Virginia Regulatory Town Hall

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Proposed Regulation
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.
Date this document prepared	9-25-2009

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.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

This regulation is being amended to reflect the most current Joint Committee on Infant Hearing Statement issued in 2007. Substantive changes include: moving risk factor criteria to identify infants at risk for hearing loss from definitions to a new section and placing detailed criteria for each category of risk under a guidance document; requiring infants who receive neonatal intensive care services for longer than five days to be tested with ABR screening technology; adding a new section to address birthing centers; and further defining reporting requirements which include provisions for confirming negative results.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the 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., the 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."

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Part 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 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."

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. In the absence of hearing screening, hearing loss is not usually identified until two to three years of age and language development has already been impacted adversely. The average deaf or hard-of-hearing adult reads at a fourth grade level. Infants can be assessed and diagnosed with hearing loss by several months of age and fitted with hearing devices as early as one month of age. Research suggests that most preschool-age children with hearing loss will have language development within the normal range if diagnosis and intervention begins by 6 to 12 months of age. Early identification reduces costs associated with special education as well.

The Code requires regulation for this program and this particular action is necessary following a periodic review of 12 VAC 5-80 pursuant to Executive Order (EO) 36 (2006). This action will incorporate principles and changes in standards for newborn hearing screening from the Joint Committee on Infant Hearing

"Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs". 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 which is now outdated.

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 and recommendations from the Attorney General's Government and Regulatory Reform Task Force. These changes will help improve the newborn hearing screening program in the Commonwealth.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

In order to be consistent with the most recent recommendations from the Joint Committee on Infant Hearing, substantive changes have been proposed for hearing screening methodology in Section 80 (Responsibilities of Hospitals). In this chapter, the type of screening methodology to be administered has been defined according to level and length of hospital newborn service provision. In addition, details on how to handle transfer and other circumstances are outlined. More details have been added regarding the specifics required for reporting.

Another substantive change relates to identification of infants at risk for hearing impairment. These criteria have been moved out of definitions and into a separate Section 75. The section outlines the review timeline and process for identifying and maintaining the list of risk indicators. The section specifies the broad categories of risk indicators (for example, syndromes known to be associated with hearing loss) however, the details of the particular category will now be maintained and published as a guidance document. The guidance document will now detail the list of known syndromes associated with hearing loss that are tracked by the program. This is necessary to allow flexibility to change with rapidly changing advances in links between genetic disorders and hearing loss as well as new findings regarding the ototoxicity of certain medications.

Other substantive changes include the addition of several sections related to different types of service providers who are part of the system. Section 85 addresses birthing centers that currently do not fall under other regulations. The Virginia Department of Health has received grant funding to work with these providers and help develop reporting ability. These facilities typically do not conduct hearing screening but refer infants for hearing screening. The Department seeks to capture information regarding infants born in these type of facilities to identify those at risk for hearing impairment and to enter those infants in the tracking system. With the number of birthing centers in the state expected to increase, the importance of capturing those infants increases.

Section 100 addresses primary health care providers and simply states that they have a responsibility to receive results and communications from the Virginia Early Hearing Detection and Intervention Program. It may be possible in the future that this provider group will have the ability to electronically access hearing screening results.

Section 110 relates to the Virginia Department of Health statutory responsibility as a partner in the Part C system. The Virginia Early Hearing Detection and Intervention Program is a component of the multi-agency early identification and intervention system in the Commonwealth. As part of this system, certain statutes, regulations, and a formal interagency agreement provide additional guidance for program operations and relationships between service providers.

Definitions (Section 10) have been added to reflect current screening methodologies and affected parties and others have been modified to be consistent with other similar regulations or correct citations.

Responsibilities of the Virginia Department of Health (Section 90) have been further refined and provide more direction regarding the reporting system. References related to false-positive and false-negative rates have been deleted.

Amendments to definitions are 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 are 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 several 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"). Recommendations from the Attorney General's Government and Regulatory Reform Task Force have also been adopted in the proposed text.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The primary advantages to the public are to families with infants born in Virginia hospitals. By amending the regulations and program practices to be current with the most recent national standard of care recommendations, infants will continue to be screened for hearing loss using the most appropriate technology and assessed for other factors which may put them at risk for hearing loss. Early identification of hearing loss is beneficial to children and their families. Without newborn hearing screening, hearing loss is not typically identified until two to three years of age and serious delays in language and other areas of cognitive development are likely to have occurred. Infants who are diagnosed and enter early intervention between 6 and 12 months of age can achieve normal language development. In addition, families who have infants identified with hearing loss can be linked with family-to-family support programs, such as Guide by Your Side where families who have had children with hearing loss serve as mentors to those with a newly diagnosed child, and medical support programs such as the Hearing Aid Loan Bank.

