



## **Economic Impact Analysis Virginia Department of Planning and Budget**

---

**12 VAC 5-71 – Regulations Governing Virginia Newborn Screening Services**  
**Virginia Department of Health**  
August 30, 2013

---

### **Summary of the Proposed Amendments to Regulation**

The State Board of Health (Board) proposes to add Severe Combined Immunodeficiency (SCID) to the newborn screening panel.

### **Result of Analysis**

The benefits likely exceed the costs for all proposed changes.

### **Estimated Economic Impact<sup>1</sup>**

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. SCID is a primary immunodeficiency disease that is estimated to occur in approximately 1 out of every 50,000 live births. Undiagnosed cases are 100% fatal. 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.

In 2011, there were 101,032 live births in the Commonwealth.<sup>2</sup> Thus adding SCID to the newborn screening panel could potentially save approximately two lives a year.

---

<sup>1</sup> All data were provided by the Virginia Department of Health.

<sup>2</sup> Calendar year 2011 was the most recent year this datum was available.

Newborn screening is a fee-for-service program, and the fee is paid by hospitals and other screeners (to DCLS) 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.

Since the SCID screening assay is based on new highly sensitive, specific molecular detection methodology not previously employed by the newborn screening laboratory, 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.

With approximately 100,000 live births a year, the estimated \$7.50 cost increase will increase aggregate costs by about \$750,000 per annum, while potentially saving approximately two lives a year. Assuming that we value life at more than \$375,000 per person, the proposed addition of Severe Combined Immunodeficiency to the newborn screening panel should produce a net benefit.

### **Businesses and Entities Affected**

The proposed amendment will affect the 63 birth hospitals and birth centers, as well as their staff, and the sixty seven licensed midwives in Virginia. Newborns and their families will also be affected.

### **Localities Particularly Affected**

The proposed amendment does not disproportionately affect particular localities.

### **Projected Impact on Employment**

The proposed amendment will likely require that the Department of General Services' Division of Consolidated Laboratory Services hire additional staff.

### **Effects on the Use and Value of Private Property**

The proposed amendment is unlikely to significantly affect the use and value of private property.

**Small Businesses: Costs and Other Effects**

The proposed amendment is unlikely to significantly affect costs for small businesses.

**Small Businesses: Alternative Method that Minimizes Adverse Impact**

The proposed amendment is unlikely to adversely affect small businesses.

**Real Estate Development Costs**

The proposed amendment is unlikely to significantly affect real estate development costs.

**Legal Mandate**

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, Section 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.