

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~PART I.~~

~~DEFINITIONS.~~

**12 VAC 5-80-10. Definitions.**

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"At risk" means considered to be in a ~~risk~~-status ~~for~~ with a significant probability of having or developing hearing ~~impairment-loss~~ as a result of the presence of one or more factors identified or manifested at birth.

"Child" means any person from birth to age 18 years of age.

"Commissioner" means the State Health Commissioner, ~~Virginia Department of Health~~ this duly designated officer, or agent.

"Diagnostic audiological evaluation" means those physiologic and behavioral procedures required to evaluate and diagnose hearing status.

"Discharge" means release from the hospital after birth to the care of the parent.

~~"Follow-up" means the process of communicating with the family and the primary care provider of all infants reported at risk and those who failed the hearing screening, regarding their status, until either a hearing impairment is diagnosed or normal hearing is documented.~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

"Hearing screening" means an objective physiological measure to be completed in order to determine the likelihood of hearing loss.

"Infant" means a child under the age of one year.

["Missed" means that an infant did not have a required hearing screening prior to discharge.]

"Neonatal ~~special care and~~ intensive care services" means those services provided ~~in a unit which is physically separated from the normal newborn nursery, equipped with monitoring and life support systems, staffed with personnel specifically qualified in providing specialized neonatal care, and is able to provide 12-24 nursing hours per infant per day, 24 hour in-house respiratory therapy, and full-time physician management by a board-eligible or board-certified neonatologist~~ by a hospital's newborn services that are designated as both specialty level and subspecialty level as defined in subdivision D 2 of 12 VAC 5-410-440.

"Phase One" means the first two years of implementation during which only those hospitals with neonatal special care and intensive care will participate.

"Phase Two" means that portion of the implementation, beginning two years after Phase One, during which those hospitals with newborn nurseries will participate. Phase One participating hospitals will continue under Phase One guidelines in Phase Two. Phase Two will remain in effect as the Hearing Impairment Identification and Monitoring System until changed.

"Registry" means a list of names and associated pertinent data regarding those children to be

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~followed by the Virginia Hearing Impairment Identification and Monitoring System.~~

“Parent” means (i) a biological or adoptive parent who has legal custody of a child, including either parent if custody is shared under a joint decree or agreement, (ii) a biological or adoptive parent with whom a child regularly resides, (iii) a person judicially appointed as a legal guardian of a child, or (iv) a person who exercises the rights and responsibilities of legal custody by delegation from a biological or adoptive parent, upon provisional adoption or otherwise by operation of law.

“Primary medical care provider” means the person to whom the infant will go for routine medical care following hospital discharge.

“Risk factors for hearing impairment factor” means those factors a factor known to place an infant at increased risk for being born with or developing a hearing impairment loss, including, but not limited to, any one of the following:

1. Family history of hereditary, childhood sensorineural hearing loss ~~or impairment of childhood onset in a blood relative;~~
2. ~~Congenital perinatal~~In utero infection (e.g., cytomegalovirus, rubella, herpes, toxoplasmosis, syphilis);
3. ~~Anatomic malformations involving the head, face, or neck (e.g., dysmorphic appearance)~~Craniofacial anomalies including ~~syndromal and nonsyndromal abnormalities, overt or submucous cleft palate, obvious morphologic~~those with morphological abnormalities of the

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~pinna, preauricular skin tags and ear canal;~~

4. Birthweight ~~of~~ less than 1500 grams;

5. Hyperbilirubinemia at a serum level exceeding indications for requiring exchange transfusion;

6. Bacterial meningitis, ~~especially Hemophilus influenzae;~~

7. ~~Severe asphyxia which may include infants with~~ Apgar scores of 0 to ~~three who fail to~~  
~~institute spontaneous respiration by 10 minutes and those with hypotonia persisting to two hours~~  
~~of age; and~~ four at one minute or 0 to six at five minutes;

8. Ototoxic ~~drug administration to an infant for greater than three days.~~ medications, including  
but not limited to the aminoglycosides, used in multiple courses or in combination with loop  
diuretics;

9. Mechanical ventilation lasting five days or longer;

10. Stigmata or other findings associated with a syndrome known to include a sensorineural  
hearing loss, a conductive hearing loss or both;

11. Neurofibromatosis Type II; and

12. Persistent pulmonary hypertension of the newborn (PPHN).

~~The presence of one or more of these factors places an infant at risk.~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~PART II.~~

~~GENERAL INFORMATION.~~

**12 VAC 5-80-20. Authority for regulations.**

Sections 32.1-64.1 and 32.1-64.2 of the Code of Virginia direct the commissioner to establish and maintain a system for the purpose of identifying and monitoring infants ~~who are at risk for~~with hearing ~~impairment-loss~~ and directs the Board of Health to promulgate the ~~rules and~~ regulations necessary for implementation of the system.

