans include the fee for the NSP in the negotiated reimbursement amount for childbirth. Hence, hospitals and birth centers are unlikely to pass on the increased costs directly to their patients. However, not all midwives accept health insurance and may pass on the increased costs to their patients. Further, the Department of Medical Assistance Services may have to update the reimbursements made on behalf of Medicaid enrollees to cover the increased fee. An adverse impact is indicated for the increased fee, since adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

Small Businesses Affected

Types and Estimated Number of Small Businesses Affected

It is not known if any of the hospitals qualify as small businesses, as many are non-profits, and those that are for profit may be too large.[3] Additionally, affected health

[2] The Department of Health Professions lists 95 currently licensed midwives, but many of them are likely to be employed by hospitals or birth centers.

[3] Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "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."

insurance companies may be too large to qualify. Birth centers and independent midwives are more likely to meet the definition of a small business. VDH estimates that there are 10-15 birth centers in Virginia; the number of midwives is unknown.

Costs and Other Effects

Any hospitals, birth centers, or midwives that do qualify as a small business would likely be adversely affected by the proposed fee increase.

Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

Localities[4] Affected[5]

The proposed amendments do not disproportionately affect any specific localities, nor do they introduce new costs for local governments.

Projected Impact on Employment

The proposed amendments are directly linked to allocations for six full-time employees at DCLS and one full-time employee at VDH. The proposed amendments are unlikely to affect employment at hospitals, birth centers, or health insurance companies more generally.

Effects on the Use and Value of Private Property

Private businesses that end up paying for either part of or all of the fee increase either directly or through reimbursements may be moderately reduced in value. Real estate development costs would not be affected.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

[4] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[5] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.