

Virginia Administrative Code

Chapter 80. Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System

12VAC5-80-10. Definitions.

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

"ABR" means an objective, electrophysiologic measurement of the brainstem's response to acoustic stimulation of the ear.

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

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

"Audiologist" means an audiologist as defined in § [54.1-2600](#) of the Code of Virginia.

"Board" means the State Board of Health.

"CDC" means the Centers for Disease Control and Prevention.

"CMV" means cytomegalovirus infection.

"Chief medical officer" means the highest position of authority on the medical staff of the hospital or other birthing place or center as defined in the organization's bylaws or applicable governance structure.

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

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

"Congenital cytomegalovirus" or "cCMV" means when an infant is born with cytomegalovirus infection.

"Department" means the Virginia Department of Health.

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

"EHDI" means early hearing detection and intervention.

"Failed newborn hearing screening" means the final newborn hearing screening that resulted in a refer or fail in one or both ears prior to discharge from hospital or other birthing place or center.

"Family-to-family support" means the provision of information and peer support among families having experience with family members having hearing loss.

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

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

"Hospital" means any facility as defined in § [32.1-123](#) of the Code of Virginia.

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

"Neonatal intensive care services" means those services provided by a hospital's newborn services that are designated as either specialty level or subspecialty level as defined in [12VAC5-410-443](#) B 3 and B 4 of the Regulations for the Licensure of Hospitals in Virginia.

"Newborn" means an infant who is 28 days old or less.

"Newborn services" means care for infants in one or more of the service levels designated in [12VAC5-410-443](#) B of the Regulations for the Licensure of Hospitals in Virginia.

"OAE" means an objective, physiologic response from the cochlea. This term may include transient evoked otoacoustic emissions and distortion product otoacoustic emissions.

"Other birthing place or center" means a place or facility outside of a hospital that provides maternity services.

"Parent" means a biological parent, adoptive parent, or a stepparent.

"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 three who are eligible for services under Part C of the Individuals with Disabilities Education Act (20 USC §§ 1431-1444) and Virginia law.

"Primary health care provider" means the person to whom the infant will go for primary health care following hospital discharge.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Risk indicator" means a factor known to place an infant at increased risk for being born with or developing a hearing loss.

"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 (42 USC 701 et seq.) of the Social Security Act).

"Virginia Hearing Impairment Identification and Monitoring System" means a coordinated and comprehensive group of services including education; screening; follow-up; diagnosis; appropriate early intervention including treatment, therapy, training, and education; and program evaluation managed by the department's Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from VR355-12-01 § 1.1, eff. April 3, 1987; amended, Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; [Volume 30, Issue 5](#), eff. December 6, 2013; [Volume 36, Issue 6](#), eff. September 1, 2020.

12VAC5-80-20. (Repealed.)

Historical Notes

Derived from VR355-12-01 § 2.1, eff. April 3, 1987; amended, Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; repealed, Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-30. (Repealed.)

Historical Notes

Derived from VR355-12-01 § 2.2, eff. April 3, 1987; amended, Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; repealed, Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-40. (Repealed.)

Historical Notes

Derived from VR355-12-01 § 2.3, eff. April 3, 1987; amended, Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; repealed, Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-50. (Repealed.)

Historical Notes

Derived from VR355-12-01 § 2.4, eff. April 3, 1987; repealed, Virginia Register Volume 16, Issue 16, eff. July 1, 2000.

12VAC5-80-60. [Reserved]. (Reserved)

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Reserved as VR335-12-01 § 2.5, Virginia Register Volume 3, Issue 11, eff. April 3, 1987.

12VAC5-80-70. [Reserved]. (Reserved)

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Reserved as VR335-12-01 § 2.6, Virginia Register Volume 3, Issue 11, eff. April 3, 1987.

12VAC5-80-75. Risk indicators associated with hearing loss.