**12 VAC 5-80-30. Purpose of chapter.**

This chapter is designed to provide consistent guidelines for implementation of this system in order to assure that infants with hearing ~~impairment-loss~~ are identified at the earliest possible age and that they receive appropriate, early intervention.

**12 VAC 5-80-40. Administration and application of chapter.**

A. This chapter is promulgated to implement the system and amended as necessary by the State Board of Health. The State Health Commissioner or his designee is charged with its administration; and the Virginia Department of Health shall provide the staff necessary for its implementation.

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~12 VAC 5-80-50. Application of chapter.~~

~~B.~~ This chapter has general application throughout the Commonwealth.

~~PART III.~~

~~PHASE ONE.~~

**12 VAC 5-80-80. Participating hospitals' Responsibilities of hospitals.**

~~Those [A. Beginning on July 1, 1999, Hospitals with newborn nurseries and] hospitals with neonatal special care and intensive care services shall be responsible for:~~

- ~~1. Completing a Virginia Department of Health reporting form on each infant transferred or discharged from special care or intensive care services, identifying the presence or absence of risk factors for hearing impairment by both medical record and family history;~~
- ~~2. Giving an information packet containing a written description of the identification and monitoring system as well as written information about hearing and speech/language development to the parent/guardian of each infant transferred or discharged from special care or intensive care services;~~
- ~~3. Prior to transfer or discharge, screening the hearing of those infants identified to be at risk by one of the following:
  - ~~a. Early latency auditory evoked response for which the following protocols shall be observed:~~~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~(1) Test both ears;~~

~~(2) Use an air conduction audiometric transducer earphone or insert receiver;~~

~~(3) Both air conduction and bone conduction;~~

~~(4) Use a click stimulus;~~

~~(5) Use a stimulus intensity between 30 and 60db nHL (re: perceptual click threshold for normal hearing adults, obtained with specific equipment used for the test);~~

~~(6) Maintain a hard copy to attach to reporting form; and~~

~~(7) If the screening is not completed because of early transfer, equipment failure, time restraints, or patient condition the total test shall be regarded as a failure and reported as such on the form.~~

~~b. An automated motion sensitive unit for which the following protocols shall be observed:~~

~~(1) All manufacturer recommended guidelines shall be followed;~~

~~(2) If the screening is not completed because of early transfer, equipment failure, time restraints, or patient condition the total test shall be regarded as a failure and reported as such on the form;~~

~~4. Sending the reporting form, with attachments if indicated, to the Virginia Department of Health within one week of transfer or discharge from the unit;~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~5. Reporting to the Virginia Department of Health, on a monthly basis, statistics regarding the number of admissions and live transfers or discharges, the total number of infants at risk as well as the number of at risk infants who passed and the total number who failed the hearing screening; and~~

1. Prior to discharge after birth, but no later than three months of age, screen the hearing, in both ears, of all infants using objective physiologic measures. The methodology used for hearing screening shall have a false-positive rate [of less than or equal to 3.0% and a false negative rate of 0 and false-negative rate no greater than those recommended by the American Academy of Pediatrics in Newborn and Infant Hearing Loss: Detection and Intervention, February 1999. If the error rates exceed these recommendations, the hospital shall examine and modify its hearing screening methodology to reduce its error rates below these maximum rates];

2. If an infant is missed, inform the parent, prior to discharge, of the need for hearing screening and provide a mechanism by which screening can occur at no additional cost to the family;

3. Prior to discharge, give written information to the parent of each infant that includes purposes and benefits of newborn hearing screening, indicators of hearing loss, procedures used for hearing screening, results of the hearing screening, the recommendations for further testing, and where the testing can be obtained;

4. Give written information to the infant's primary medical care provider that includes procedures used for hearing screening, the limitations of screening procedures, the results of the



REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

hearing screening, and the recommendations for further testing;

5. Within one week of discharge complete the Virginia Department of Health report, as required by the board pursuant to § 32.1-64.1 F of the Code of Virginia and in a manner devised by the department, which may be electronic, on each infant who does not pass the hearing screening and send it to the Virginia Department of Health;

6. On a monthly basis, send to the Virginia Department of Health a report of the total number of discharges the total number of infants who passed the newborn hearing screening the total number who failed and, the total number not tested due to parents' exercise of their rights under § 32.1-64.1 H of the Code of Virginia; and

~~6. Reporting~~7. Report to the Virginia Department of Health, on a yearly basis, the ~~individual(s) responsible for the hearing screening, equipment used, date of last calibration/maintenance, stimuli used, pass/fail criteria, test procedures used by the newborn hearing screening program, the name of the program director, the name of the advising audiologist, equipment calibration records, screening protocols, and referral procedures.~~

