



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

12 VAC 5-71 Regulations Governing Virginia Newborn Screening Services
12 VAC 5-72 Regulations Governing Virginia Critical Congenital Heart Disease Newborn Screening Services
Virginia Department of Health
Town Hall Action/Stage: 6671 / 10628
May 13, 2025

The Department of Planning and Budget (DPB) 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 19. The analysis presented below represents DPB's best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

As a result of a 2021 periodic review,² the State Board of Health (Board) proposes to relocate part of this regulation (Chapter 71) into a new regulation (Chapter 72) that applies only to screenings for critical congenital heart disease.

Background

Currently, this regulation establishes rules for protocols, screenings, results reporting, care coordination, records, and screening refusals for three types of newborn screenings: newborn dried blood spot screenings, newborn heart hearing screenings, and critical congenital heart disease (CCHD) screenings. However, CCHD rules have a narrower applicability in that out-of-hospital (OOH) births and providers (e.g., births at home and midwives) are not subject to CCHD screening rules. The Virginia Department of Health (VDH) reports that this has caused

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.

² <https://townhall.virginia.gov/L/ViewPReview.cfm?PRid=2041>

confusion for the regulated community, particularly for OOH birth providers. Thus, the Board proposes to remove the CCHD provisions from the current newborn screening regulation and create a new regulation that just addresses CCHD screening. In addition, the proposed changes make strictly editorial and stylistic changes to improve clarity of CCHD screening rules.

Estimated Benefits and Costs

The proposal would relocate the CCHD regulation into a new chapter and clarify the requirements. Thus, no significant economic impact is expected other than clarifying roles and responsibilities of the health care providers for the different newborn screenings.

Businesses and Other Entities Affected

According to VDH, there are 49 birthing hospitals and 72 non-birthing hospitals. In 2023, 52,919 CCHD screenings were conducted. No entity appears to be disproportionately affected.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.³ An adverse impact is indicated if there is any increase in net cost or reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.⁴ No adverse impact is indicated on any entity.

Small Businesses⁵ Affected:⁶

The proposed amendments do not adversely affect small businesses.

³ 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.

⁴ Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.

⁵ 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.”

⁶ 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.

Localities⁷ Affected⁸

The proposed amendments do not introduce costs or other effects on localities, nor do they particularly affect any locality.

Projected Impact on Employment

The proposed amendments do not affect total employment.

Effects on the Use and Value of Private Property

No effects on the use and value of property nor on real estate development costs are expected.

⁷ “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.

⁸ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.