



Virginia
Regulatory
Town Hall

Final Regulation Agency Background Document

Agency Name:	Virginia Department of Health
VAC Chapter Number:	12 VAC 5-80
Regulation Title:	Regulations for the Administration of the Virginia Hearing Impairment Identification and Monitoring System
Action Title:	Enter Action Title
Date:	March 27, 2000

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The proposed amendments comply with the statutory changes to the Code of Virginia. The regulations provide consistent guidance for the implementation and administration of a system to insure that all infants born in Virginia with hearing loss are identified and receive appropriate intervention at the earliest possible age after birth. The proposed regulation amends the responsibilities of hospitals with neonatal intensive care services and hospitals with newborn nurseries regarding newborn hearing screening, parent education and follow-up; modifies the newborn hearing screening protocols; amends the Virginia Department of Health responsibilities; and adds reporting requirements for persons who provide audiological services to children following discharge from the hospital after birth. These responsibilities are identified as beginning July 1, 1999, in hospitals with neonatal intensive care services and July 1, 2000, in all hospitals with newborn nurseries.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

There have been changes made since the proposed stage, but several of these are in the nature of "housecleaning," and are not particularly significant in terms of the substance of regulatory compliance. The changes include:

- ? Added a definition for “missed”. This definition is important as there are specific activities required of hospitals when infants are not screened prior to discharge.
- ? Omitted reference to specific false-positive and false-negative rates for screening methodology used by hospitals (12 VAC 5-80-80) and instead added wording stating a) that error rates shall not exceed those recommended by the American Academy of Pediatrics and, b) that hospitals examine and modify their screening methodology when maximum rates are exceeded. This wording establishes benchmarks without including specific rates that could become quickly outdated.
- ? Added wording regarding responsibilities of hospitals to 12 VAC 5-80-80, section A. and omitted 12 VAC 5-80-80, section C, 1-7 in order to simplify and reduce the length of the document. This sizeable change, in fact, has no appreciable effect. The law was written to phase in the screening program beginning July 1999. By July 1, 2000, all hospitals will be required to screen all infants. Therefore it is not necessary to include phases in the regulatory language. This change does not effect the responsibilities of hospitals. These regulations will be effective July 1, 2000.
- ? Added wording in 12 VAC 5-80-95 to clarify manner in which report should be sent to VDH.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On March 20, 2000, the State Health Commissioner, pursuant to authorization granted by Section 32.1-20 of the Code of Virginia, adopted a final regulation entitled “Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System” (12 VAC 5-80-10).

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the

specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

The existing Virginia Hearing Impairment Identification and Monitoring System was adopted in 1987 under the authority of Sections 32.1-64.1 and 32.1-64.2 of the Code of Virginia. Section 32.1-64.1 of the Code requires the State Health Commissioner to establish and maintain the Virginia Hearing Impairment Identification and Monitoring System and requires the State Board of Health to promulgate regulations for implementing this system. In addition, SB 591 (Acts of Assembly, 1998, Chapter 506) amended Section 32.1-64.1 to require the State Board of Health to "provide by regulation for the giving of hearing screening tests for all infants born in all hospitals," thereby requiring the proposed amendments.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulations, and the intended amendments, is to provide consistent guidance for the implementation and administration of a system designed to ensure that all infants born in Virginia with hearing loss are identified and receive appropriate intervention at the earliest possible age after birth. This system promotes early intervention that is crucial in preventing learning problems, social problems and costly remedial education activities for children with hearing loss. The amendments are needed to improve and hone the system and allow it to comport with the changes in the law.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The proposed regulations will specify the responsibilities of hospitals with neonatal intensive care services, hospitals with newborn nurseries, the Virginia Department of Health, and persons providing audiological services to children following discharge from the hospital after birth. These responsibilities are identified as beginning July 1, 1999, and July 1, 2000.

As required by SB 591, on July 1, 1999, hospitals with neonatal intensive care services will be responsible for: screening the hearing of all infants prior to discharge after birth; providing test results and other pertinent information to the parent and the child's primary medical care provider; and reporting those results and other data to the Virginia Department of Health. Hospitals with newborn nurseries and no neonatal intensive care services will be responsible for: identifying infants who are at-risk for hearing loss, as they are required to do under the current regulations; providing specific information and recommendations for follow-up to the parent and to the child's primary medical care provider; and reporting those infants who are at-risk to the Virginia Department of Health.

