



WEST VIRGINIA SECRETARY OF STATE

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ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Health

RULE TYPE: Legislative

TITLE-SERIES: 64-91

RULE NAME: NEWBORN SCREENING SYSTEM

CITE AUTHORITY: W. Va. Code §16-1-4, §16-22-3, and §16-22A-3, §16-44-1, and §16-44-2.

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Virginia M Payne -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

64CSR91

TITLE 64

LEGISLATIVE RULE

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

SERIES 91

NEWBORN SCREENING SYSTEM

§64-91-1. General.

1.1. Scope. -- This rule directs the Bureau for Public Health, in cooperation with other state agencies and attending physicians, to provide medical, dietary, and related assistance to children determined to be afflicted with any disease specified in W. Va. Code §16-22-3, and certain other diseases specified by the Bureau for Public Health, including a cost-effective screening protocol, and reporting and referral requirements, for the screening of newborn infants for hearing impairments. The rule provides for a means of payment for the required screenings, and any further referral or treatment services considered necessary by the Bureau for Public Health to implement the provisions of the statute on newborn screening. ~~This rule should be read in conjunction with W. Va. Code §16-22-3 and §16-22A-1 et seq. and the rule on Newborn Hearing Screening, 64CSR24. The W. Va. Code is available in public libraries and on the Legislature's website, <http://wvlegislature.gov/>~~

1.2. Authority. -- W. Va. Code §16-1-4, §16-22-3, ~~and §16-22A-3, §16-44-1, and §16-44-2.~~

1.3. Filing Date. -- ~~May 1, 2024.~~

1.4. Effective Date. -- ~~May 1, 2024.~~

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect on August 1, ~~2029~~ 2032.

1.6. The fee for a newborn screening system kit established in section 6 of this rule supersedes the amount in the Bureau for Public Health's "Fees for Services" rule, 64CSR51, Appendix A.

§64-91-2. Application and Enforcement.

2.1. Application. -- This rule applies to all infants born in West Virginia and to the hospital or birthing facility in which an infant is born, the parents or legal guardians, the physician attending a newborn child, or any person attending a newborn child not under the care of a physician and the director of the state laboratory performing mandatory newborn screening tests.

2.2. Enforcement. -- This rule is enforced by the Commissioner of the Bureau for Public Health.

§64-91-3. Definitions.

3.1. Auditory Brainstem Response (ABR). - Newborn hearing screening equipment that provides information about the auditory pathway up to the brainstem.

~~3.1.~~ 3.2. Birthing Facility. -- Any licensed medical facility, hospital, or health care facility that offers birthing services.

~~3.2.~~ 3.3. Bureau. -- The Bureau for Public Health in the West Virginia Department of Health and Human Resources. The bureau is the agency responsible for administering the Newborn Screening System.

~~3.3.~~ 3.4. Commissioner -- The Commissioner of the Bureau for Public Health or his or her designee.

3.5. Congenital Heart Defects (CHD) - Structural abnormalities of the heart that are present at birth. Some critical congenital heart defects can cause severe and life-threatening symptoms which require intervention within the first days of life.

3.6. DRG (Diagnosis Related Group). -- The payment code incorporating a group of inpatient hospital charges or costs.

~~3.4.~~ 3.7. Newborn Screening. -- The statutorily mandated screening of newborns by hospitals, birthing facilities, physicians, or others.

~~3.5.~~ 3.8. Newborn Screening System. -- The coordinated effort by the bureau and West Virginia physicians who deliver and care for children, to ensure that each newborn child is screened for ~~metabolic~~ certain disorders before discharge from birthing facilities. Infants identified with a disorder must receive continuing care and treatment provided through a collaborative effort between the primary physician, medical specialist, the bureau, and community support services.

~~3.6.~~ 3.9. Office of Maternal, Child and Family Health. -- The office in the bureau that provides coordination and leadership in working with public and private community partners and families to assure the availability and use of health care for all mothers, infants and children including children with special health care needs.

3.10. OAE (Otoacoustic Emissions Test). -- A screening test that provides data about hearing distortion to the cochlea.

~~3.7.~~ 3.11. Primary Care Provider. -- The physician, physician's assistant, nurse, nurse practitioner, or other licensed medical professional responsible for the infant's health services during and/or after discharge from the birthing facility.

3.12. Pulse Oximetry Testing - A noninvasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen.

~~3.8.~~ 3.13. State Laboratory. -- The Department of Health and Human Resources, Bureau for Public Health's Office of Laboratory Services, that supplies newborn screening services to all birthing facilities in the state.

§64-91-4. When Screening is Required.

