

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #3

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2012 AUG 27 PM 1:04

OFFICE WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: DHHR - BUREAU FOR PUBLIC HEALTH TITLE NUMBER: 64

CITE AUTHORITY: WV Code §§16-1-4, 16-44-1 and 16-44-2.

AMENDMENT TO AN EXISTING RULE: YES NO

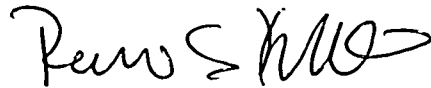
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 100

TITLE OF RULE BEING PROPOSED: PULSE OXIMETRY NEWBORN TESTING

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.



Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 64CSR100 PULSE OXIMETRY NEWBORN TESTING

Type of Rule: X Legislative Interpretive Procedural

Agency: Health and Human Resources

Address: One Davis Square
Suite 303
Charleston, WV 25301

Phone Number: 304-558-2971 Email: Ann.A.Goldberg@wv.gov

Fiscal Note Summary

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

The proposed rule (in accordance with HB4327, passed in the 2012 Regular Session) implements the Pulse Oximetry Newborn Testing Act. The proposed rule requires all birthing facilities licensed by the Department of Health and Human Resources, that provide birthing services and newborn care services, to perform pulse oximetry testing on all newborns.

There are no additional costs or revenues to the state anticipated as a result of this proposed rule.

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		
	2012 Increase/Decrease (use "-")	2013 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues	0	0	0

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

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

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.

Date

Agency

Authorized Representative



Department of Health and Human Resources

Rocco S. Fucillo
Cabinet Secretary

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: August , 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(Agency Name, Address & Phone No.) Ann Goldberg, Director, Public Health Regulations
350 Capitol Street, Room 702
Charleston, WV 25301
(304) 558-2971 phone
(304) 558-1035 fax
ann.a.goldberg@wv.gov

LEGISLATIVE RULE TITLE: PULSE OXIMETRY NEWBORN TESTING

1. Authorizing statute(s) citation WV Code §§16-1-4, 16-44-1 and 16-44-2

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
Public Comment period June 29 - July 29, 2012

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

c. Date of Public Hearing(s) *or* Public Comment Period ended:
public comment period ended July 29, 2012.

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

Attached _____ No comments received X

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

no hearing - Agency Approved rule filed August _____, 2012

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

Ann Goldberg, Director, Public Health Regulations
Bureau for Public Health
350 Capitol Street, Room 702
Charleston, WV 25301
304 558-2971 phone
304 558-1035 fax
ann.a.goldberg@wv.gov

- 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)

Anne Williams, Director OMCFH
Bureau for Public Health
350 Capitol Street, Room 427
Charleston, WV 25301
304 558-5388 phone
304 558-4984 fax
anne.a.williams@wv.gov

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.

n/a

b. Date of hearing or comment period:

Comment period from June 29th to July 29, 2012

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

n/a/

d. Attach findings and determinations and reasons:

Attached

64CSR100, Pulse Oximetry Newborn Testing
Department of Health and Human Resources
Bureau for Public Health
Office of Maternal, Child and Family Health

BRIEF SUMMARY

This rule implements the Pulse Oximetry Newborn Testing Act by authorizing the Commissioner of the Bureau for Public Health to require all birthing facilities licensed by the Department of Health and Human Resources, that provide birthing services and newborn care services, to perform pulse oximetry testing on all newborns. The testing is to be performed when the newborn is twenty-four to forty-eight hours of age, or as late as possible if the newborn is to be discharged from the facility before he or she is twenty-four hours of age.

STATEMENT OF CIRCUMSTANCES

This rule is being proposed in accordance with legislation, HB 4327, passed in the Regular Session of 2012.

TITLE 64

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

SERIES 100

PULSE OXIMETRY NEWBORN TESTING

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SECRETARY OF STATE

§64-100-1. General.

1.1. Scope -- This rule implements the Pulse Oximetry Newborn Testing Act to require testing and provide timing requirements for such testing. This rule should be read in conjunction with WV Code §16-44-1 and §16-44-2. The WV Code is available in public libraries and on the Legislature's web page, <http://www.legis.state.wv.us/>.

1.2. Authority -- WV Code §§16-44-1 and 16-44-2.

1.3. Filing Date --

1.4. Effective Date --

§64-100-2. Application.

2.1. Application -- This rule applies to all birthing facilities licensed by the Department of Health and Human Resources that provide birthing services and newborn care services.

§64-100-3. Definitions.

3.1. Birthing Facility – An inpatient or ambulatory health care facility licensed by the Department of Health and Human Resources that provides birthing and newborn care services.

3.2. Commissioner – The Commissioner of the Bureau for Public Health or his or her authorized representative.

3.3. 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.

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

§64-100-4. Responsibilities of Birthing Facilities.

4.1. All birthing facilities shall cause to be performed a pulse oximetry screening on every newborn in its care.

4.2. The pulse oximetry screening shall be performed when the newborn is twenty-four to forty-eight hours of age, or as late as possible if the newborn is to be discharged from the facility before he or she is twenty-four hours of age.

4.3. 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.

§64-100-5. Recommended Protocol for Pulse Oximetry Testing.

5.1. The following are recommendations from the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, the American Academy of Pediatrics, and the Centers for Disease Control and Prevention.

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

5.3. The pulse oximetry screening shall be performed when the newborn is twenty-four to forty-eight hours of age, or as late as possible if the newborn is to be discharged from the facility before he or she is twenty-four hours of age.

5.4. 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 pass the screening test and no additional evaluation will be required unless signs or symptoms of CHD are present.

5.5. 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 their pediatrician and if indicated referred for an echocardiogram at the closest ultrasound facility that has experience in newborn cardiac echocardiograms. The echocardiogram will be interpreted by a pediatric cardiologist who will then make appropriate arrangements for follow-up when necessary.

5.6. If the newborn's oxygen saturation is <90% in either the hand or foot he or she should be immediately referred for additional evaluation.

5.7. The pulse oximetry guidelines and supporting information may be found online at <http://www.wvdhhr.org/mcfh>.

§64-100-6. Confidentiality.

The pulse oximetry screening results recorded on the birth score sheet or other data reporting form shall be confidential and shall not be released or disclosed to anyone other than the child, his or her parents, guardian or representatives for any reason other than data analysis and planning purposes by public health officials.

§64-100-7. Administrative Due Process.

Any persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the bureau for public health's rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.