

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

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2012 JUN 29 PM 3: 08

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

Form #2

**NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE**

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

RULE TYPE: LEGISLATIVE CITE AUTHORITY: WV Code §§16-4-1, 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

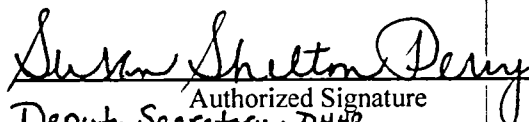
TITLE OF RULE BEING PROPOSED: PULSE OXIMETRY NEWBORN TESTING

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 JULY 29, 2012 AT 12 NOON ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

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

Ann Goldberg, Director  
~~Public Health Regulations~~  
Bureau for Public Health  
350 Capitol St. Room 702  
Charleston, WV 25301  
ann.a.goldberg@wv.gov  
(304) 558-2971 phone  
(304) 558-1033 fax

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

  
Authorized Signature  
Deputy Secretary, DHR

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

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 proposed rule further 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 and such testing 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.

### **STATEMENT OF CIRCUMSTANCES**

The rules and regulations regarding the Pulse Oximetry Newborn Testing are being proposed as mandated by legislation.

# 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.

There are no costs to the state associated with this 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)
<b>1. Estimated Total Cost</b>	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
<b>2. Estimated Total Revenues</b>	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

Department of Health and Human Resources

Authorized Representative

*Susan Shelton Perry*  
Deputy Secretary  
Michael J. Lewis, M.D., Ph.D.  
Cabinet Secretary

TITLE 64

FILED

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

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OFFICE WEST VIRGINIA  
SECRETARY OF STATE

SERIES 100

PULSE OXIMETRY NEWBORN TESTING

**§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.