

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #7

Do Not Mark In This Box
Filing Date

2011 JUL 27 11 58 AM

SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

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

CITE AUTHORITY: WV Code §§16-1-4, 16-22-3, and 16-22A-3

EMERGENCY 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 IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

House Bill 2583, passed March 10, 2007, requires an immediate expansion of the number of diseases or conditions for which a newborn infant must be tested. Currently, tests are conducted for six diseases and for hearing. The new law establishes two dates for inclusion of certain additional disease screens to be added. The first date in the statute is July 1, 2007, at which time the Bureau for Public Health is to have in place additional screening tests for three more diseases. The second date in the law is July 1, 2008, at which time the Bureau shall also be required to test for the full spectrum of 29 diseases, including hearing. The law states in §16-22-3(c)(2) that this rule shall include: "A means for payment for the screening provided for in this section." The Bureau is filing this emergency rule to define the procedure the Bureau will use to bill appropriate parties for this two-tiered increase in testing. It is an emergency because the first portion of the expansion is required to occur by July 1, 2007. The Bureau will also file this rule as a regular rule to be considered in the 2008 legislative session.

Use additional sheets if necessary


Authorized Signature

**64CSR91, Newborn Screening System rule,
EXPLANATION OF THE EMERGENCY**

The State of West Virginia has been performing newborn metabolic screening since 1965 as mandated by WV Code Chapter 16, Article 22, for Phenylketenuria (PKU), Galactosemia, Congenital Hypothyroidism and Sickle Cell. In 2005, the Commissioner of the Bureau for Public Health issued a policy statement to begin screening for Hemoglobinopathies; including Sickle Cell Anemia, Thalassemia and Sickle Cell Disease for all infants.

The cost of newborn screening has always been borne by the Bureau for Public Health through the Office of Maternal, Child, and Family Health using Title V federal dollars. Costs have included laboratory services, tracking and follow-up of positive screens, genetic and nutrition services including counseling under a contract from WVU, educational materials and nutritional supplements not covered by WIC or insurance.

In recent years the U.S. Secretary's Advisory on Heritable and Genetic Disorders has recommended that the number of disorders screened on newborns be increased to 29. The Bureau for Public Health has, for the past two years, been exploring options to enable the expansion to occur. The major barrier to the expansion has been cost for new equipment rental, personnel, support services, educational material, medical expertise and medically necessary prescriptions.

Program expense has been approximately \$1,100,000 per year. The cost of adding 22 additional screens will be approximately \$1,400,000 per year. The total cost, after July 1, 2008, for performing all 29 screens will be approximately \$2,500,000 annually.

With this in mind, the Office of Maternal, Child and Family Health cannot continue to pay for the current system, much less cover the additional expenses to complete the expansion. Title V federal dollars have remained static over the last several years, and adjusted for inflation the program has lost money while continuing to provide vital screening services to infants.

All but six states across the nation, including West Virginia, have already expanded newborn screening. It is imperative that West Virginia meet the national standard, but in order to do so we must have a sustainable method to fund the cost of the newborn screening system.

The 2007 passage of House Bill 2583 mandated that expanded screening occur and allowed for the establishment of a means for payment to be developed. This rule is that means for payment. The time frame for implementation of the expanded screening is extremely short with three screens to begin on July 1, 2007 and the remainder to begin July 1, 2008. The need to specifically outline and authorize a system to bill for the services is critical and immediate.

We respectfully request that this application to file the NEWBORN SCREENING SYSTEM rule as an Emergency rule be granted.

Department of Health and Human Resources
Bureau for Public Health
Legislative Rule
Title 64, Series 91

NEWBORN SCREENING SYSTEM

BRIEF SUMMARY OF PROPOSED RULE

This rule expands the number of newborn disorders to be screened for all children born in this state. The expansion brings West Virginia into compliance with the U.S. Department of Health and Human Services Advisory for Heritable and Genetic Disorders recommendations. This rule also provides for the establishment of a means of payment to finance the expansion of the system.

