Virginia Regulatory Town Hall

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-80
Regulation title	Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System
Action title	Amend 12 VAC 5-80 "Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System" as a result of periodic review.
Date this document prepared	July 20, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

This regulation details responsibilities of entities that are responsible for newborn hearing screening under the Code of Virginia. This regulation underwent periodic review in 2007 and has been recommended to be amended.

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 auditory brainstem response (ABR) screening technology; adding several new sections to address responsibilities of other birthing places or centers, reporting responsibilities to primary health care providers, and the program relationship to the Part C system; and further defining reporting requirements which include provisions for confirming negative results.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The Virginia State Board of Health approved final amendments to the text of "Regulations for the Administration of the Virginia Hearing Impairment Identification and Monitoring System", 12VAC5-80. The Board of Health requested one additional definition be added and authorized the State Health Commissioner to approve this modification in the final text at its meeting on June 9, 2011. The State Health Commissioner approved the final modification and text on behalf of the Virginia State Board of Health on August 11, 2011.

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."

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal 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 12VAC5-80 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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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 section, 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 other birthing places or centers that currently

do not fall under other regulations. These facilities typically do not conduct hearing screening but refer infants for hearing screening. The Department seeks to capture information regarding infants born in non-hospital settings 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 130 addresses reporting responsibilities to primary health care providers and details the various entities that must provide results to them. This section allows for secure electronic transmission of results. In the future it may be possible that this provider group will be able to electronically access hearing screening results.

Section 140 relates to the Virginia Department of Health statutory responsibility as a partner in the early intervention system (Part C of the Individuals with Disabilities Education Act). The Virginia Early Hearing Detection and Intervention Program is a component of the multi-agency early 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 to define specific partners with responsibilities in the hearing screening program. Other definitions have been modified to be consistent with other similar regulations. Amendments to definitions are proposed to update references to other state regulations which are referred to in these regulations (12VAC5-410 "Rules and Regulations for the Licensure of Hospitals in Virginia"). In addition amendments are proposed to make this regulation consistent with other relevant state regulations which have been repealed (12VAC5-70 "Regulations Governing the Newborn Screening and Treatment Program" and 12VAC5-190 "State Plan for the Provision of Children's Specialty Services") and replaced with new regulations within the past several years (12VAC5-71 "Regulations Governing Virginia Newborn Screening Services" and 12VAC5-191 "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.

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.

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 there are no disadvantages to the public or the Commonwealth, please 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 the 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Definition of "Audiologist" means a person licensed to engage in the practice of audiology as defined in § 54.1-2600 of the Code of Virginia.	Definition changed to: "Audiologist" means an audiologist as defined in § 54.1-2600 of the Code of Virginia	This change was made to provide a closer definition to that in the Code of Virginia.
10*	Definition: "Birthing Center" means a facility outside of a hospital that provides maternity services.	This definition has been modified to "Other birthing place or center" means a place or facility outside of a hospital that provides maternity services.	This change has been made to be more consistent with the term "other birthing places or centers" as used in the Code of Virginia.
10*	None	Added definition for "chief medical officer" means the highest	This definition was added to clarify the

		position of authority on the medical staff of the hospital or other birthing place or center as defined in the organization's by-laws or applicable governance structure.	responsible person as named, but not further defined, in the Code of Virginia.
10	Definition of "Part C" means the state early intervention program that provides medically necessary speech and language therapy, occupational therapy, physical therapy, and assistive technology services and devices for dependents from birth to age three who are certified by the Department of Behavioral Health and Developmental Services as eligible for services under Part C of the Individuals with Disabilities Education Act of 2004 (20 USC §§ 1431-1444)	Definition changed to "Part C" means the state early intervention services program that provides medically necessary speech and language therapy, occupational therapy, physical therapy, and assistive technology services and devices for children from birth to age 3 who are eligible for services under Part C of the Individuals with Disabilities Education Act (20 USC §§ 1431-1444) and Virginia law.	Changes were made to remove "certified" clause as this is not a formal designation. Style change was made to citation of federal law and Virginia law was added for clarity.
10	Definition: "Title V" means the U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Services Block Grant (Title V of the Social Services Act).	Change in reference in "Title V" definition from "Bureau" to "Services".	This change has been made to be more consistent with name commonly cited for Title V Block Grant.
80	Infants shall have both ears screened	Addition of text to state that infants shall have both ears screened "at the same time" in 1 (a), (b), and (c).	This clarifies that ears should not be screened individually at different times.
80	"Notify the infant's primary health care provider, within two weeks of discharge after birth, the status of the hearing screening..."	Addition of word "of" before "the hearing screening".	This change is for grammatical clarity.
80	"Primary contact information including address, telephone, and relationship type primary health care provider, address, and telephone;"	Addition of word "number" after telephone.	This change is for grammatical clarity.
80	"Primary health care provider, address, and telephone;"	Addition of word "number" after telephone.	This change is for grammatical clarity.
85	Use of term "birthing center"	All references to "birthing center" have been changed to "other birthing places or centers".	This change has been made to be more consistent with the term "other birthing places or centers" as used in the Code of Virginia.
85	"Primary contact information including address, telephone, and relationship type;"	Addition of word "number" after telephone.	This change is for grammatical clarity.

