

Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes  Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



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

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**12 VAC 5-71; 191 Regulations Governing Virginia Newborn Screening Services; State Plan for the Children with Special Health Care Needs Program**  
**Virginia Department of Health**  
**Town Hall Action/Stage: 4262/7245**  
August 14, 2015

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

Pursuant to Chapter 4 of the 2014 Acts of Assembly, the proposed regulations permanently require hospitals with a newborn nursery to screen all infants born in Virginia for critical congenital heart disease within 24-48 hours after birth using pulse-oximetry.

### **Result of Analysis**

The benefits likely exceed the costs for all proposed changes.

### **Estimated Economic Impact**

Pursuant to Chapter 4 of the 2014 Acts of Assembly, the proposed regulations permanently require hospitals with a newborn nursery to screen all infants born in Virginia for critical congenital heart disease (CCHD) within 24-48 hours after birth using pulse-oximetry.

More specifically, the proposed changes require that hospitals develop protocols for the screening of all newborns for CCHD, and that they have protocols for the follow-up and referral for any infants that have positive screens. Newborns that have an abnormal screen will not be discharged from the hospital until the cause of the abnormal screen has been evaluated and an appropriate plan for care is in place. Any diagnosis resulting from an abnormal screen will be entered in the electronic birth certificate, and the attending physician will notify the parent and

the primary care provider of the diagnosis. Infants who are diagnosed with CCHD will be referred to the Care Connections for Children program for care coordination services. A parent may refuse to have their child screened on the basis of religious practices or tenets. Such refusal must be documented in writing. These requirements were already implemented on December 24, 2014 under emergency regulations.

CCHD is a serious health condition affecting newborns that can result in death if not diagnosed and treated early. According to the Virginia Department of Health (VDH), congenital heart defects are the most common birth defects in the United States, affecting about one in every 110 babies. A few babies born with congenital heart defects have more serious forms of heart disease, which are referred to as critical congenital heart disease (affecting approximately 2 of every 1,000 births). CCHDs are heart defects that result in abnormal blood flow and oxygen deprivation. These defects require intervention within the first year of life and delayed diagnosis can result in death. Screening newborns for CCHD using pulse oximetry has been recommended through the U.S. Department of Health and Human Services Recommended Uniform Screening Panel. The screening is simple, quick, and painless. A sensor wrapped around the baby's right hand or either foot measures the amount of oxygen in the baby's blood.

The purpose of the proposed regulatory action is to ensure that all Virginia hospitals with newborn nurseries implement CCHD screening, and to ensure that newborns diagnosed with CCHD are reported to VDH so that they may be linked to care coordination services through the Care Connections for Children program. Increased CCHD detection at birth hospitals through screening may lead to decreased hospital costs and avoid some deaths during infancy.<sup>1</sup> Initial actions to educate hospitals and develop a tracking and recording system for CCHD were supported by a \$299,000 federal grant.

Additional reporting of screening results and confirmed cases that are required by these regulations occurs through existing systems (electronic birth certificate and VaCARES); therefore additional costs to implement these regulations are projected to be minimal. Based on a recent study in New Jersey, the estimated screening time per newborn was just over nine minutes and the associated labor and equipment costs per newborn screened were \$6.68 and \$6.82,

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<sup>1</sup> Peterson et al., Hospitalizations, Costs, and Mortality among Infants with Critical Congenital Heart Disease: How Important Is Timely Detection? *Birth Defects Research*, 2013, Oct, 97(10):664-72.

respectively, yielding a total estimate of \$13.50 per newborn.<sup>2</sup> Similarly, initial VDH estimates suggest CCHD screening time is 9 minutes and 45 seconds on average and the average cost of CCHD screening is \$13.28 in Virginia.<sup>3</sup>

Screening infants for CCHD is considered a best practice and was already adopted by 51 of the 55 hospitals prior to the requirements enacted by the 2014 General Assembly. Thus, most hospitals in Virginia are already voluntarily performing this screening. The proposed amendments would require the four additional hospitals to implement the screening.

The administrative costs to VDH for referral to the Care Connections for Children program to obtain care coordination services are considered small and will be absorbed by agency's existing resources.

### **Businesses and Entities Affected**

These regulations apply to 55 hospitals in Virginia of which 51 were already performing required screening voluntarily prior to emergency regulations. There were approximately 101,700 infants born in Virginia and approximately 142 newborns were diagnosed with CCHD in 2014.

### **Localities Particularly Affected**

The proposed changes apply throughout the Commonwealth.

### **Projected Impact on Employment**

The proposed amendments are unlikely to significantly affect employment as most hospitals were already voluntarily performing the proposed screening.

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

The proposed amendments are unlikely to significantly affect the use and value of private property as most hospitals were already voluntarily performing the proposed screening.

### **Real Estate Development Costs**

The proposed amendments are unlikely to affect real estate development costs.

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<sup>2</sup> Peterson et al., A public health economic assessment of hospitals' cost to screen newborns for critical congenital heart disease. Public Health Reports, 2014, Jan-Feb, 129 (1):86-93.

<sup>3</sup> These estimates are preliminary and subject to change.

**Small Businesses:****Definition**

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.”

**Costs and Other Effects**

Only a few of the 55 hospitals in Virginia may be considered as small businesses. None of the four hospitals that had not been voluntarily performing the CCHD screening is believed to be a small business. Thus, no significant effect on small businesses is expected.

**Alternative Method that Minimizes Adverse Impact**

The proposed screening is not expected to have an adverse impact on small businesses.

**Adverse Impacts:****Businesses:**

Since all but four hospitals were already performing required screening, the proposed regulations impose some additional compliance costs on only four hospitals.

**Localities:**

The proposed amendments will not adversely affect localities.

**Other Entities:**

No significant impact on other entities is expected. Additional administrative costs of the required screening will be absorbed by VDH's existing resources.

**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 Number 17 (2014). 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.

**Adverse impacts:** Pursuant to Code § 2.2-4007.04(C): 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.

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