

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

Form #2

Do Not Mark In This Box

2007 06 27

SECRET

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

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

RULE TYPE: Legislative CITE AUTHORITY: §§16-1-4 and 16-22-3

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

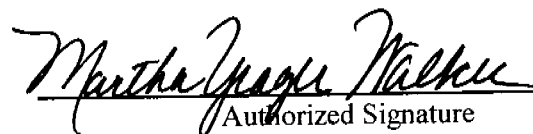
IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON 27 July 2007 AT 12:00am ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

John Law or Ann Spaner
DHHR / BPH
350 Capitol Street, Room 702
Charleston, WV 25301

OR

Kathy Cummons or Pat Moss
OMCFH
350 Capitol Street, Room 427
Charleston, WV 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.


Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

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.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

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, Research,
Evaluation & Planning

350 Capitol Street, Room 427
Charleston, WV 25301 304 558-5388

LEGISLATIVE RULE TITLE: _____
NEWBORN SCREENING SYSTEM

1. Authorizing statute(s) citation §§16-1-4 and 16-22-3

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

b. What other notice, including advertising, did you give of the hearing?

c. Date of Public Hearing(s) *or* Public Comment Period ended:

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____ No comments received _____

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

- f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

~~Kathy Cummons, Director, Research, Evaluation and Planning Division
350 Capitol Street, Room 427, Charleston, WV 25301-3710 ph. 558-7171
kathycummons@wvdhhr.org Fax: 558-3510
Pat Moss, Office Director, OMCFH, 350 Capitol Street, Rm 427, Charleston, WV
25301-3710, 558-5388. patmoss@wvdhhr.org Fax: 558-3510
Ann Spaner, Director, Public Health Regulations, 350 Capitol Street, Room 702,
Charleston, WV 25301-3712, 558-0035, annspaner@wvdhhr.org Fax: 5581035~~

- g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

d. Attach findings and determinations and reasons:

Attached _____

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Newborn Screening System

Type of Rule: X Legislative Interpretive Procedural

Agency: Health and Human Resources

Address: Bldg. 3 Room 206
Capitol Complex
Charleston, West Virginia 25305

Phone Number: 558-7171 Email: kathycummons@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

The purpose of this rule is to expand the newborn metabolic screening system to include all diseases and conditions identified effective July 1, 2008. The Department of Health and Human Resources, Bureau for Public Health currently expends approximately \$1.1 million of Maternal and Child Health Block Grant funds as well as maternal and child health general revenue funds to support the system. An emergency rule effective July 1, 2007 provided for an initial expansion of the screening system at an estimated cost of \$481,149. The final expansion of the system that will be implemented effective July 1, 2008 will cost an estimated additional \$764,697. The estimated cost to expand the system to include all diseases and conditions added as a result of changes implemented in this rule is \$1,245,846. The total estimated cost of the fully implemented newborn metabolic screening system will be \$2,345,846.

This rule allows the Department to charge a fee to support the newborn metabolic screening system. Effective July 1, 2007, the Department expects to bill birthing facilities a fee of \$45 per live birth. The fee is based on the historical costs of the current system. Effective July 1, 2008, the Department expects to increase the fee not to exceed \$125 per live birth. At an average of 21,000 live births per year, the Department could receive up to \$2,625,000 in revenue.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2008 Increase/Decrease (use "-")	2009 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	1,245,846	1,245,846
Personal Services		123,846	123,846
Current Expenses		1,122,000	1,122,000
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues		2,625,000	2,625,000

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

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

Personal Services: \$123,846, OLS - Chemist II @ \$35,000 X 19.19% (FICA, Ret., Workers Comp) = \$6,717 + \$6,418 (Admin Fees, Health Insurance per FTE) = \$13,135; 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: \$1,122,000**. OLS - \$12,000 Supplies, \$22,000 courier service, Reagent rental for Auto Delphia System \$325,000, Reagent rental for Tandem Mass Spectrometer \$351,000; OMCFH - Provider Education \$50,000; Computers \$2,000; Nutritional Supplements \$50,000; Expanded WVU Pediatrics and Genetics Services Grant \$310,000.

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 full expansion of the newborn screening system are in addition to the costs of the current system. Costs estimated for the emergency rule effective July 1, 2008, (\$481,149) are included in the SFY 2009 estimate costs for the total expansion system. Estimated costs for the final expansion of diseases and conditions to be included in the newborn screening system are \$764,697. Total system costs after that expansion would be \$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. The rule allows for periodic review of the fee and adjustment to the fee to cover the actual costs of the newborn screening system.

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 JUL 27
C...
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;

- SS;
- 3.5.a.3.B. Sickle cell anemia, Hb
- S/C;
- 3.5.a.3.C. Sickle C disease, Hb
- 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:
- ASA;
- 3.5.c.1. Argininosuccinic acidemia,
- BKT;
- 3.5.c.2. Beta-ketothiolase deficiency,
- 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;
- MSUD;
- 3.5.c.10. Maple syrup urine disease,
- 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.