Form: TH-01 April 2020



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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-80
VAC Chapter title(s)	Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring Systems
Action title	Amend regulations as a result of periodic review
Date this document prepared	May 4, 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 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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 this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.

These regulations detail the responsibilities of entities that perform newborn hearing screening under the Code of Virginia.

The regulatory action follows a periodic review of the Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring Systems. This action would update the existing regulations to remove outdated information; reflect recommended national best practices based on the Joint Committee on Infant Hearing; change the chapter title from Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System to reflect more culturally inclusive language; and to clarify and adjust reporting requirements to meet national best practices.

Acronyms and Definitions

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Define all acronyms or technical definitions used in this form.

EHDI – Early Hearing Detection and Intervention

VDH - Virginia Department of Health

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 Executive Order 14 (as amended, July 16, 2018), "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."

In 2021, VDH conducted a periodic review of 12VAC5-80 "Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring Systems" pursuant to Executive Order (EO) 14 (as amended, July 16, 2018). In its finding, filed on March 10, 2022, VDH recommended the regulations be amended.

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.

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 32.1-64.1 of the Code of Virginia requires the State Health Commissioner to establish and maintain the Virginia Hearing Impairment Identification and Monitoring System.

Subsection E of Section 32.1-64.1 requires the Commissioner to appoint an advisory committee to assist in the design, implementation, and revision of this identification and monitoring system.

Subsection F of Section 32.1-64.1 requires that the Board of Health with assistance from the advisory committee promulgate rules and regulations as may be necessary to implement this identification and monitoring system. The subsection states "These rules and regulations shall include criteria, including current screening methodology, for the identification of infants (i) with hearing impairment and (ii) at risk of hearing impairment and shall include the scope of the information to be reported, reporting forms, screening protocols, appropriate mechanisms for follow up, relationships between the identification and monitoring system and other state agency programs or activities and mechanisms for review and evaluation of the activities of the system. The identification and monitoring system shall collect the name, address, sex, race, and any other information determined to be pertinent by the Board, regarding infants determined to be at risk of hearing impairment or to have hearing loss."

Purpose

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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.

Subsection A of Section 32.1-64.1 of the Code of Virginia mandates the necessity of the Virginia Hearing Impairment Identification and Monitoring System to protect public health as stated, "In order to identify hearing loss at the earliest possible age among newborns and to provide early intervention for all infants so identified as having hearing impairment, the Commissioner shall establish and maintain the Virginia Hearing Impairment Identification and Monitoring System. This system shall be for the purpose of identifying and monitoring infants with hearing impairment to ensure that such infants receive appropriate early intervention through treatment, therapy, training and education."

Early identification of hearing loss through screening and identification and tracking of infants at risk for acquiring hearing loss is essential to the health, well-being, and eventual language development of infants and children in the Commonwealth.

The regulations are required under § 32.1-64.1 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.

The proposed regulations will include revisions to remove or amend outdated requirements. VDH intends to add language that reflects current practices and updated scientific information relevant to newborn hearing 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 regulations may also be proposed based on public comment or which arise from Virginia Early Hearing Detection and Intervention Advisory Committee, which will meet and discuss the 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 § 32.1-64.1 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

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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.

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 Robin Buskey, 109 Governor Street, 10th Floor, Richmond, VA 23219, 804-864-7253, robin.buskey@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.