~~[B. Beginning on July 1, 1999 and ending June 30, 2000, hospitals with newborn nurseries and no neonatal intensive care services shall:~~

1. Prior to discharge after birth, identify infants at risk for hearing loss;

2. Give written information to the parent of each infant, prior to discharge, that includes the

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~purposes and benefits of newborn hearing screening, what to do if the parent suspects hearing loss, the infant's risk factor or factors for hearing loss if present, the recommendations for hearing screening, and where the screening can be obtained;~~

~~3. Complete the Virginia Department of Health report on each infant identified at risk for hearing loss in a manner devised by the department, which may be electronic;~~

~~4. Send the report to the Virginia Department of Health within one week of discharge;~~

~~5. On a monthly basis, send to the Virginia Department of Health a report of the total number of discharges and the total number of infants identified at risk for hearing loss; and~~

~~6. For infants identified at risk for hearing loss, give written information to the infant's primary medical care provider that includes the identified risk factor or factors for hearing loss, the recommendations for hearing screening, and where the screening can be obtained.]~~

~~[C. Beginning on July 1, 1999, hospitals with newborn nurseries and no neonatal intensive care services that elect to screen the hearing of all infants prior to discharge after birth shall:~~

~~1. Prior to discharge after birth screen the hearing, in both ears, of all infants using objective physiologic measures. The methodology used for hearing screening shall have a false positive rate of less than or equal to 3.0% and a false negative rate of 0;~~

~~2. If an infant is missed, inform the parent, prior to discharge, of the need for hearing screening and provide a mechanism by which screening can occur at no additional cost to the family;~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

- ~~3. Prior to discharge, give written information to the parent of each infant that includes purposes and benefits of newborn hearing screening, indicators of hearing loss, procedures used for hearing screening, results of the hearing screening, the recommendations for further testing, and where the testing can be obtained;~~
- ~~4. Give written information to the infant's primary medical care provider that includes procedures used for hearing screening, the limitations of screening procedures, the results of the hearing screening, and the recommendations for further testing;~~
- ~~5. Within one week of discharge, complete the Virginia Department of Health report, as required by § 32.1-64.1 F of the Code of Virginia and in a manner devised by the department, which may be electronic, on each infant who does not pass the hearing screening and send it to the Virginia Department of Health;~~
- ~~6. On a monthly basis, send to the Virginia Department of Health a report of the total number of discharges, the total number of infants who passed the newborn hearing screening, the total number who failed, and the total number not tested due to parents' exercise of their rights under § 32.1-64.1 H; and~~
- ~~7. Report to the Virginia Department of Health, on a yearly basis, the test procedures used by the newborn hearing screening program, the name of the program director, the name of the advising audiologist, equipment calibration records, screening protocols, and referral procedures.]~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~[D. Beginning on July 1, 2000, hospitals with neonatal intensive care services and hospitals with newborn nurseries shall be responsible for activities required by subsection A of this section.]~~

12 VAC 5-80-90. **Responsibilities of the Virginia Department of Health responsibilities.**

The Virginia Department of Health shall ~~be responsible for~~:

1. ~~Collecting~~ Collect, maintain and evaluate hospital newborn hearing screening data from reporting forms received and entering those data on a computer registry in a database;
2. ~~Providing follow-up on~~ Provide follow-up for all infants reported ~~at risk and those who failed the hearing screening including but not limited to:~~ Follow-up includes, but is not limited to:
  - a. ~~Communicating with the primary medical care provider (if stated) by mail two or four months after receipt of the reporting form on those who passed and those who failed the screening, to explain the program and to advise of the child's status;~~
  - ba. Communicating with the family-parent by mail, ~~four to six months after receipt of the reporting form on~~ for those infants who failed the hearing screening ~~(intensive care units- Phases One and Two) or,~~ those who had one or more risk factors identified ~~(newborn nurseries-Phase Two),~~ and were not screened prior to discharge, those who were not screened, and those who are at risk for progressive hearing loss in order to advise of the need for ~~a hearing evaluation~~ audiological services as well as to provide information on locating an approved center that provides diagnostic audiological services or a licensed

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

audiologist;

~~eb.~~ Receiving results of both the hearing-audiological evaluations, ~~reviewing the reports for recommendations and the intervention referrals~~, and adding the information to the ~~computer registrydatabase~~; and

~~d.~~ Mailing a reminder to the family if no information is received on the child within two months of the initial mailing; and,

~~ec.~~ Communicating with the family-parent by mail ~~after the results of the hearing evaluation are reported, confirming the results, and, if for any child found to have~~ a hearing loss ~~is diagnosed, providing the family within order to provide~~ information about hearing loss and appropriate ~~referral sources~~ resources.

