

**WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

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2003 JUN 24 A 8: 52

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: DHHR - Division of Health TITLE NUMBER: 64

RULE TYPE: legislative CITE AUTHORITY: WV Code §§16-1-4 and 16-40-7

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: 81

TITLE OF RULE BEING PROPOSED: Birth Defects Information 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 July 24 2003 AT 4:30 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Division of Maternal, Child & Family
Health - DHHR
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

4.20

Statement of Circumstances

The rules and regulations regarding the West Virginia Birth Defects Surveillance System are being proposed as mandated by WV Code §16-40-7.

Brief Summary of the Rule

This rule provides for the establishment and implementation of a statewide birth defects information system for the collection and reporting of congenital anomalies and abnormal conditions, and provides for the appointment of an advisory council for the system. This represents an expansion of the existing West Virginia Birth Defects Surveillance System.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Birth Defects Information System, 64csr81

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: Division of Health
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$		\$222,604	\$200,604
Personal Services				\$163,217	\$163,217
Current Expense				\$50,387	\$37,387
Repairs & Alterations					
Equipment				\$9,000	
Other					
Revenue					

2. Explanation of above estimates.

Personal Services

2.0 - FTE Nurse III	\$83,112
1.0 - FTE HHR Specialist, Senior	\$27,252
0.33 - FTE Programmer Analyst II	\$11,021
FICA, Workers Comp, PERS @ 23.59%	\$28,635
Admin. Fees & Public Employees Health Insurance @ 2.33 FTE @ \$5,664	\$13,197
	<u>\$163,217</u>

Current Expense

Travel	\$8,000
Supplies	\$23,000
Hospitality	\$3,000
Indirect Costs @ 13.5%	\$16,387
	<u>\$50,387</u>

Equipment

Computers, printers and monitors for 3 FTEs will be required	\$9,000
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Total \$222,604

3. Objectives of this rule:

The purpose of this bill is to establish and implement a statewide birth defects information system.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

The Department of Health and Human Resources has a federal grant award from the Centers for Disease Control to establish a statewide birth defects information system. The federal grant funds will be available for three years, thereafter, the State will be required to pay the cost of maintaining the system. The estimated cost is \$ 222,604 for the first year and \$200,604 a year thereafter. Two (2) nurses, one (1) health and human resource specialist, senior and a part time (.33 FTE) programmer analyst will be needed to implement this legislation.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

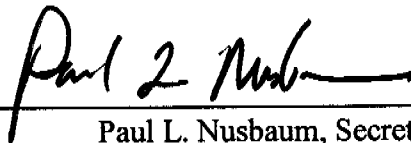
We anticipate no expense for any political subdivision, specific industries, or Specific group of citizens.

C. Economic Impact on Citizens/Public at Large.

We anticipate no expense for any citizens/public at large.

Date: _____

Signature of Agency Head or Authorized Representative:



Paul L. Nusbaum, Secretary
Department of Health and Human Resources

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: June 24, 2003

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Martha Barnitt

Department of Health and Human Resources

State Capitol Complex, Building 3, Room 206; Charleston, WV 25305

Telephone: (304) 558-5598

LEGISLATIVE RULE TITLE: Birth Defects Information System

1. Authorizing statute(s) citation: WV Code §§ 16-1-4 and 16-40-7

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period: June 24, 2003

b. What other notice, including advertising, did you give of the hearing?
Notice of the proposed rule will be sent to the stakeholders relevant to the West Virginia Birth Defects Surveillance System, including state agencies and birthing facilities.

c. Date of Public Hearing(s) or Public Comment Period ended: July 24, 2003

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

Attached N/A No comments received N/A

- 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):

 Martha Barnitt

 Policy Development & Regulatory Affairs - DHHR

 Capitol Complex, Building 3, Room 206

 Charleston, WV 25305

 Tel: 558-5598

- 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):

 Kathy Cummons

 Office of Maternal, Child & Family Health

 350 Capitol Street, Room 427

 Charleston, West Virginia 25301

 Tel: 558-5388

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 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:

N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

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

FILED

2001 JUN 24 A 8:52

SERIES 81
BIRTH DEFECTS INFORMATION SYSTEM

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§64-81-1. General.