A. The Virginia EHDI program shall maintain a list of specific risk indicators consistent with, but not necessarily identical to, the most recent recommendations from the Joint Committee on Infant Hearing to identify infants at risk of hearing loss.

B. The Virginia EHDI Program Advisory Group shall provide guidance with the development and maintenance of the list of specific risk indicators.

C. The list of specific risk indicators shall be maintained in a guidance document, which shall be reviewed at a minimum biennially. The list of specific risk indicators may be changed or amended more frequently as needed to reflect changes in standards of care or updates to Joint Committee on Infant Hearing recommendations.

D. The guidance document shall contain specific assessment and reporting criteria for the following general categories of risk indicators associated with hearing loss:

1. Family history of permanent childhood hearing loss;
2. Caregiver concerns;
3. In utero and post natal infections;
4. Neonatal intensive care services;
5. Head trauma and craniofacial anomalies;
6. Syndromes, neurodegenerative disorders, and sensory motor neuropathies;
7. Stigmata or other physical findings associated with certain syndromes;
8. Ototoxic medications, treatments, and chemotherapies; and
9. Other indicators as needed.

E. All infants born in Virginia hospitals shall be assessed prior to hospital discharge after birth for risk indicators associated with hearing loss as outlined in this chapter and the corresponding guidance document.

Statutory Authority

§§ [32.1-12](#) and [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-80. Responsibilities of the chief medical officer of hospitals.

The chief medical officer of a hospital providing newborn services or his designee shall:

1. Cause all infants to be given a hearing screening test prior to discharge after birth as appropriate for the level of newborn services provided as defined in [12VAC5-410-443](#) B of the Regulations for the Licensure of Hospitals in Virginia.
 - a. Infants in general or intermediate newborn services shall have both ears screened at the same time for hearing using either ABR or OAE testing prior to discharge after birth, but no later than one month of age.
 - b. Infants in neonatal intensive care services who receive this level of newborn service care for more than five days shall have both ears screened at the same time using ABR testing prior to discharge after birth or transfer to a lower level of newborn services. Infants should receive newborn hearing screening as early as development or medical stability will permit such screening. The hearing screening performed for infants requiring neonatal

intensive care services for more than five days using ABR testing shall be reported as the initial hearing screen regardless of whether the infant is transferred to another lower level of newborn services within the same facility or to another facility.

c. Infants in neonatal intensive care services who receive this level of newborn service care for five days or less shall have both ears screened at the same time for hearing using either ABR or OAE testing prior to discharge after birth, but no later than one month of age.

2. Identify all infants who fail hearing screening in one or both ears.

a. Infants who fail hearing screening in one or both ears using ABR testing shall not be rescreened using OAE testing. These infants shall be referred for an audiological evaluation.

b. Infants who fail hearing screening in one or both ears using OAE testing may be rescreened using ABR testing. If the infant fails subsequent ABR testing in one or both ears, the infant shall be referred for an audiological evaluation.

3. Identify all infants not receiving an appropriate hearing screening test.

a. For infants who did not receive a hearing screening test due to transfer to another facility, written notification shall be made upon transfer to the health care provider in charge of the infant's care that testing was not completed. The hospital discharging the infant after birth is responsible for conducting an appropriate hearing screening test, except for infants who have been transferred to a lower level of newborn service care from another facility providing neonatal intensive care services to that infant for more than five days.

b. For infants who did not receive a hearing screening test prior to discharge after birth, 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.

c. For infants who did not receive screening due to refusal by the parent or guardian because the screening conflicts with religious convictions, documentation shall be made in the medical record.

4. Cause all infants to be assessed for risk indicators associated with hearing loss prior to discharge after birth as defined in [12VAC5-80-75](#). For infants who are found to have one or more risk indicators associated with hearing loss, inform the parent of the need for a diagnostic audiological assessment by 24 months of age.