85	"Primary health care provider, address, and telephone;"	Addition of word "number" after telephone.	This change is for grammatical clarity.
90	Use of the term "birthing center"	All references to "birthing center" have been changed to "other birthing places or centers".	These changes have been made to be more consistent with the term "other birthing places or centers" as used in the Code of Virginia.
90	"Provide hospitals and other birthing places or centers with a secure reporting system, which may be electronic, that meets all applicable federal and state privacy statutes."	Delete word "statutes" and substitute word "laws".	This change is for grammatical clarity.
90	"The following goals shall change as needed to be consistent with federally required performance measures:"	Move second sentence in 90 (C) to new subsection 5 and change second sentence to read "The goals shall change as needed to be consistent with federally required performance measures."	This change is to increase logic and readability of statements as federal goals which guide the program and may change.
90	None	Addition of text: "The goals are:" before listing the goals.	This change is to increase logic and readability of statements.
130*	"Responsibilities of primary health care providers"	Section name changed to "Reporting responsibilities to primary health care providers".	Change made to reflect correct direction of "statutory obligation.
130*	"Receive hearing screening, risk indicator findings, and evaluation results from hospitals, audiological providers, and the Virginia EHDI program."	Subsection 1 removed as written.	Change made to remove passive obligation which may be out of scope of authority.
130*	"Receive information from the Virginia EHDI program regarding available resources to assist practitioners and families whose child is at risk or diagnosed with hearing loss."	Subsection 2 removed as written.	Change made to remove passive obligation which may be out of scope of authority.
130*	None	A. The chief medical officer of a hospital providing newborn services or his designee shall report hearing screening results to the infant's primary health care provider as defined in 12VAC5-80-80.	Change made to specify active reporting requirement to primary health care providers.
130*	None	B. The chief medical officer of an other birthing place or center or his designee or the attending practitioner shall report the status of the hearing screening results including if the infant was not tested to the infant's primary	Change made to specify active reporting requirement to primary health care providers.

		health care provider as defined in 12VAC5-80-85.	
130*	None	C. The Virginia EHDI Program shall report infants identified with risk indicators for progressive hearing loss as defined in 12VAC5-80-75 and infants identified with hearing loss to the infant's primary health care provider pursuant to § 32.1-64.2 of the Code of Virginia. The Virginia EHDI Program shall provide other hearing screening and resource information to the infant's primary health care provider as defined in 12VAC5-80-90.	Change made to specify active reporting requirement to primary health care providers.
130*	None	D. Persons providing audiological services shall report hearing screening and audiological evaluati results to the infant's primary health care provider as defined in 12VAC5 80-95.	Change made to specify active reporting requirement to primary health care providers.
130*	None	E. Reporting hearing screening and audiological evaluation results to primary health care providers may be done through an electronically secure system that meets all applicable federal and state privacy laws.	Change made to specify that results may be reported electronically.
140	"Individuals with Disabilities Education Act of 2004"	Removal of "of 2004"	This change is for clarity of reference to federal law.
140*	The state interagency agreement shall contain policies and procedures related to identification of resources…as part of the state early intervention system.	Paragraph B removed completely.	This paragraph was removed as it may be beyond scope of authority.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Dave	"New here just trying to getting used to the public forum. May speak later."	None

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

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, chief medical officer, hospital, newborn services, other birthing places or centers); 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	Repealed. This section is not needed as it is covered in the Code of Virginia.
30	30	Purpose	Repealed. This section is not needed as it is covered in the Code of Virginia.
40	40	Administration	Repealed. This section is not needed as it is covered in the Code of Virginia.
80	80	Responsibilities of chief medical officer	Section renamed to clarify the responsible party as defined in the Code of Virginia. 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 infants who are transferred to other hospitals. 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	Section renamed to specify the program. This section is revised to detail

		Detection and Intervention Program	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). 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.
85	Adds section on other 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 other birthing places or centers shall identify infants at risk of hearing impairment.	Intent is to formally include other birthing places or 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 practitioners who deliver at other birthing places or centers to facilitate reporting by paper.
130	Adds section on reporting	Part G of 32.1-64.1 of the	Intent is to formally include this

	responsibilities to primary healthcare providers.	Code of Virginia states that anyone making determination that infant has hearing loss or is at risk of hearing loss shall notify the primary healthcare provider.	important group of service providers as part of the overall screening system. Specific reporting responsibilities of hospitals, other birthing places or centers, Virginia EHDI program, and persons providing audiological services to primary health care providers are outlined. Section states that reporting may be done electronically.
140	Adds section on relationship to Part C.	Individuals with Disabilities Education Act (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.

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 pre-filling of certain data elements. 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.

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.

This regulatory action will potentially strengthen parents' ability to assure appropriate education for their child 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 have been demonstrated to save costs for both families and governmental institutions.

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