Hospitals that are not required to screen the hearing of all infants before July 1, 2000, but elect to do so will not be required to report infants who are at-risk for hearing loss. They will be given the same responsibilities as hospitals with neonatal intensive care services.

As of July 1, 2000, all hospitals with newborn nurseries and all hospitals with neonatal intensive care services will be responsible for: screening the hearing of all infants prior to discharge after birth; providing test results and other pertinent information to the child's parent and to the child's primary medical care provider; and reporting those results and other data to the Virginia Department of Health.

The Virginia Department of Health will be responsible for: collecting, maintaining and evaluating the data reported by hospitals, reports from audiological follow-up and information regarding intervention referrals in a database; providing follow-up for reported infants that includes letters and information to parents; supplying the reporting format, written information, as well as training and technical assistance on the program to hospitals; conducting a yearly review and evaluation of the program; and communicating performance data to hospitals on a yearly basis.

Persons who provide audiological services to a child once that child is discharged from the hospital after birth will be responsible for: providing screening or evaluation results to the parent and the child's primary medical care provider; sending a complete report to the Virginia Department of Health; advising the parent about and offering referral to early intervention and education programs; and providing the parent of any child found to have a hearing loss with information about hearing loss, such as communication and amplification options and resource agencies and services.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

The primary advantages of these amendments for the public are for parents, children who are born with hearing loss, hospitals and local education agencies. Parents will be informed of results of the hearing screening and need for further testing before their newborn is discharged from the hospital after birth. With the early identification of a child's hearing loss, parents can make informed choices regarding early intervention and education methods that will benefit both the child and the family. Recent research suggests that when hearing loss is identified by three months of age and intervention is offered before six months of age, children with hearing loss stay competitive with hearing peers in language and social skills. Further, the advantages remain regardless of the level of hearing loss, the child's cognitive skills or the method of intervention.

The amount of information that hospitals will be required to report to the Virginia Department of Health is reduced, as they are currently submitting a report form on every infant discharged after birth.

With the early identification of hearing loss, there will be a savings to local education agencies. Research suggests that costs of special education services are reduced when hearing loss is identified and intervention initiated within the first year of life.

There are no disadvantages to the public or to the Commonwealth.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

The Virginia Department of Health (VDH) received one written and no oral response during the notice of comment period. Susan C. Ward, Vice President and General Counsel, wrote on behalf of the members of the Virginia Hospital & Healthcare Association. The comments were:

- >omit references to specific numerical error rates for screening methodology used by hospitals
- >replace the wording with references to a standard, such as recommended by the American Academy of Pediatrics, in order to avoid the regulations becoming outdated as technology changes
- >supportive of the requirement that VDH conduct an annual evaluation of the program in order to assure continued cost-effectiveness and wise use of health care resources.

VDH concurs with the recommendation to change references to specific false-positive and false-negative rates. The wording of 12 VAC 5-80-80 A. 1. has been changed to remove reference to specific error rates, to refer to recommendations from the American Academy of Pediatrics and to further clarify the hospitals' responsibility to maintain error rates below maximum rates.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

Definitions, 12 VAC 5-80-10:

Addition of definitions for child, diagnostic audiological evaluation, discharge, hearing screening, infant, missed, parent, and primary medical care provider.

Modified and updated definitions for at-risk, neonatal intensive care services and risk factors for hearing loss.

Deletion of the definitions for follow-up, Phase One, Phase Two and registry.

12 VAC 5-80-80:

Deletion of the reference to phases of implementation. The proposed amendments now address the responsibilities of hospitals, the Virginia Department of Health, and persons providing audiological services to infants after discharge, beginning July 1, 1999 and July 1, 2000.

Deletion of responsibilities of hospitals with neonatal intensive care services to report to the Virginia Department of Health the presence or absence of risk factors for hearing impairment of each infant transferred or discharged from special care or intensive care services.

