

**WEST VIRGINIA
SECRETARY OF STATE
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SECRETARY OF STATE

Form #6

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 91

TITLE OF RULE BEING PROPOSED: NEWBORN SCREENING SYSTEM

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB 398

SECTION 64-5-1(f), PASSED ON March 8, 2008

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE

FOLLOWING DATE: April 2, 2008

Martha Yeager Walker
Authorized Signature

TITLE 64
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH
LEGISLATIVE RULE

SERIES 91

NEWBORN SCREENING SYSTEM

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DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH
STATE OF WEST VIRGINIA

§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 WV Code §16-22-3, and certain other diseases specified by the Bureau for Public Health. 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 WV Code §16-22-3 and §16-22A-1, et seq. and the rule on Newborn Hearing Screening, 64CSR24. The WV Code is available in public libraries and on the Legislature's webpage, www.legis.state.wv.us.

1.2. Authority. -- WV Code §§16-1-4, 16-22-3 and 16-22A-3.

1.3. Filing Date. -- April 2, 2008.

1.4. Effective Date. -- April 2, 2008.

1.5. The fee for a newborn screening system kit established in section 8 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. Birthing Facility. -- Any licensed medical facility that offers birthing services.

3.2. 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. Commissioner -- The Commissioner of the Bureau for public health or his or her designee.

3.4. Laboratory. -- The State laboratory facility that supplies newborn screening services to all birthing facilities in the state.

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

3.6. 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 disorders before discharge from birthing facilities. Infants identified with a disorder shall receive continuing care and treatment provided through a collaborative effort between the primary physician, medical specialist, the Bureau and community support services.

3.7. 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.

3.8. 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.

§64-91-4. Newborn screening implementation.

4.1. Each child born in this state has historically been screened for:

4.1.a. Galactosemia, GALT;

4.1.b. Hearing deficiency, HEAR;

4.1.c. Hemoglobinopathies; which include:

4.1.c.1. Hemoglobin S/Beta-thalassemia, Hb S/Th;

4.1.c.2. Sickle cell anemia, Hb SS;

4.1.c.3. Sickle C disease, Hb S/C;

4.1.d. Hypothyroidism, CH; and

4.1.e. Phenylketonuria, PKU;

4.2. The Bureau shall require screening for:

4.2.a. Biotinidase deficiency, BIOT;

4.2.b. Congenital adrenal hyperplasia, CAH; and

4.2.c. Cystic fibrosis, CF;

4.3. On July 1st, 2008, the Bureau shall also require screening for:

4.3.a. Argininosuccinic acidemia, ASA;

4.3.b. Beta-ketothiolase deficiency, BKT;

4.3.c. Carnitine uptake defect, CUD;

4.3.d. Citrullinemia, CIT;

4.3.e. Glutaric acidemia type I, GAI;

4.3.f. Homocystinuria, HCY;

4.3.g. 3-Hydroxy-3-methylglutaric aciduria, HMG;

4.3.h. Isovaleric acidemia, IVA;

4.3.i. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;

4.3.j. Maple syrup urine disease, MSUD;

4.3.k. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;

4.3.l. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;

4.3.m. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;

4.3.n. Methylmalonic acidemia-mutase deficiency form, MUT;

4.3.o. Multiple carboxylase deficiency, MCD;

4.3.p. Propionic acidemia, PROP;

4.3.q. Trifunctional protein deficiency, TFP;

4.3.r. Tyrosinemia type I, TYRI;

4.3.s. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD; and

4.3.t. Any additional diseases or conditions as determined by the Commissioner.

§64-91-5. When Screening is Required.

5.1. WV 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 sections 4 and 6 of this rule.

5.2. When the birth takes place in a licensed birthing facility the primary care provider shall perform or cause to be performed newborn screening as listed in sections 4 and 6 of this rule within forty-eight hours of birth, or before discharge from the birthing facility, whichever comes first.

5.3. If an infant is born in a non-hospital or non-birthing facility, including a home, the person in attendance at the birth shall perform or cause to be performed the newborn screening as listed in sections 4 and 6 of this rule within forty-eight hours of the birth.

5.4. If a specimen is unacceptable or a positive screen result occurs, the primary care provider shall perform or cause to be performed a second screen.

§64-91-6. Complete list of diseases and conditions to be screened after July 1st, 2008.