STATEMENT OF CIRCUMSTANCES

The rules for newborn metabolic screening are being proposed as mandated by legislation passed in the 2007 session, HB 2583.

PUBLIC COMMENT PERIOD

The Office of Maternal, Child and Family Health in the Bureau for Public Health intends to notify stakeholders who are interested in the West Virginia Newborn Metabolic Screening system, including, but not limited to; physicians who care for children, county health departments, Schools of Medicine, the WV Medical Association, the WV Hospital Association, third party payors, birthing facilities, and other interested parties.

EMERGENCY RULE QUESTIONNAIRE

DATE: _____

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* The Bureau for Public Health, Office of Maternal, Child
And Family Health, Kathy Cummons, Director of Research
Evaluation and Planning
350 Capitol Street, Room 427
Charleston, WV 25301 302-558-5388

EMERGENCY RULE TITLE: NEWBORN SCREENING SYSTEM

1. Date of filing June, 2007

2. Statutory authority for promulgating emergency rule:
§§16-4-1 and 16-22-3

3. Date of filing of proposed legislative rule: simultaneously

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? It is a new rule with entirely new language. However, it incorporates a number of statutorily mandated newborn screening test or procedures into one comprehensive rule.

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.
Please see attached letter of EXPLANATION OF EMERGENCY

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

~~West Virginia Code §16-22-3 sets forth the requirement that the Bureau for Public Health increase the number of newborn screening tests to be performed on all infants born in the state by the first of July 2007 and it also authorizes the Bureau to establish a means for payment for these additional tests. The rule establishes the means for payment through the mechanism of billing birthing centers for newborn screening test kits for each live birth in West Virginia.~~

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

~~Please see the EXPLANATION OF EMERGENCY.~~

~~Briefly, there are insufficient funds in the Bureau to carry out the statutory mandate for screening newborns. This rule will allow the agency to receive payment for providing this important health care service for all of West Virginia's children.~~



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

Joe Manchin III
Governor

Commissioner's Office
350 Capitol Street, Room 702
Charleston, West Virginia 25301-3712
Telephone: (304) 558-2971 Fax: (304) 558-1035

Martha Yeager Walker
Secretary

64CSR91, Newborn Screening System rule,

EXPLANATION OF THE EMERGENCY

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The 2007 passage of House Bill 2583 mandated that expanded screening occur and allowed for the establishment of a means for payment to be developed. This rule is that means for payment. The time frame for implementation of the expanded screening is extremely short with three screens to begin on July 1, 2007 and the remainder to begin July 1, 2008. The need to specifically outline and authorize a system to bill for the services is critical and immediate.

We respectfully request that this application to file the NEWBORN SCREENING SYSTEM rule as an Emergency rule be granted.

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

The above estimates reflect the additional cost to the program for Phase I of the expansion. The estimate is only for SFY2008 as this fiscal note only applies to the emergency rule filing. The estimated costs for SFY2009 and thereafter will be included on the fiscal note attached to the filing of the proposed rule change under the regular rule revision process.

Personal Services: \$75,711, OLS - \$0; OMCFH - 1 Nurse III @ \$34,116 + 1 Accounting Tech @ \$18,636 = \$52,752 X 19.19% (FICA, Ret. Workers Comp.) = \$10,123 + \$6,418 (Admin. Fees, Health Insurance per FTE) X 2 FTEs = \$22,959 **Current Expense: \$405,438**, OLS - \$12,000 Supplies, Reagent rental for Auto Delphia System \$325,000; OMCFH - Provider Education \$10,000; Computers \$2,000; Nutritional Supplements \$7,500; Expanded WVU Pediatrics and Genetics Services Grant \$48,938

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The costs estimated for the implementation of Phase I (\$481,149) as described in the emergency rule are in addition to the costs to support the current system (\$1.1 million). Total estimated cost for SFY2008 is \$1,581,149. A rule to be filed and effective July 1, 2008 calls for the Phase II expansion of the system. Newborn screening system costs for final expansion of diseases and conditions are estimated to be an additional \$764,697. Total system costs after that expansion would be \$2,345,846 (\$481,149+\$1.1million+\$764,697= \$2,345,846). Effective July 1, 2008, the rule allows the Department to bill up to \$125 per live birth which could result in total estimated revenue of up to \$2,625,000.