Addition of responsibilities of all hospitals with neonatal intensive care services to: test all newborns prior to discharge after birth; provide an alternative mechanism for screening to parents if an infant is missed; give specific written information to parents of each infant prior to discharge; give specific written information to primary medical care provider of each infant; report specific information on infants who do not pass the screening to the Virginia Department of Health; report monthly totals to the Virginia Department of Health on discharges, infants who pass, infants who fail and infants whose parents refuse the screening; and, report information regarding person responsible for the hospital's newborn hearing screening program, equipment calibration, test protocols and referral procedures to the Virginia Department of Health on a yearly basis.

Addition of responsibilities of all hospitals with newborn nurseries and no neonatal intensive care services, beginning July 1, 1999 and ending June 30, 2000, to: give specific written information to parents of each infant prior to discharge; and, give specific written information to the primary medical care provider of each infant.

Addition of responsibilities of all hospitals with newborn nurseries, beginning July 1, 2000, to: test all newborns prior to discharge after birth; provide an alternative mechanism for screening to parents if an infant is missed; give specific written information to parents of each infant prior to discharge; give specific written information to primary medical care provider of each infant; report specific information on infants who do not pass the screening to the Virginia Department of Health; report monthly totals to the Virginia Department of Health on discharges, infants who pass, infants who fail and infants whose parents refuse the screening; and, report information regarding person responsible for the hospital's newborn hearing screening program, equipment calibration, test protocols and referral procedures to the Virginia Department of Health on a yearly basis.

Addition of responsibilities of hospitals with newborn nurseries and no neonatal intensive care services that elect to screen hearing of all infants prior to discharge, beginning July 1, 1999, to: test all newborns prior to discharge after birth; provide an alternative mechanism for screening to parents if an infant is missed; give specific written information to parents of each infant prior to discharge; give specific written information to primary medical care provider of each infant; report specific information on infants who do not pass the screening to the Virginia Department of Health; report monthly totals to the Virginia Department of Health on discharges, infants who pass, infants who fail and infants whose parents refuse the screening; and, report information regarding person responsible for the hospital's newborn hearing screening program, equipment calibration, test protocols and referral procedures to the Virginia Department of Health on a yearly basis.

Deletion of a list of specific tests to be used for newborn hearing screening and instead giving a standard of false-positive and false-negative rates by which hospitals choose screening methodology.

12 VAC 5-80-90:

Deletion of the requirement that the Virginia Department of Health contact a child's primary medical care provider to report results of the hearing screening.

Changes in the requirements that the Virginia Department of Health send letters to parents by eliminating mention of specific time frames and focusing on information to be provided in various situations.

Additions to responsibilities of the Virginia Department of Health to include the collection, maintenance and evaluation of newborn hearing screening and follow-up data in a database and deletion of the term "registry".

Deletion of the requirement that the Virginia Department of Health report information on children who are diagnosed with hearing loss and on those who are lost to follow-up to the Virginia Department for the Deaf and Hard of Hearing and to the Virginia Department of Education.

Addition of the requirement that the Virginia Department of Health conduct a review and evaluation of the system and communicate performance data to hospitals on a yearly basis.

12 VAC 5-80-95

Addition of responsibilities of persons providing audiological services after discharge to: send a report to the Virginia Department of Health on any child whom they determine has failed to pass a hearing screening, was not successfully tested, or has a hearing loss; provide information to the parent regarding test results and early intervention or education programs; provide test results to the child's primary medical care provider; and, give resource information to parent of any child who is found to have hearing loss.

12 VAC 5-80-100, 110 and 120:

Deletion of these sections is consistent with deletion of reference to phases of implementation.

The consequences of these changes are that the responsibilities of hospitals, the Virginia Department of Health and persons who provide audiological services in the implementation and administration of the identification and monitoring system are clarified in light of the amendments to the Code.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

These proposed regulations will have no effect on the authority and rights of parents in the education, nurturing and supervision of their children.

These proposed regulations will have no effect on the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents.

These proposed regulations will have no effect on the marital commitment.

These proposed regulations will not directly increase or decrease disposable family income.