

Office of Regulatory Management  
Economic Review Form

<b>Agency name</b>	Virginia Department of Health (VDH)
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12 VAC5-71
<b>VAC Chapter title(s)</b>	Regulations Governing Virginia Newborn Screening Services
<b>Action title</b>	Amend Regulations Following Periodic Review
<b>Date this document prepared</b>	10/10/24
<b>Regulatory Stage (including Issuance of Guidance Documents)</b>	Fast-track

**Cost Benefit Analysis**

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

**Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)**

<p>(1) Direct &amp; Indirect Costs &amp; Benefits (Monetized)</p>	<p>Direct Costs: There are no monetized direct costs associated with this action.</p> <p>Indirect Costs: There are no monetized indirect costs associated with this action.</p> <p>Direct Benefits: There are no monetized direct benefits associated with this action.</p> <p>Indirect Benefits: There are no monetized indirect benefits associated with this action.</p>	
<p>(2) Present Monetized Values</p>	<p>Direct &amp; Indirect Costs</p>	<p>Direct &amp; Indirect Benefits</p>
	<p>(a) \$0</p>	<p>(b) \$0</p>
<p>(3) Net Monetized Benefit</p>	<p>\$0</p>	
<p>(4) Other Costs &amp; Benefits (Non-Monetized)</p>	<p>There are no non-monetized costs associated with the proposed changes. The non-monetized benefit of the proposed changes is that improved clarity of the regulations may result in a greater understanding among stakeholders (particularly hospitals and health care providers) of the screening and reporting requirements for CCHD. Clearer requirements will help ensure that more children are screened for CCHD and that results are correctly reported to VDH. This in turn will allow the CCHD Newborn Screening Program at VDH to improve health outcomes by connecting children with CCHD and their families to appropriate services.</p>	
<p>(5) Information Sources</p>	<p>Public comment during the periodic review suggested that the regulations as currently written (the CCHD newborn screening regulations and the dried blood spot newborn screening regulations in the same chapter) causes confusion, as not all regulations in Chapter 71 are applicable to all birth providers.</p>	

**Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)**

<p>(1) Direct &amp; Indirect Costs &amp; Benefits (Monetized)</p>	<p>Direct Costs: There are no monetized direct costs associated with this action.</p> <p>Indirect Costs: There are no monetized indirect costs associated with this action.</p> <p>Direct Benefits: There are no monetized direct benefits associated with this action.</p>	
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	Indirect Benefits: There are no monetized indirect benefits associated with this action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Net Monetized Benefit	\$0	
(4) Other Costs & Benefits (Non-Monetized)	Failure to repeal, promulgate, and update the CCHD newborn screening regulations could result in a continued lack of clarity by health care providers and hospitals about screening and reporting requirements for CCHD. Clarity is necessary to ensure that all eligible children are screened for CCHD and results are correctly reported to VDH, so that the CCHD Newborn Screening Program at VDH may identify children and families that may need to be connected to services.	
(5) Information Sources	Stakeholder and agency staff input	

**Table 1c: Costs and Benefits under Alternative Approach(es)**

(1) Direct & Indirect Costs & Benefits (Monetized)	Section 32.1-65.1 of the Code of Virginia requires critical congenital heart disease newborn screening to be conducted on every infant born in the Commonwealth of Virginia, and Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement these screenings.  Alternatives to this regulatory change are limited to maintaining the status quo – not amending the regulations. As the regulations as written may cause confusion with regard to provider duties and responsibilities as they relate to newborn screenings, the Board has determined that amendments are necessary.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	

(4) Other Costs & Benefits (Non-Monetized)	N/A
(5) Information Sources	N/A

**Impact on Local Partners**

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

**Table 2: Impact on Local Partners**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no monetized direct costs for local partners associated with this action. Costs associated with administering CCHD screenings will remain the same.</p> <p>Indirect Costs: There are no monetized indirect costs for local partners associated with this action.</p> <p>Direct Benefits: There are no monetized direct benefits for local partners associated with this action.</p> <p>Indirect Benefits: There are no monetized indirect benefits for local partners associated with this action.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	<p>There are no non-monetized costs associated with the proposed changes in the guidance document. The non-monetized benefit of the proposed changes to the regulations is a greater understanding among health care providers and hospitals regarding screening and reporting requirements for CCHD.</p>	
(4) Assistance	<p>No assistance to local partners is required as a result of these changes.</p>	
(5) Information Sources	<p>Stakeholder and staff input.</p>	

