



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Health TITLE-SERIES: 64-91
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: Newborn Screening System
CITE STATUTORY AUTHORITY: W. Va. Code §§16-1-4, 16-22-3, and 16-22A-3

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 07/20/2018 4:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

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PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

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. 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.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

Statement of Circumstances: The current rule includes a cap on the on the fee the Bureau may charge to cover the cost of laboratory testing by the Bureaus Office of Laboratory Services (OLS). The Bureau proposes to amend the rule to remove the fee cap. If the current cap is not removed, the state will have to incur the excess costs rather than including it in the fee charged to birthing facilities.

The proposed rule amendment includes:

Amends subsection 1.5 to include a sunset provision as required by law;

Amends the definition section to properly rename definition of Laboratory to State Laboratory;

Removes section 4 as it is now unnecessary given the passage of time. The provisions of section 6 are sufficient to address the intent of the rule;

Non-substantive changes are made to renumbered section 4 to conform with proper grammar and style requirements, and to conform the section to changes made elsewhere in the rule;

Renumbered section 5 is amended to add the condition Adrenoleukodystrophy and to remove the following text Any additional diseases or conditions as determined by the Commissioner.;

Non-substantive changes are made to renumbered section 6 to conform with proper grammar and style requirements, and to conform the section to changes made elsewhere in the rule;

Renumbered section 7 is significantly amended to remove the current cap on the amount that the State may bill for mandatory testing services, The cap is replaced with language that authorizes the bureau to 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;

Renumbered section 7 is additionally amended for clarity and to conform with proper grammar and style requirements;

Non-substantive changes are made to renumbered section 8 to conform with proper grammar and style requirements, and to conform the section to changes made elsewhere in the rule;

Renumbered section 9 is amended for clarity and to conform with proper grammar and style requirements; and

Renumbered section 10 is removed in its entirety as it is superfluous given that criminal penalties are provide elsewhere in the West Virginia Code.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

The current rule includes a cap on the on the fee the Bureau may charge to cover the cost of laboratory testing by the Bureaus Office of Laboratory Services (OLS). The Bureau proposes to amend the rule to remove the fee cap. If the current cap is not removed, the state will have to incur the excess costs rather than including it in the fee charged to birthing facilities.

B. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

n/a

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2018 Increase/Decrease (use "-")	2019 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

The rule amendment will result in an increase in revenues for the state. The Bureau is currently in the process of determining the extent of the increase.

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

Yes

Heather J Mcdaniel -- 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. 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 webpage, www.legis.state.wv.us.

1.2. Authority. -- *W. Va. 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. Sunset Provision. -- This rule shall terminate and have no further force of effect upon the expiration of five years from its effective date.

~~1.5.~~ 1.6. The fee for a newborn screening system kit established in section ~~8-6~~ 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. 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.~~ 3.4. Newborn Screening. -- The statutorily mandated screening of newborns by hospitals, birthing facilities, physicians or others.

~~3.6.~~ 3.5. 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~~ must receive continuing care and treatment provided through a collaborative effort between the primary physician, medical specialist, the bureau and community support services.

~~3.7.~~ 3.6. 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.~~ 3.7. 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.

3.8. 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. 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 de hydrogenase deficiency, LCHAD;~~
 - ~~4.3.j. Maple syrup urine disease, MSUD;~~
 - ~~4.3.k. Medium chain acyl CoA dehydro genase 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 de hydrogenase deficiency, VLCAD;~~
 - ~~4.3.t. Any additional diseases or conditions as determined by the Commissioner.~~

~~§64-91-5~~ §64-91-4. When Screening is Required.

~~5.1.~~ 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 ~~sections 4 and 6~~ section 5 of this rule.

~~5.2.~~ 4.2. When the birth takes place in a licensed birthing facility the primary care provider ~~shall~~ must perform or cause to be performed newborn screening as listed in ~~sections 4 and 6~~ section 5 of this rule within ~~forty-eight~~ 48 hours of birth, or before discharge from the birthing facility, whichever comes first.

~~5.3.~~ 4.3. If an infant is born in a non-hospital or non-birthing facility, including a home, the person in attendance at the birth ~~shall~~ must perform or cause to be performed the newborn screening as listed in ~~sections 4 and 6~~ section 5 of this rule within ~~forty-eight~~ 48 hours of the birth.

~~5.4.~~ 4.4. If a specimen is unacceptable or a positive screen result occurs, the primary care provider ~~shall~~ must perform or cause to be performed a second screen.