~~4.1. W. Va. Code §16-22-3 requires that all infants born in the state be screened for detection and control of diseases in newborn children as listed in section 5.~~

~~4.2.~~ 4.1. When the birth takes place in a licensed birthing facility the primary care provider must perform or cause to be performed newborn screening as listed in section 5 within 48 hours of birth, or before discharge from the birthing facility, whichever comes first.

~~4.3.~~ 4.2. If an infant is born in a non-hospital or non-birthing facility, including a home, the person in attendance at the birth must perform or cause to be performed the newborn screening as listed in section 5 within 48 hours of the birth.

~~4.4.~~ 4.3. If a specimen is unacceptable or a positive screen result occurs, the primary care provider must perform or cause to be performed a second screen.

4.4. W. Va. Code §16-22A-1 et seq. requires that all infants born in a licensed birthing facility be screened for hearing impairments except when there is no third-party payor for the screening and the parents refuse to have the screening performed, as set forth in W. Va. Code §16-22A-3(c).

4.5. When the birth takes place in a licensed birthing facility and there is a third-party payor, the primary care provider present at the birth shall immediately perform or cause to be performed screening for hearing impairments.

4.6. When an infant is born in a nonlicensed facility, including a home, the primary care provider shall inform the parents of the need to obtain the screening within the first month of the infant's life.

4.7. A birthing facility shall cause to be performed a pulse oximetry screening on every newborn in its care.

4.8. The pulse oximetry screening shall be performed when the newborn is 24 to 48 hours of age, or as late as possible if the newborn is to be discharged from the facility before he or she is 24 hours of age.

4.9. The pulse oximetry screening results shall be recorded on the newborn's Birth Score sheet or through an alternate means of data collection that has been approved by the Commissioner.

§64-91-5. Complete list of diseases and conditions.

5.1. Every infant born in West Virginia must be screened for the following diseases and conditions contained in this section. This section is not an all-inclusive list of diseases and conditions which may be screened, and does not preclude or limit additional screenings, which may be performed.

~~5.2.~~ 5.1.1. Adrenoleukodystrophy

~~5.3.~~ 5.1.2. Argininosuccinic acidemia, ASA;

~~5.4.~~ 5.1.3. Beta-ketothiolase deficiency, BKT;

~~5.5.~~ 5.1.4. Biotinidase deficiency, BIOT;

~~5.6.~~ 5.1.5. Carnitine uptake defect, CUD;

~~5.7.~~ 5.1.6. Citrullinemia, CIT;

~~5.8.~~ 5.1.7. Congenital adrenal hyperplasia, CAH;

~~5.9.~~ 5.1.8. Cystic fibrosis, CF;

~~5.10~~ 5.1.9. Galactosemia, GALT;

- ~~5.11.~~ 5.1.10. Glutaric acidemia type I, GAI;
- ~~5.12.~~ 5.1.11. Hearing deficiency, HEAR;
- ~~5.13.~~ 5.1.12. Hemoglobinopathies; including:
 - ~~5.13.a.~~ 5.1.12.a. Hemoglobin S/Beta-thalassemia, Hb S/Th;
 - ~~5.13.b.~~ 5.1.12.b. Sickle cell anemia, Hb SS;
 - ~~5.13.c.~~ 5.1.12.c. Sickle C disease, Hb S/C;
- ~~5.14.~~ 5.1.13. Homocystinuria, HCY;
- ~~5.15.~~ 5.1.14. 3-Hydroxy-3-methylglutaric aciduria, HMG;
- ~~5.16.~~ 5.1.15. Hypothyroidism, CH;
- ~~5.17.~~ 5.1.16. Isovaleric acidemia, IVA;
- ~~5.18.~~ 5.1.17. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;
- ~~5.19.~~ 5.1.18. Maple syrup urine disease, MSUD;
- ~~5.20.~~ 5.1.19. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;
- ~~5.21.~~ 5.1.20. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;
- ~~5.22.~~ 5.1.21. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;
- ~~5.23.~~ 5.1.22. Methylmalonic acidemia-mutase deficiency form, MUT;
- ~~5.24.~~ 5.1.23. Multiple carboxylase deficiency, MCD;
- ~~5.25.~~ 5.1.24. Phenylketonuria, PKU;
- ~~5.26.~~ 5.1.25. Propionic acidemia, PROP;
- ~~5.27.~~ 5.1.26. Trifunctional protein deficiency, TFP;
- ~~5.28.~~ 5.1.27. Tyrosinemia type I, TYRI;
- ~~5.29.~~ 5.1.28. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD;
- ~~5.30.~~ 5.1.29. Lysosomal Storage Disorders;
- ~~5.31.~~ 5.1.30. X-Linked Adrenoleukodystrophy, X-ALD; and
- ~~5.32.~~ 5.1.31. Spinal Muscular Atrophy, SMA.

§64-91-6. Screening Protocol.

