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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	State Board of Health
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12VAC5-71
<b>VAC Chapter title(s)</b>	Regulations Governing Virginia Newborn Screening Services
<b>Action title</b>	Amend regulations as a result of periodic review
<b>Date this document prepared</b>	April 6, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

### Brief Summary

*Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).*

The proposed regulatory action follows a periodic review of the Virginia Newborn Screening Services regulation. This action would amend the existing newborn screening regulation to update the text to remove outdated information and reflect recommended national best practices in newborn screening; identify the Newborn Screening Advisory Committee and remove the Virginia Genetics Advisory Committee as the advisory group for this regulation; and clarify reporting requirements.

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). On a national level, genetic disorders are included in the Recommended Uniform Screening Panel (RUSP) of the US Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children. Additions of disorders to Virginia's newborn screening panel in alignment with the RUSP are recommended by the Virginia Newborn Screening Advisory Committee. Currently, there are 33 heritable disorders and diseases on the Virginia newborn screening panel. Following a 2021

periodic review, VDH has determined the regulation requires updates. VDH is recommending the regulations be amended to reflect current practices and updated scientific information relevant to newborn screening. This regulatory action seeks to clarify content that may be unclear, inconsistent, or obsolete, and ensure consistency with the RUSP.

## Acronyms and Definitions

*Define all acronyms or technical definitions used in this form.*

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DCLS – Division of Consolidated Laboratory Services

RUSP – Recommended Uniform Screening Panel

VDH – Virginia Department of Health

VNSP – Virginia Newborn Screening Program

## Mandate and Impetus

*Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation, (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in the ORM procedures, “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”*

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In 2021, VDH conducted a periodic review of 12VAC5-71 “Regulations Governing Virginia Newborn Screening Services” pursuant to Executive Order (EO) 14 (as amended, July 16, 2018). In its finding, filed on July 29, 2021, VDH recommended the regulation be amended. VDH is recommending the regulations be amended to reflect current practices and updated scientific information relevant to newborn screening.

## Legal Basis

*Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency’s overall regulatory authority.*

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The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

Section 32.1-65 of the Code of Virginia requires newborn screening to be conducted on every infant born in the Commonwealth of Virginia.

Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services. The regulations are required to include a list of

newborn screening tests pursuant to Section 32.1-65.

## Purpose

*Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.*

Section 32.1-65 of the Code of Virginia mandates the necessity of newborn screening to protect the public health of all infants born in Virginia. This Code section states that newborn screening is necessary “in order to prevent mental retardation and permanent disability or death”.

Section 32.1-66 of the Code of Virginia requires the Commissioner of Health to notify the attending physician and to “perform or provide for additional testing required to confirm or disprove the diagnosis” whenever a result indicates suspicion of a possible disorder as screened for pursuant to § 32.1-65.

The regulation is required under § 32.1-67 of the Code of Virginia.

## Substance

*Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.*

Provisions for proposed regulation include revisions to remove or amend outdated requirements. VDH intends to add language that reflects current practices and updated scientific information relevant to newborn screening. VDH also intends to amend sections that may be determined, upon further review, to be outdated or inconsistent with policy and practice. All citations that reference federal requirements will also be reviewed to ensure these citations, and any associated language, are accurate. Other revisions to the regulation may also be proposed based on public comment or which arise from the Newborn Screening Advisory Committee workgroup that will meet to discuss proposed changes.

## Alternatives to Regulation

*Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.*

There are no alternatives which would comply with the current § 32.1-67 of the Code of Virginia. This section would need to be amended through the legislative process to make promulgation of these regulations optional. This is not a viable or desired alternative.

## Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

## Public Participation

*Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia, describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.*

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The Virginia Department of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Vanessa Walker-Harris, 109 Governor Street, 10<sup>th</sup> Floor, Richmond, VA 23219, 804-864-7253, [vanessa.walkerharris@vdh.virginia.gov](mailto:vanessa.walkerharris@vdh.virginia.gov). In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.