It is expected that the birthing facilities will recover costs incurred through appropriate third party payment processes available to them.

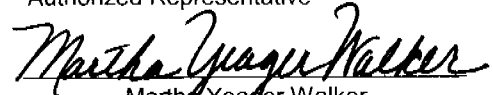
Early screening of children with special health care needs and congenital disorders at birth is a priority across the country. For several years, West Virginia has focused on the development of a plan that will support new test technologies and the expansion of the number of newborn screening conditions. The successful implementation will require public and private healthcare to incur the cost of the service system. Cost and benefit related to the screening has been evaluated by the US Congress Office of Technology and Assessment and has been determined to be cost effective both in terms of early infant development and hospital/medical costs.

Date

Agency

Authorized Representative

Department of Health and Human Resources



Martha Yeager Walker
Secretary

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

2007 JUN 27 11:03

SECRETARY

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 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. -- June , 2007

1.4. Effective Date. --

1.5. The fee for a newborn screening system kit established in section 7 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 center 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 State 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.

3.5.a. Presently each infant born in this state is screened for:

3.5.a.1. Galactosemia, GALT;

3.5.a.2. Hearing deficiency, HEAR;

3.5.a.3. Hemoglobinopathies; which include:

3.5.a.3.A. Hemoglobin S/Beta-thalassemia, Hb S/Th;

3.5.a.3.B. Sick cell anemia, Hb
SS;

3.5.a.3.C. Sick C disease, Hb
S/C;

3.5.a.4. Hypothyroidism, CH; and

3.5.a.5. Phenylketonuria, PKU;

3.5.b. No later than July 1st, 2007, the
bureau shall require screening for:

3.5.b.1. Biotinidase deficiency, BIOT;

3.5.b.2. Congenital adrenal
hyperplasia, CAH; and

3.5.b.3. Cystic fibrosis, CF;

3.5.c. No later than July 1st, 2008, the
bureau shall require screening for:

3.5.c.1. Argininosuccinic acidemia,
ASA;

3.5.c.2. Beta-ketothiolase deficiency,
BKT;

3.5.c.3. Carnitine uptake defect, CUD;

3.5.c.4. Citrullinemia, CIT;

3.5.c.5. Glutaric acidemia type I, GAI;

3.5.c.6. Homocystinuria, HCY;

3.5.c.7. 3-Hydroxy-3-methylglutaric
aciduria, HMG;

3.5.c.8. Isovaleric acidemia, IVA;

3.5.c.9. Long-chain hydroxyacyl-CoA
dehydrogenase deficiency, LCHAD;

3.5.c.10. Maple syrup urine disease,
MSUD;

3.5.c.11. Medium-chain acyl-CoA

dehydrogenase deficiency, MCAD;

3.5.c.12. 3-Methylcrotonyl-CoA
carboxylase deficiency, 3MCC;

3.5.c.13. Methylmalonic acidemia -
Cbl A and Cbl B forms, Cbl A,B;

3.5.c.14. Methylmalonic acidemia-
mutase deficiency form, MUT;

3.5.c.15. Multiple carboxylase
deficiency, MCD;

3.5.c.16. Propionic acidemia, PROP;

3.5.c.17. Trifunctional protein
deficiency, TFP;

3.5.c.18. Tyrosinemia type I, TYRI;

3.5.c.19. Very long-chain acyl-CoA
dehydrogenase deficiency, VLCAD; and

3.5.c.23. Any additional diseases or
conditions as determined by the Commissioner.