6.1. The primary care provider must perform, or cause to be performed, newborn screening listed in section 5 shortly after birth and before discharge from the birthing facility and send the specimen to the state laboratory to perform the tests.

6.2. The screening listed in section 5 must be performed by trained personnel, according to the Clinical Laboratory Improvement Amendments (CLIA) standards as recommended by the American Academy of Pediatrics.

6.3. The primary care provider must perform, or cause to be performed, newborn hearing screening in both ears shortly after birth, using either the ABR and/or OAE screening equipment, following the equipment manufacturer's guidelines.

6.4. Newborn hearing screening shall be performed by trained personnel, according to the American Academy of Pediatrics (AAP) standards.

6.5. If an infant does not pass the initial screening test, the primary care provider shall perform a second screening test prior to the infant's discharge from the birthing facility.

6.6. Pulse oximetry should be performed on the right hand and one foot. If the newborn's oxygen saturation is > 95% in either extremity, with a < 3% difference between the two, he or she will be considered to have passed the screening test and no additional evaluation will be required unless signs or symptoms of CHD are present.

6.7. If the oxygen saturation is <95% in both the hand and foot or there is a >3% difference between the hand and foot on three measures, each separated by one hour, the newborn should be evaluated by his or her primary care provider and referred, if indicated, for an echocardiogram at an ultrasound facility that has experience in newborn cardiac echocardiograms. The echocardiogram shall be interpreted by a pediatric cardiologist who shall then make appropriate arrangements for follow-up when necessary.

6.8. A newborn with oxygen saturation that is <90% in either the hand or foot should be referred immediately for additional evaluation.

~~6.3.~~ 6.9. The Commissioner may update or modify the screening procedures according to screening protocol, technology, and current national standards.

~~6.4.~~ 6.10. If the primary care provider is unable to screen or cause to have screened the infant before discharge, then the primary care provider must refer the infant for an outpatient newborn screening.

~~6.5.~~ 6.11. For infants born in a non-hospital or non- birthing facility, including a home, the primary care provider must order an outpatient newborn screen.

~~6.6.~~ 6.12. A specimen must be collected on collection kits obtained through the state laboratory.

~~6.7.~~ 6.13. A specimen must be submitted to the state laboratory within 24 hours of collection through the U.S. mail or have the specimen ready for pick-up by courier service at a designated time and location.

§64-91-7. Screening Fee Schedule.

7.1. The bureau may bill the birthing facility or individual attending the birth for services provided for each newborn screen consistent with prevailing health insurance reimbursement rates for newborn screening to cover the administrative, laboratory, and follow-up costs associated with the performance of screening tests required by this rule.

7.2. All licensed birthing facilities shall charge a fee for initial newborn hearing screening that will be applied to all payors at a rate not to exceed the rate established by the Medicaid DRG process.

7.3. For infants born in a nonlicensed birthing facility, including a home, primary care providers shall charge a fee for an outpatient newborn hearing screen at a rate not to exceed the rate established by Medicaid.

~~7.2.~~ 7.4. No newborn may be denied testing required by this rule because of inability of the newborn's parents or legal guardian to pay the prescribed fee.

~~7.3.~~ 7.5. The bureau will periodically review the newborn screening program to determine the efficacy and cost-effectiveness of the program and determine whether adjustments to the program are necessary to protect the health and welfare of this state's newborns, and to maximize the number of newborn screenings that may be conducted with the funding available for the screenings.

~~7.4.~~ 7.6. The bureau shall prepare an annual report to be submitted to the legislature, and to be made available to any interested party, that will include actual expenses incurred and revenue generated by the newborn screening system each year.

§64-91-8. Screening Reporting and Assistance to Afflicted Children.

8.1. The birthing facility must record or cause to be recorded the newborn screening results in the infant's medical record.

8.2. Positive results on any screen specified in section 5, ~~or~~ any other diseases specified by the bureau, and newborn hearing screening must be promptly reported to the bureau and the primary care provider by the director of the state laboratory performing the test.

8.3. The primary care provider must report all newborn screening results to the infant's parents or legal guardian.

8.4. Assistance with referrals must be offered by the bureau in cooperation with other state agencies to children determined to be afflicted with any disease specified in section 5 for medical and dietary needs. Regarding newborn hearing screening, the primary care provider shall arrange for diagnostic testing with local audiological testing facility.

8.5. When an infant is born in a non-hospital or non-birthing facility, including a home, the provisions of subsection 4.3. apply.

§64-91-9. Confidentiality.

9.1. Confidential information obtained while performing the required screenings may only be disclosed to:

9.1.a. Reporting sources;

9.1.b. Persons demonstrating a need essential to health-related research or care of the infant; or

9.1.c. As required by law.

9.2. Prior to receipt of confidential information, the requestor must agree to maintain the confidentiality and privacy of the information as required by law.