5. Provide written information to the parent or guardian of each infant that includes purposes and benefits of newborn hearing screening, risk indicators of hearing loss, procedures used for hearing screening, results of the hearing screening, recommendations for further testing, where further testing can be obtained, and contact information for the Virginia EHDI program;

6. Notify the infant's primary health care provider within one week of discharge after birth of (i) the status of the hearing screening including if the infant was not tested, (ii) procedures used for hearing screening, (iii) identified risk indicators associated with hearing loss as defined in [12VAC5-80-75](#), (iv) the results of the hearing screening, and (v) the recommendations for further testing in writing or through an electronically secure method that meets all applicable state and federal privacy laws;

7. Provide the department with information 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 the hearing screening and risk indicator status of infants born at their hospital. This information shall be provided within one week of discharge after birth unless otherwise stated and includes:

- a. Demographic information on infants including name, date of birth, race, ethnicity, and gender;
 - b. Primary contact information including address, telephone number, and relationship type;
 - c. Primary health care provider name, address, and telephone number;
 - d. Risk indicators identified as defined in [12VAC5-80-75](#);
 - e. Special circumstances regarding infants as needed by the department to provide follow-up;
 - f. Screening methodology used, date screened, and both right and left ear results;
 - g. Screening status for pass with risk indicator, fail, unable to test, refusal, and inconclusive results;
 - h. Status of infants not screened prior to discharge that includes infants who were transferred to other facilities and parents who refused screening;
 - i. Hearing rescreening information including date, type of screening methodology used, results in both left and right ears, and further recommendations within two weeks after the hospital rescreening date;
 - j. Confirmatory data on the status of all infants born in the hospital facility. The department shall receive confirmation that infants not reported as passed with risk, failed, transferred, refused testing, not tested prior to discharge, expired, or other final disposition have had a negative assessment for risk indicators and that physiological hearing screening was conducted with passing results in both ears within 30 days after birth; and
 - k. cCMV screening results if performed as defined in [12VAC5-80-150](#).
8. Report to the department on a yearly basis hospital specific information including (i) the test procedures used by the newborn hearing screening program, (ii) the name of the program director, (iii) the name of the advising audiologist, (iv) equipment calibration records, (v) screening protocols, and (vi) referral procedures;
9. Develop written policies and procedures to implement hearing screening in the chief medical officer's facility in accordance with [12VAC5-80](#) including separate protocols for specialty and subspecialty newborn services; and
10. Ensure that training of staff on newborn hearing screening test procedures, follow-up, and reporting requirements is implemented in a way that an adequately trained and knowledgeable workforce is maintained to conduct hearing screening program requirements.

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from VR355-12-01 § 3.1, eff. April 3, 1987; amended, Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; [Volume 30, Issue 5](#), eff. December 6, 2013; [Volume 36, Issue 6](#), eff. September 1, 2020.

12VAC5-80-85. Responsibilities of other birthing places or centers.

The chief medical officer of other birthing places or centers or his designee or the attending practitioner shall:

1. Cause all infants to be assessed for risk indicators associated with hearing loss as defined in [12VAC5-80-75](#);

2. Provide written information to the parent or guardian of each infant that includes purposes and benefits of newborn hearing screening, risk indicators for hearing loss, procedures used for hearing screening, providers where hearing screening can be obtained, and contact information for the Virginia EHDI program;
3. Notify the infant's primary health care provider within one week after birth of (i) the status of the hearing screening including if the infant was not tested, (ii) identified risk indicators associated with hearing loss as defined in [12VAC5-80-75](#), and (iii) the recommendations for testing in writing or through an electronically secure method that meets all applicable state and federal privacy laws; and
4. Provide the department with information 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 on the hearing screening and risk indicator status of infants born at the other birthing place or center. This information shall be provided within one week after birth unless otherwise stated and includes:
 - a. Demographic information on infants including name, date of birth, race, ethnicity, and gender;
 - b. Primary contact information including address, telephone number, and relationship type;
 - c. Primary health care provider name, address, and telephone number;
 - d. Risk indicators identified as defined in [12VAC5-80-75](#);
 - e. Special circumstances regarding infants as needed by the department to provide follow-up;
 - f. Screening methodology used, date screened, and both right and left ear results if applicable;
 - g. Screening status for pass with risk indicator, failures, unable to test, refusals, and inconclusive results if applicable;
 - h. Status of infants not screened that includes infants who were transferred to other facilities and parents who refused screening;
 - i. Hearing rescreening information including date, type of screening methodology used, results in both left and right ears, and further recommendations within two weeks after the rescreening date if applicable;
 - j. Confirmatory data on the status of all infants born in the birthing place or center. The department shall receive confirmation that infants not reported with a screening status have had a negative assessment for risk indicators and have been referred for a hearing screening; and
 - k. cCMV screening results if performed as defined in [12VAC5-80-150](#).