~~3.~~ Maintaining ~~both a registry of those children diagnosed with hearing impairment and a list of those concerning whom no response has been received on follow-up;~~

~~4.~~ Reporting appropriate information from the registry and the list to the Virginia Department for the Deaf and Hard of Hearing and the Virginia Department of Education;

~~5.~~ Supplying ~~3.~~ Supply the reporting ~~forms-format~~ and written information ~~packets to the participating hospitals; and~~

~~6.~~ Providing ~~4.~~ Provide training and technical assistance on this program to ~~the participating hospitals;~~ and

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

5. Conduct a review and evaluation of the Virginia Hearing Impairment Identification and Monitoring System, including but not limited to the false-positive rate, false-negative rate, referral rate, follow-up rate, referral mechanisms, and effectiveness of tracking, and communicating critical performance data to hospitals on a yearly basis.

**12 VAC 5-80-95. Responsibilities of persons providing audiological services after discharge.**

Persons [who provide audiological services and] who determine that a child has failed to pass a hearing screening, was not successfully tested, or has a hearing loss shall:

1. Provide the screening or evaluation results to the parent and to the child's primary medical care provider;
2. Send a Virginia Department of Health report including test results, diagnosis, and recommendations to the Virginia Department of Health[, in a manner devised by the department, which may be electronic,] within two weeks of the visit;
3. Advise the parent about and offer referral to local early intervention or education programs; and
4. Give resource information to the parent of any child who is found to have a hearing loss, including but not limited to the degrees and effects of hearing loss, communication options, amplification options, the importance of medical follow up, and agencies and organizations that provide services to children with hearing loss and their families.

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

~~PART IV.~~

~~PHASE TWO.~~

**12 VAC 5-80-100. ~~Phase One participating hospitals' responsibilities. (Repealed.)~~**

~~Those hospitals with neonatal special care and intensive care services shall maintain all procedures and protocols required by 12 VAC 5-80-80.~~

**12 VAC 5-80-110. ~~Other participating hospitals' responsibilities. (Repealed.)~~**

~~Those hospitals with newborn nurseries shall be responsible for:~~

- ~~1. Completing a reporting form on each infant transferred or discharged from the newborn nursery, identifying the presence or absence of risk factors for hearing impairment by both medical record and family history;~~
- ~~2. Giving an information packet containing a written description of the identification and monitoring system as well as written information about hearing and speech/language development to the parent/guardian of each infant transferred or discharged from the newborn nursery;~~
- ~~3. Sending the reporting form to the Virginia Department of Health within a week of transfer or discharge from the unit; and~~
- ~~4. Reporting to the Virginia Department of Health, on a monthly basis, statistics regarding the number of admissions and live transfers or discharges, and the total number of infants at risk.~~

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

**12 VAC 5-80-120. ~~Virginia Department of Health responsibilities. (Repealed.)~~**

~~The Virginia Department of Health shall be responsible for:~~

- ~~1. Collecting data from reporting forms and entering those data on a computer registry;~~
- ~~2. Providing follow up on all infants reported at risk and those who failed the hearing screening (Phase One) and on all infants reported at risk (Phase Two) including but not limited to:
  - ~~a. Communicating with the primary medical care provider (if stated) by mail two to four months after receipt of the reporting form on those who passed and those who failed the screening, to explain the program and to advise of the child's status;~~
  - ~~b. Communicating with the family by mail, four to six months after receipt of the reporting form on those who failed the hearing screening (intensive care units—Phases One and Two) or those who had one or more risk factors identified (newborn nurseries—Phase Two), in order to advise of the need for a hearing evaluation as well as to provide information on locating a licensed audiologist;~~
  - ~~c. Receiving results of the hearing evaluations, reviewing the reports for recommendations, and adding the information to the computer registry;~~
  - ~~d. Mailing a reminder to the family if no information is received on the child within two months of the initial mailing; and~~
  - ~~e. Communicating with the family by mail after the results of the hearing evaluation are~~~~



REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

- ~~reported, confirming the results, and, if a hearing loss is diagnosed, providing the family with information about hearing loss and appropriate referral sources.~~
- ~~3. Maintaining both a registry of those children diagnosed with hearing impairment and a list of those concerning whom no response has been received on follow up;~~
  - ~~4. Reporting appropriate information from the registry and the list to the Virginia Department for the Deaf and Hard of Hearing and the Virginia Department of Education;~~
  - ~~5. Supplying the reporting forms and information packets to the participating hospitals; and~~
  - ~~6. Providing training and technical assistance on this program to the participating hospitals.~~

I certify that this regulation is full, true and correctly dated.

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E. Anne Peterson, M.D., M.P.H.

State Health Commissioner

Virginia Department of Health

Date: \_\_\_\_\_

FORM

REGULATIONS FOR ADMINISTRATION OF THE  
VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND  
MONITORING SYSTEM.

**~~Reporting Form, CSS 312 (eff. 6/90).~~**

**Report of Follow-Up (eff. 7/99).**