~~§64-91-6, §64-91-5.~~ **Complete list of diseases and conditions ~~to be screened after July 1st, 2008.~~**

~~6.1.~~ 5.1. ~~After July 1st, 2008,~~ Every infant born in West Virginia ~~shall~~ must be screened for the additional diseases and conditions contained in this section. ~~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:~~

5.2. Adrenoleukodystrophy

~~6.2.~~ 5.3. Argininosuccinic acidemia, ASA;

~~6.3.~~ 5.4. Beta-ketothiolase deficiency, BKT;

~~6.4.~~ 5.5. Biotinidase deficiency, BIOT;

~~6.5.~~ 5.6. Carnitine uptake defect, CUD;

~~6.6.~~ 5.7. Citrullinemia, CIT;

~~6.7.~~ 5.8. Congenital adrenal hyperplasia, CAH;

~~6.8.~~ 5.9. Cystic fibrosis, CF;

~~6.9.~~ 5.10 Galactosemia, GALT;

~~6.10.~~ 5.11. Glutaric acidemia type I, GAI;

~~6.11.~~ 5.12. Hearing deficiency, HEAR;

~~6.12.~~ 5.13. Hemoglobinopathies; including:

~~6.12.a.~~ 5.13.a. Hemoglobin S/Beta-thalassemia, Hb S/Th;

~~6.12.b.~~ 5.13.b. Sickle cell anemia, Hb SS;

~~6.12.c.~~ 5.13.c. Sickle C disease, Hb S/C;

- ~~6.13.~~ 5.14. Homocystinuria, HCY;
- ~~6.14.~~ 5.15. 3-Hydroxy-3-methylglutaric aciduria, HMG;
- ~~6.15.~~ 5.16. Hypothyroidism, CH;
- ~~6.16.~~ 5.17. Isovaleric acidemia, IVA;
- ~~6.17.~~ 5.18. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;
- ~~6.18.~~ 5.19. Maple syrup urine disease, MSUD;
- ~~6.19.~~ 5.20. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;
- ~~6.20.~~ 5.21. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;
- ~~6.21.~~ 5.22. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;
- ~~6.22.~~ 5.23. Methylmalonic acidemia-mutase deficiency form, MUT;
- ~~6.23.~~ 5.24. Multiple carboxylase deficiency, MCD;
- ~~6.24.~~ 5.25. Phenylketonuria, PKU;
- ~~6.25.~~ 5.26. Propionic acidemia, PROP;
- ~~6.26.~~ 5.27. Trifunctional protein deficiency, TFP;
- ~~6.27.~~ 5.28. Tyrosinemia type I, TYRI; and
- ~~6.28.~~ 5.29. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD; ~~and~~
- ~~6.29.~~ Any additional diseases or conditions as determined by the Commissioner.

~~§64-91-7~~ §64-91-6. Screening Protocol.

~~7.1.~~ 6.1. The primary care provider ~~shall~~ must perform, or cause to be performed, newborn screening listed in ~~sections 4 and 6~~ section 5 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.~~ 6.2. The screening ~~shall~~ must be performed by trained personnel, according to the Clinical Laboratory Improvement Amendments (CLIA) standards as recommended by the American Academy of Pediatrics.

~~7.3.~~ 6.3. The Commissioner may update or modify the screening procedures according to screening protocol, technology and current national standards.

~~7.4.~~ 6.4. If the primary care provider is unable to screen or cause to have screened the infant before discharge, then the primary care provider ~~shall~~ must refer the infant for an out-patient newborn screening.

~~7.5.~~ 6.5. For infants born in a non-hospital or non- birthing facility, including a home, the primary care provider ~~shall~~ must order an outpatient newborn screen.

~~7.6.~~ 6.6. A specimen ~~shall~~ must be collected on collection kits obtained through the state laboratory.

~~7.7.~~ 6.7. A specimen ~~shall~~ must be submitted to the state laboratory within ~~twenty four~~ 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.

~~§64-91-8~~ §64-91-7. Screening Fee Schedule.

~~8.1.~~ 7.1. 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 rescreens. 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.

~~8.2.~~ 7.2. The fees shall be sufficient to cover the costs of the newborn screening system, kit, laboratory equipment, reagents, personnel and other associated costs. 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.

~~8.3.~~ 7.3. 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. 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.

~~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 W. Va. Code §16-22-3(c).

~~8.7.~~ 7.4. The Bureau ~~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~~ §64-91-8. Screening Reporting and Assistance to Afflicted Children.

~~9.1.~~ 8.1. The birthing facility ~~shall~~ must record or cause to be recorded the newborn screening results in the infant's medical record.

~~9.2.~~ 8.2. Positive results on any screen specified in ~~sections 4 or 6 of this rule~~ section 5, or any other diseases specified by the bureau, ~~shall~~ must be promptly reported to the bureau and the primary care provider by the director of the state laboratory performing the test.

~~9.3.~~ 8.3. The primary care provider ~~shall~~ must report all newborn screening results to the infant's parents or legal guardian.

~~9.4.~~ 8.4. Assistance with referrals ~~shall~~ must 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~~ section 5 of this rule for medical and dietary needs.

~~9.5.~~ 8.5. When an infant is born in a non-hospital or non-birthing facility, including a home, the provisions of subsection ~~5.3~~ 4.3. ~~of this rule~~ apply.

~~§64-91-10~~ §64-91-9. Confidentiality.

~~10.1.~~ 9.1. ~~Any person who obtains Confidential information~~ obtained while performing the required screenings implementing W. Va. Code §16-22-3 and this rule may only be disclosed ~~it only~~ to:

9.1.a. Reporting sources;

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

9.1.c. As required by law

~~10.2.~~ 9.2. ~~Prior to receipt of~~ Any person who obtains confidential information while implementing W. Va. Code §16-22-3 and this rule ~~the requestor shall~~ must agree to maintain the written confidentiality stating that he or she fully understands the and privacy of the information as required by law. of the information and will maintain it.

~~§64-91-11.~~ Penalties.

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