



Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC_5-80
Regulation title	Virginia Hearing Impairment Identification and Monitoring System
Action title	Amend 12 VAC 5-80 "Virginia Hearing Impairment Identification and Monitoring System" as a result of Periodic Review results.
Date this document prepared	1-14-2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Virginia Department of Health conducted a periodic review of 12 VAC 5-80 "Virginia Hearing Impairment Identification and Monitoring System" pursuant to Executive Order (EO) 36 (2006). The public comment for the periodic review closed 11/19/2007. As a result of this review, the Virginia Department of Health plans to begin the regulatory process to amend these regulations. This is necessary to incorporate principles from the "Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs" published by the Joint Committee on Infant Hearing in 2007. The current regulations which have not changed since 2001 refer to and are congruent with the American Academy of Pediatrics position statement "Newborn and Infant Hearing Loss: Detection and Intervention" published in 1999. The amended regulations will reflect changes in the nationally accepted standards for newborn hearing screening. The amended regulations will also reflect relevant changes in related state regulations.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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.

Part 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.

Part 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. This part 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.”

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Part A of Section 32.1-64.1 mandates the necessity of the Virginia Hearing Impairment Identification and Monitoring System to protect public health as such “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.” The need for the regulation is previously discussed and mandated by Part F of Section 32.1-64.1 of the Code of Virginia.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Changes will be proposed for Chapters 10 (Definitions), 80 (Responsibilities of Hospitals), 90 (Responsibilities of the Virginia Department of Health), 95 (Responsibilities of persons providing audiological services after discharge) and Documents Incorporated by Reference to reflect updated national standards “Year 2007 Position Statement: Principles and Guidelines for early Hearing Detection and Intervention Programs” published by the national Joint Committee on Infant Hearing. Amendments to definitions will be proposed for certain definitions to update references to other state regulations which are referred to in these regulations (12 VAC 5-410 “Rules and Regulations for the Licensure of Hospitals in Virginia”). In addition amendments will be proposed to make these regulations consistent with other relevant state regulations which have been repealed (12 VAC 5-70 “Regulations Governing the Newborn Screening and Treatment Program” and 12 VAC 5-190 “State Plan for the Provision of Children’s Specialty Services”) and replaced with new regulations within the past two years (12 VAC 5-71 “Regulations Governing Virginia Newborn Screening Services” and 12 VAC 5-191 “State Plan for the Children with Special Health Care Needs Program”).

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no alternatives which would comply with the current Code of Virginia Section 32.1-64.1. This Section would need to be amended through the legislative process to make promulgation of regulations optional. This is not a viable or desired alternative.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives

stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Susan Tlusty, Policy Analyst, Virginia Department of Health, 109 Governor Street, Richmond Virginia 23219, Phone: (804) 864-7686, Fax: (804) 864-7722, e-mail: Susan.Tlusty@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The Virginia Early Hearing Detection and Intervention Program Advisory Committee is the mandated State Health Commissioner appointed advisory body for the program as defined in Part E of Section 32.1-64.1 of the Code of Virginia:

“The Commissioner shall appoint an advisory committee to assist in the design, implementation, and revision of this identification and monitoring system. The advisory committee shall meet at least four times per year. A chairman shall be elected annually by the advisory committee. The Department of Health shall provide support services to the advisory committee. The advisory committee shall consist of representatives from relevant groups including, but not limited to, the health insurance industry; physicians, including at least one pediatrician or family practitioner, one otolaryngologist, and one neonatologist; nurses representing newborn nurseries; audiologists; hearing aid dealers and fitters; teachers of the deaf and hard-of-hearing; parents of children who are deaf or hard-of-hearing; adults who are deaf or hard-of-hearing; hospital administrators; and personnel of appropriate state agencies, including the Department of Medical Assistance Services, the Department of Education, and the Department for the Deaf and Hard-of-Hearing. The Department of Education, the Department for the Deaf and Hard-of-Hearing, and the Department of Mental Health, Mental Retardation and Substance Abuse Services shall cooperate with the Commissioner and the Board in implementing this system.”

This advisory committee met on November 9, 2007 and formed the “Hearing Regulations Task Force” to proceed with changes needed identified as a result of the Periodic Review and to work on proposed regulatory text.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory action will potentially strengthen parents’ ability to assure appropriate education because early detection and treatment of hearing impairment can reduce learning disabilities which often result with delayed identification and treatment of hearing impairment. By reducing potential disability, economic self-sufficiency may be strengthened and lessen the potential erosion of disposable family income. Early intervention and treatment for hearing impairment has been demonstrated to save costs for both families and governmental institutions.

Periodic review – Public comment

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

No public comments were received as the result of the Notice of Periodic Review which began October 29, 2007 and ended November 19, 2007.

Part A of Section 32.1-64.1 mandates the necessity of the Virginia Hearing Impairment Identification and Monitoring System to protect public health as such “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.” The need for the regulation is previously discussed and mandated by Part F of Section 32.1-64.1 of the Code of Virginia.

Commenter	Comment	Agency response

Periodic review - Discussion

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review or if the periodic review is to be performed in combination with the NOIRA, please include a discussion of the agency's consideration of: (1) the continued need for the rule; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

12 VAC 5-80 "Virginia Hearing Impairment Identification and Monitoring System" was first promulgated and became effective 7/1/2000 as required by Part F of Section 32.1-64.1 of the Code of Virginia.

A Periodic Review pursuant to Executive Order (EO) 36 (2006) was started on October 3, 2007. The public comment period ran from October 29, 2007 through November 19, 2007. No public comments were received.

Technological changes in conducting hearing screening, changes in national standards as set forth by the national Joint Committee on Infant Hearing, and more recent changes to applicable state regulations (12 VAC 5-410 "Rules and Regulations for the Licensure of Hospitals in Virginia, 12 VAC 5-71 "Regulations Governing Virginia Newborn Screening Services" and 12 VAC 5-191 "State Plan for the Children with Special Health Care Needs Program") necessitate proposing amendments to 12 VAC 5-80 "Virginia Hearing Impairment Identification and Monitoring System".

It is not anticipated that these amendments will be complex or have an impact on small business.