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013; amended, Virginia Register [Volume 36, Issue 6](#), eff. September 1, 2020.

12VAC5-80-90. Scope and content of Virginia Early Hearing Detection and Intervention Program.

A. The mission of the Virginia EHDI program is to identify hearing loss at the earliest possible age and to assure that appropriate early intervention services are received to reduce the risk of developmental delays.

B. The scope of the Virginia EHDI program shall include the following:

1. 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 laws. This electronic system may include existing demographic data captured by other department population-based systems and the commissioner may authorize hospitals required to report to view existing data to facilitate accurate reporting and increase the department's ability to conduct successful follow-up and identify infants at risk for hearing loss pursuant to § [32.1-127.1:04](#) of the Code of Virginia;

2. Collect, maintain and evaluate hospital newborn hearing screening data in a database including initial screening, risk indicators, rescreening, and diagnostic audiological evaluations, in a secure data management information system;

3. Provide follow-up of results of screening for cCMV and for infants whose results indicate screening failure, identified risk indicators, inconclusive or missing results, or other circumstances requiring follow up. Follow-up includes:

a. Communicating with the parent or guardian for those infants who failed the hearing screening, those who were not screened, and those who are at risk for progressive hearing loss in order to advise of the need for audiological services as well as to provide information on locating an approved center that provides diagnostic audiological services or a licensed audiologist;

b. Communicating with audiologists, hospitals, other birthing places or centers, primary health care providers, and others as needed to ascertain follow up status and receive results of audiological evaluations and intervention referrals, including Part C services;

c. Communicating with the parent or guardian for any child found to have a hearing loss in order to provide information about hearing loss and appropriate resources including family-to-family support and referral to the Part C program; and

d. Communicating to the Part C program regarding any child found to have hearing loss in order to facilitate early intervention services;

4. Provide training and technical assistance to hospitals and other birthing places or centers;

5. Develop and disseminate protocols for hospitals, audiologists, and primary health care providers;

6. Develop and disseminate parent education materials;

7. Maintain an approved list of audiological providers meeting program criteria;

8. Evaluate Virginia Hearing Impairment Identification and Monitoring System components, including screening, referral and follow-up rates, referral mechanisms and tracking indicators;

9. Communicate critical performance data to hospitals and other birthing places or centers on a quarterly basis; and

10. Collect and report data required annually for Title V national performance measures, CDC national EHDI goals, and other funding sources as needed that measure how well the system functions.

C. Title V national performance measures and the CDC national EHDI goals, as required by the Government Performance and Results Act (GPRA; Pub. L. 103-62), shall be used to establish newborn hearing screening goals. The goals are:

1. All infants who are born in Virginia hospitals shall be screened for hearing loss prior to hospital discharge. Residents of Virginia who do not pass screening, do not receive screening, or who have an identified risk indicator shall receive appropriate evaluation, diagnostic, follow-up, and early intervention services. Infants who are not residents of Virginia and who do not pass screening, do not receive screening, or who have an identified risk indicator will be referred to their state of residence for appropriate evaluation, diagnostic, follow-up, and early intervention services;
2. All infants born in Virginia shall receive a hearing screening prior to one month of age;
3. Infants who are referred shall receive a diagnostic audiological evaluation before three months of age; and
4. All infants identified with a hearing loss shall receive appropriate early intervention services before six months of age.