3.6. Newborn Screening System. – The
coordinated effort by the Bureau for Public Health
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. When Screening is Required.

4.1. 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 section 3.5. and section 5. of this rule.

4.2. 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 section 3.5. and section 5. of this rule within 48 hours of birth or before hospital discharge whichever comes first.

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 perform or cause to be performed the newborn screening as listed in section 3.5 and section 5. of this rule within 48 hours of the birth.

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

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

5.1. After July 1st, 2008, every infant born in West Virginia shall be screened for the diseases and conditions enumerated in section 3.5. of this rule. For the purpose of clarity and to make the list more readily accessible to readers, these diseases and conditions are listed below in alphabetical order:

5.2. Argininosuccinic acidemia, ASA;

5.3. Beta-ketothiolase deficiency, BKT;

5.4. Biotinidase deficiency, BIOT;

5.5. Carnitine uptake defect, CUD;

5.6. Citrullinemia, CIT;

5.7. Congenital adrenal hyperplasia, CAH;

5.8. Cystic fibrosis, CF;

5.9. Galactosemia, GALT;

5.10. Glutaric acidemia type I, GAI;

5.11. Hearing deficiency, HEAR;

5.12. Hemoglobinopathies; including:

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

5.12.b. Sickle cell anemia, Hb SS;

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

5.13. Homocystinuria, HCY;

5.14. 3-Hydroxy-3-methylglutaric aciduria, HMG;

5.15. Hypothyroidism, CH;

5.16. Isovaleric acidemia, IVA;

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

5.18. Maple syrup urine disease, MSUD;

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

5.20. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;

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

5.22. Methylmalonic acidemia-mutase deficiency form, MUT;

5.23. Multiple carboxylase deficiency, MCD;

5.24. Phenylketonuria, PKU;

5.25. Propionic acidemia, PROP;

5.26. Trifunctional protein deficiency, TFP;

5.27. Tyrosinemia type I, TYRI;

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

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

§64-91-6. Screening Protocol.

6.1. The primary care provider shall perform, or cause to be performed, newborn screening listed in section 3.5. and section 5 of this rule shortly after birth and before discharge from the hospital and sent to the State laboratory which performs such tests.

6.2. 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.

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

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 is responsible for referring the infant for an outpatient newborn screening.

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

6.6. Specimen shall be collected on collection kits obtained through the State laboratory.

6.7. Specimen shall be submitted to the State laboratory within 24 hours of collection through the U.S. mail or have ready for pick-up by courier

service at a designated time and location.

§64-91-7. Screening Fee Schedule.

7.1. The Bureau for Public Health 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.

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.

7.3. The first fee charged shall reflect the recent historical cost of the current system. Beginning July 1, 2007, the Bureau may charge birthing facilities at a rate not to exceed \$50.00 per newborn screening system kit.

7.4. After July 1, 2008, the fee may be increased to \$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 \$125.00 per newborn screening system kit.

7.5. 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.

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

8.1. The birthing facility shall 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 3.5. or section 5. of this rule, or any other diseases specified by the Bureau for Public Health, shall be promptly reported to the Bureau for Public Health and the primary care provider by the director of the State laboratory performing such test.

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

8.4. Assistance with referrals shall be offered by the Bureau for Public Health in cooperation with other state agencies to children determined to be afflicted with any disease specified in section 3.5. or section 5. of this rule for medical and dietary needs.

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

§64-91-9. Confidentiality.

9.1. Any person who obtains confidential information while implementing WV Code §16-22-3et seq. 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.

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

64-91-10. Penalties.

10.1. 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.

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

Department of Health and Human Resources
Bureau for Public Health
Legislative Rule
Title 64, Series 91

NEWBORN SCREENING SYSTEM

BRIEF SUMMARY OF PROPOSED RULE

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