**Impacts on Families**

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

**Table 3: Impact on Families**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no monetized direct costs for families associated with this action.</p> <p>Indirect Costs: There are no monetized indirect costs for families associated with this action.</p> <p>Direct Benefits: There are no monetized direct benefits for families associated with this action.</p> <p>Indirect Benefits: There are no monetized indirect benefits for families associated with this action.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	<p>There are no non-monetized costs associated with the proposed changes in the guidance document. The non-monetized benefit of the proposed changes to the regulations is that with increased clarity for health care providers and hospitals, VDH hopes to receive more consistent CCHD screening results, which in turn will allow the CCHD Newborn Screening Program at VDH to better understand the prevalence of CCHD and refer children with CCHD and their families to services.</p>	
(4) Information Sources	Stakeholder input	

**Impacts on Small Businesses**

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

**Table 4: Impact on Small Businesses**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: There are no monetized direct costs for small businesses associated with this action.</p> <p>Indirect Costs: There are no monetized indirect costs for small businesses associated with this action.</p>	
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	<p>Direct Benefits: There are no monetized direct benefits for small businesses associated with this action.</p> <p>Indirect Benefits: There are no monetized indirect benefits for small businesses associated with this action.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) \$0	(b) \$0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs or benefits associated with these changes for small businesses, as this program does not involve or affect small businesses.	
(4) Alternatives	N/A	
(5) Information Sources	N/A	

**Changes to Number of Regulatory Requirements****Table 5: Regulatory Reduction**

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

*Change in Regulatory Requirements*

<b>VAC Section(s) Involved*</b>	<b>Authority of Change</b>	<b>Initial Count</b>	<b>Additions</b>	<b>Subtractions</b>	<b>Total Net Change in Requirements</b>
12VAC5-71-10	<b>(M/A):</b>	0	0	0	0
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-150	<b>(M/A):</b>	3	0	0	0
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-190	<b>(M/A):</b>	3	0	0	0
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-210	<b>(M/A):</b>	4	0	4	-4
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-220	<b>(M/A):</b>	4	0	4	-4
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-230	<b>(M/A):</b>	12	0	12	-12
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-240	<b>(M/A):</b>	1	0	1	-1

	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	1	0	1	-1
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-250	<b>(M/A):</b>	1	0	1	-1
	<b>(D/A):</b>	1	0	1	-1
	<b>(M/R):</b>	4	0	4	-4
	<b>(D/R):</b>	0	0	0	0
12VAC5-71-260	<b>(M/A):</b>	1	0	1	-1
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	2	0	2	-2
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-10	<b>(M/A):</b>	0	0	0	0
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-20	<b>(M/A):</b>	0	4	0	+4
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-30	<b>(M/A):</b>	0	4	0	+4
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-40	<b>(M/A):</b>	0	12	0	+12
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-50	<b>(M/A):</b>	0	1	0	+1
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	1	0	+1
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-60	<b>(M/A):</b>	0	1	0	+1

	<b>(D/A):</b>	0	1	0	+1
	<b>(M/R):</b>	0	4	0	+4
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-70	<b>(M/A):</b>	0	1	0	+1
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	2	0	+2
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-80	<b>(M/A):</b>	0	0	0	0
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
12VAC5-72-90	<b>(M/A):</b>	0	0	0	0
	<b>(D/A):</b>	0	0	0	0
	<b>(M/R):</b>	0	0	0	0
	<b>(D/R):</b>	0	0	0	0
<b>Grand Total of Changes in Requirements:</b>					<b>(M/A): 0</b>
					<b>(D/A): 0</b>
					<b>(M/R): 0</b>
					<b>(D/R): 0</b>

**Key:**

*Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:*

**(M/A):** Mandatory requirements mandated by federal and/or state statute affecting the agency itself

**(D/A):** Discretionary requirements affecting agency itself

**(M/R):** Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

**(D/R):** Discretionary requirements affecting external parties, including other agencies

*Cost Reductions or Increases (if applicable)*

<b>VAC Section(s) Involved*</b>	<b>Description of Regulatory Requirement</b>	<b>Initial Cost</b>	<b>New Cost</b>	<b>Overall Cost Savings/Increases</b>

*Other Decreases or Increases in Regulatory Stringency (if applicable)*

<b>VAC Section(s) Involved*</b>	<b>Description of Regulatory Change</b>	<b>Overview of How It Reduces or Increases Regulatory Burden</b>

*Length of Guidance Documents (only applicable if guidance document is being revised)*

<b>Title of Guidance Document</b>	<b>Original Word Count</b>	<b>New Word Count</b>	<b>Net Change in Word Count</b>

\*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).