The goals shall change as needed to be consistent with federally required performance measures.

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from VR355-12-01 § 3.2, eff. April 3, 1987; amended, Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; [Volume 30, Issue 5](#), eff. December 6, 2013; [Volume 36, Issue 6](#), eff. September 1, 2020.

12VAC5-80-95. 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, either in writing or in an electronically secure manner, to the parent or guardian and to the child's primary health care provider;
2. Send a report including screening methodology, test results, diagnosis, and recommendations to the department, in a manner devised by the department, which may be electronic, within two weeks of the visit;
3. Provide information to the parent or guardian about and offer referral for the child to local early intervention or education programs, including the Part C program; and
4. Give resource information to the parent or guardian 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, including the Part C program, that provide services to children with hearing loss and their families.

Statutory Authority

§§ [32.1-12](#) and [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from Virginia Register [Volume 16, Issue 16](#), eff. July 1, 2000; amended, Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-100. (Repealed.)

Historical Notes

Derived from VR355-12-01 §§ 4.1 to 4.3, eff. April 3, 1987; repealed, Virginia Register Volume 16, Issue 16, eff. July 1, 2000.

12VAC5-80-130. Reporting Responsibilities to primary health care providers.

- 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](#).
- B. The chief medical officer of another 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 health care provider as defined in [12VAC5-80-85](#).
- 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](#).
- D. Persons providing audiological services shall report hearing screening and audiological evaluation results to the infant's primary health care provider as defined in [12VAC5-80-95](#).
- 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.

Statutory Authority

§§ [32.1-12](#) and [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-140. Relationship to the Part C system.

The department is a participating agency in the state Part C system as defined in § [2.2-5300](#) of the Code of Virginia. The Virginia Hearing Impairment Identification and Monitoring System is a component of this statewide system to identify infants and children who may be eligible for Part C early intervention services. The Virginia EHDI program shall develop policies and operating procedures that are consistent with the Individuals with Disabilities Education Act (20 USC §§ 1431-1444); 34 CFR Part 303; § [2.2-5303](#) of the Code of Virginia; and the most recent state interagency agreement.

Statutory Authority

§§ [32.1-12](#) and [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from Virginia Register [Volume 30, Issue 5](#), eff. December 6, 2013.

12VAC5-80-150. Screening for congenital cytomegalovirus.

- A. If a newborn has a failed newborn hearing screening, the discharging hospital or other birthing center shall collect and submit a sample for cCMV testing prior to discharge. If the newborn is under the care of a specialty

level or subspecialty level nursery, the cCMV screening shall be performed in accordance with the protocols.

To ensure full implementation of cCMV testing, the department may establish contracts with a designated testing laboratory to ensure testing, and the established contracts shall comply with all federal assurances.

B. The department shall develop or approve and publish informational materials for the general public, healthcare providers, women who may become pregnant, expectant parents, and parents of infants regarding:

1. The incidence of CMV;
2. The transmission and prevention of CMV to pregnant women and women who may become pregnant;
3. Birth defects caused by cCMV;
4. Methods of diagnosing cCMV;
5. Potential benefits of screening for and diagnosis of cCMV;
6. Available methods of treating cCMV; and
7. Resources available for families of children born with cCMV.

C. Healthcare providers providing prenatal care are encouraged to provide patients with information about cCMV.

D. Birthing facilities providing care to an infant who was screened for cCMV are required to report to the Department of Health identification and monitoring system within one week of discharge.

Statutory Authority

§ [32.1-64.1](#) of the Code of Virginia.

Historical Notes

Derived from Virginia Register [Volume 36, Issue 6](#), eff. September 1, 2020.

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