The disadvantage to the public for families with infants born in Virginia hospitals would be if an infant or child required further audiological evaluation and the family did not have insurance coverage or could not find a provider willing to accept public insurance (FAMIS plans). Another disadvantage may be stress involved for families of infants who may be identified at risk for hearing loss. These infants may undergo further testing but not be found to have hearing loss at any point during childhood.

The primary advantage for providers of hearing screening (birthing hospitals) is clarified guidance from the state regarding their mandate and to have guidance which is consistent with most recent national standards of care. Changes in the reporting requirements and changes being made to the current electronic reporting system will provide basic demographic information to hospital users and reduce duplicative data entry.

The primary disadvantage will be for hospitals with neonatal intensive care services that will need to acquire ABR technology to meet the new standard.

The primary advantages to the agency and the Commonwealth are to have a well defined and managed program which successfully identifies infants with hearing loss as early as possible to meet the mandate in the Code of Virginia. Early identification is key to reducing negative impact on language and cognitive development. Infants who are identified with hearing loss and receive early identification and amplification by six months of age will be one to two years ahead of their later identified peers in first grade in the areas of language, cognitive, and social skills. Children with undetected hearing loss in one ear are more likely to be held back in school than those without hearing loss. It is estimated that $400,000 in special education costs are saved by high school graduation for a child identified early with hearing loss who receives appropriate educational, medical and audiological services.

There are no disadvantages to the agency and Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There is no federal statute mandating newborn hearing screening. The only federal requirements are reporting requirements which are contingencies of receiving grant funding from the U.S. Department of Health and Human Services, Health Resources and Services Administration.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality will be particularly affected by the proposed regulation.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to:
Susan Tlusty, Policy Analyst, Sr.
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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 date of the public comment period.
A public hearing will not be held.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	There is no additional cost to the state to implement and enforce the proposed regulation.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There is no current or projected cost for the amended regulations for localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities affected by the amended regulations include all infants and their families born in Virginia hospitals, birthing hospitals in Virginia, birthing centers in Virginia, persons providing audiological services in Virginia, and the Department of Behavioral Health and Developmental Services (lead agency for Part C early intervention program).
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means 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.	Infants born in Virginia hospitals: 105,000 annually Birthing hospitals in Virginia: 64 Birthing centers in Virginia: 2 Persons providing audiological services for infants and children: 107
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	Two of the 64 birthing hospitals which have specialty neonatal intensive care services would have to purchase ABR equipment to test those infants with stays of greater than five days. It is estimated that new ABR equipment may cost between $15,000 to $25,000. The other hospitals with these types of neonatal intensive care services already have the capability or are using this equipment. Birthing centers have not previously reported formally to the department although the Code of Virginia has a provision for birthing centers. Risk

	assessments and referrals for hearing screening are currently being done in practice. Reporting findings to the department may require staff effort of one to three hours per month. Birthing centers typically have 25 or fewer births per month. Birthing hospitals currently perform testing on all infants. Reporting time will be decreased with provision by the department of certain existing demographic data from births and elimination of monthly report totals, however with the new modified risk indicator list and primary information or confirmation on infants assumed to pass, reporting time and effort may have a net increase by 2 to 30 hours monthly depending on the number of births at the facility.
Beneficial impact the regulation is designed to produce.	Increased early identification of hearing loss in infants and decreased delays in cognitive and language development among those infants with hearing loss will be the primary benefit. In addition, costs related to special education should be reduced.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

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 desired or viable alternative.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Less stringent standards would not be consistent with the most current national recommendations and cannot be argued to be consistent with the intent of the law and the role of promoting health for infants

born in the Commonwealth. The time for certain reporting requirements actually has been extended by one week to allow for use of existing demographic birth data to reduce data entry. This is a reporting simplification due to prepopulation of certain data requirements. The proposed regulations place details of the required at risk criteria in a guidance document which will provide for more flexibility in administering the regulations and to amend specific criteria. Less stringent reporting requirements for risk categories would not be consistent with the most current national recommendations and would not be consistent with the intent of the law and the role of public health to track infants at risk for acquiring hearing loss.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
No public comments following publication of the NOIRA		

Family impact

Please assess the 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.