6.1. After July 1st, 2008, every infant born in West Virginia shall be screened for the additional diseases and conditions enumerated in subsection 4.3. of this rule. For the purpose of clarity and to make the list more readily accessible to readers, all of the tests for newborn screening for diseases and conditions are listed below in alphabetical order:

6.2. Argininosuccinic acidemia, ASA;

6.3. Beta-ketothiolase deficiency, BKT;

6.4. Biotinidase deficiency, BIOT;

6.5. Carnitine uptake defect, CUD;

6.6. Citrullinemia, CIT;

6.7. Congenital adrenal hyperplasia, CAH;

6.8. Cystic fibrosis, CF;

6.9. Galactosemia, GALT;

6.10. Glutaric acidemia type I, GAI;

6.11. Hearing deficiency, HEAR;

6.12. Hemoglobinopathies; including:

6.12.a. Hemoglobin S/Beta-thalassemia, Hb S/Th;

6.12.b. Sickle cell anemia, Hb SS;

6.12.c. Sickle C disease, Hb S/C;

6.13. Homocystinuria, HCY;

6.14. 3-Hydroxy-3-methylglutaric aciduria, HMG;

6.15. Hypothyroidism, CH;

6.16. Isovaleric acidemia, IVA;

6.17. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;

6.18. Maple syrup urine disease, MSUD;

6.19. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;

6.20. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;

6.21. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;

6.22. Methylmalonic acidemia-mutase deficiency form, MUT;

6.23. Multiple carboxylase deficiency, MCD;

6.24. Phenylketonuria, PKU;

6.25. Propionic acidemia, PROP;

6.26. Trifunctional protein deficiency, TFP;

6.27. Tyrosinemia type I, TYRI;

6.28. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD; and

6.29. Any additional diseases or conditions as determined by the Commissioner.

§64-91-7. Screening Protocol.

7.1. The primary care provider shall perform, or cause to be performed, newborn screening listed in sections 4 and 6 of this rule shortly after birth and before discharge from the birthing facility and send the specimen to the State laboratory to perform the tests.

7.2. The screening shall be performed by trained personnel, according to the Clinical Laboratory Improvement Amendments (CLIA) standards as recommended by the American Academy of Pediatrics.

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

7.4. If the primary care provider is unable to screen or cause to have screened the infant before discharge, then the primary care provider shall refer the infant for an out-patient newborn screening.

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

7.6. A specimen shall be collected on collection kits obtained through the State laboratory.

7.7. A specimen shall be submitted to the State laboratory within twenty-four 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.

§64-91-8. Screening Fee Schedule.

8.1. The Bureau shall bill birthing facilities for each live birth in the state at the rate established in this rule. All birthing facilities shall pay the appropriate fee to the Bureau for one initial newborn screening system kit per live birth. There shall be no charge for second or subsequent retests.

8.2. The fees shall be sufficient to cover the costs of the newborn screening system, kit, laboratory equipment, reagents, personnel and other associated costs.

8.3. The first fee charged shall reflect the recent historical cost of the current system. The Bureau may charge birthing facilities at a rate not to exceed fifty dollars (\$50.00) per newborn screening system kit.

8.4. After July 1, 2008, the fee may be increased to one hundred twenty-five (\$125.00) to reflect the cost of the numerous additional newborn screening tests and associated system costs as required by law. The fee shall be charged to birthing facilities at a rate not to exceed one hundred twenty-five dollars (\$125.00) per newborn screening system kit.

8.5. The fee for newborn screening system kits may be reviewed periodically by the Commissioner. As medical science evolves the number of disorders on the panel may increase to reflect national standards of care and the costs may incrementally increase to accommodate the number of disorders screened. The fee may be adjusted to cover the actual costs of the laboratory tests, reagent, materials and equipment and support for the newborn screening system. The initial amount and any increase in the fee shall be published in the State Register.

8.6. The Bureau shall bill all birthing facilities at the rate of one fee per live birth as the means for payment authorized in WV Code §16-22-3(c).

8.7. 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.

§64-91-9. Screening Reporting and Assistance to Afflicted Children.

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

9.2. Positive results on any screen specified in sections 4 or 6 of this rule, or any other diseases specified by the Bureau, shall be promptly reported to the Bureau and the primary care provider by the director of the State laboratory performing the test.

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

9.4. Assistance with referrals shall be offered by the Bureau in cooperation with other state agencies to children determined to be afflicted with any disease specified in sections 4 or 6 of this rule for medical and dietary needs.

9.5. When an infant is born in a non-hospital or non-birthing facility, including a home, the provisions of subsection 5.3 of this rule apply.

§64-91-10. Confidentiality.

10.1. Any person who obtains confidential information while implementing WV Code §16-22-3 and this rule may disclose it only to reporting sources, persons demonstrating a need that is essential to health related research or care of the infant, or as required by law.

10.2. Any person who obtains confidential information while implementing WV Code §16-22-3 and this rule shall provide a written statement of confidentiality stating that he or she fully understands the privacy of the information and will maintain it.

§64-91-11. Penalties.

11.1. Any person who violates the provisions of WV Code §16-22-3, or this rule is subject to the penalties provided in WV Code §16-1-18.

11.2. For a second or subsequent failure to comply, the Bureau may file a complaint against a provider with the state board of medicine.