Parents maintain the right to refuse hearing screening under the Code of Virginia.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
10	10	Definitions	Definitions added for current screening methodologies (ABR and OAE); acronyms used (CDC, EHDI); programs (Part C, Virginia Hearing Impairment Identification and Monitoring System, family-to-family support); services/providers (audiologist, birthing center, hospital, newborn services); and other entities (board, guardian, newborn, and resident). Definitions modified for parent, neonatal intensive care services unit, and primary healthcare provider. These definitions were modified to be consistent with other regulations and to define terms within the regulation. Unused definitions deleted.
20	20	Authority	Minor edits made for grammar.
30	30	Purpose	Added statement that section is designed to be consistent with most recent recommendations of Joint Committee on Infant Hearing.
40	40	Administration	Edited to allow issuance of guidance documents. Removed reference to general application.
80	80	Responsibilities of chief medical officer	Section renamed to clarify the responsible party as defined in the Code. This section is revised to include separate screening methodologies for different levels of newborn care and how to handle screening failures in one or both ears. This section defines how to handle transfer infants. Reporting requirements are more detailed. The screening timeframe is reduced to one month of age, except for those receiving neonatal intensive care services, to be aligned with CDC national goals. References to the 1999 American Academy of Pediatrics statement and false-positive and false-negative rates are removed.
90	90	Scope and content of the Virginia Early Hearing Detection and Intervention Program	Section renamed to specify the program. This section is revised to detail responsibilities regarding developing and maintaining reporting system. In addition, responsibilities for communicating with Part C, developing and disseminating protocols, parent education materials, and maintaining list of approved audiologists are added. National performance

			measures required for grant funding are added.
95	95	Responsibilities of persons providing audiological services after discharge	Section edited to specifically name Part C program for referrals.

For new chapters, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
75	Adds section on risk indicators associated with hearing loss. Previously risk factors were in definitions. Risk indicators have been updated to reflect the most current national standards. Certain risk indicators have been deleted (low birthweight, low Apgar scores, mechanical ventilation five days or longer). Other risk indicator categories have been added (neonatal intensive care services for five or more days, ototoxic chemotherapy, head trauma, syndromes associated with hearing loss, neurodegenerative disorders). Details regarding specifics for each category removed and put into guidance document to be reviewed at least biennially.	Part F of 32.1-64.1 of the Code of Virginia directs Board to establish criteria for determination of at risk for hearing impairment.	Intent is to reflect most current national standard for risk indicators. Movement of details to guidance document will allow risk indicators to be amended as needed to keep up with current research without lengthy wait under regulatory process. Likely impact could be change in numbers of infants identified at risk for hearing loss.
95	Adds section on birthing places or centers. It is proposed to have this group report risk indicators to the department and confirm that screening was not done and that infants were referred.	Part C of 32.1-64.1 of the Code of Virginia states that birthing places and centers shall identify infants at risk of hearing impairment.	Intent is to formally include birthing centers which are specified in the law but not currently reporting. This is important as more birthing centers are expected to open in the state to meet obstetrical need. The department will work with birthing centers to facilitate reporting either by paper or electronically.
130	Adds section on responsibilities of primary healthcare providers. States that they will receive hearing screening results and program information.	Part G of 32.1-64.1 of the Code of Virginia states that anyone making determination that infant has hearing loss or is at risk of hearing loss shall notify the primary	Intent is to formally include this important group of service providers as part of the overall screening system. Change in current practice unlikely as primary healthcare

		healthcare provider.	providers do receive results.
140	Adds section on relationship to Part C.	Individuals with Disabilities Education Act of 2004 (20 U.S.C. §§ 1431-1444); 34 CFR Part 303; §2.2-5303 of the Code of Virginia. Section 2.2-5300 and 5303 of the Code of Virginia.	Intent is to formally include relationship between program and Part C early intervention system. Participating Part C agencies, including the Virginia Department of Health, will continue to formalize relationships regarding referrals, service provision and outcomes, evaluation, and data exchange through interagency agreements as required by federal and state law.

The current Form (Report of Follow-Up) and Document Incorporated by Reference (Newborn and Infant Hearing Loss: Detection and Intervention, Pediatrics Vol. 103, No. 2, February 1999, American Academy of Pediatrics) will be deleted.