1.1. Scope. – This rule establishes and implements a statewide birth defects information system for the collection and reporting of congenital anomalies and abnormal conditions. This rule should be read in conjunction with W. Va. Code §§16-1-18 and 16-40-1 et seq. The W. Va. Code is available in public libraries and on the Legislature's web page, <http://www.legis.state.wv.us/>.

1.2. Authority. – W. Va. Code §§16-1-4 and 16-40-7.

1.3. Filing Date. –

1.4. Effective Date. –

§64-81-2. Application and Enforcement.

2.1. Application. – This rule applies to all infants born in West Virginia and to the health care providers caring for children at birth and up to the age of six (6) that are diagnosed with a congenital anomaly or abnormal condition based upon national standards.

2.2. Enforcement. – This rule is enforced by the commissioner of the bureau for public health.

§64-81-3. Definitions.

3.1. Advisory Council. – The committee appointed pursuant to W. Va. Code §16-40-6 to advise on the establishment and implementation of the birth defects information system.

3.2. Freestanding Birthing Center. – A health care facility in which births routinely occur, that is not licensed under W. Va. Code §16-5B-1 et seq.

3.3. Health Care Providers. – A physician, or his or her designee, at any medical facility including, but not limited to private clinics, health departments and hospitals.

3.4. Hospital. - A facility licensed as a hospital pursuant to W. Va. Code §16-5B-1 et seq. and Welch Emergency Hospital.

3.5. Nurse-Midwife. – An individual authorized under W. Va. Code §30-15 to practice nurse-midwifery.

3.6. Congenital Anomaly and Abnormal Condition. - An abnormality of the body's structure or inherent function present at birth, whether the abnormality is detected at the time of delivery or becomes apparent at a later date.

3.7. Birth Defects Information System - The data base that contains individual case demographic and diagnostic information maintained by the Office of Maternal, Child and Family Health within the Bureau for Public Health.

§64-81-4. Purposes of Birth Defects Information System.

Purposes of Birth Defects Information System include:

- 4.1. To identify and describe congenital anomalies and abnormal conditions;
- 4.2. To detect trends and clusters of congenital anomalies and abnormal conditions;
- 4.3. To quantify morbidity and mortality of congenital anomalies and abnormal conditions;
- 4.4. To stimulate epidemiological research regarding congenital anomalies and abnormal conditions;
- 4.5. To identify the risk factors in and the prevention of congenital anomalies and abnormal conditions;
- 4.6. To facilitate access to treatment of persons with congenital anomalies and abnormal conditions; and
- 4.7. To inform and educate the public about congenital anomalies and abnormal conditions and their prevention.

§64-81-5. Reporting Requirements.

5.1. The commissioner shall require each physician, nurse-midwife, hospital and freestanding birthing center to provide information to the birth defects information system on all patients up to the age of six (6) that have been diagnosed with a congenital anomaly or abnormal condition.

5.1.a. The commissioner may not require the reporting of personal identifying information or enter into the system any personal identifying information regarding congenital anomalies or abnormal conditions of a child whose parent or legal guardian objects on the basis of religious beliefs according to W. Va. Code §16-40-2.

5.2. The information shall be provided on forms obtained from the Office of Maternal, Child and Family Health in the Bureau.

5.3. Cases to be included in the information system must consist of the International Classification of Diseases (ICD) diagnoses. After the information is submitted, the advisory council shall recommend the types of cases that are reportable to the information system based on national standards.

5.4. If a child's parent or legal guardian wants information concerning the child removed from the birth defects information system for religious reasons:

5.4.a. The commissioner shall remove all identifying information from the record, but leave the case in the system for reporting purposes; and

5.4.b. A form for the parent or legal guardian to complete for the removal of the child's identifying information shall be available upon request from the Bureau for Public Health and on the Bureau's web page: <http://www.wvdhhr.org/>.

§64-81-6. Confidentiality.

6.1. Anyone who obtains confidential information while implementing W.Va. Code §16-40-1 et seq. may disclose it only to reporting sources, persons demonstrating a need that is essential to health related research or care of persons with congenital anomalies and abnormal conditions, or as required or permitted by law.

6.2. Anyone who obtains confidential information while implementing W.Va. Code §16-40-1 et seq. shall provide a statement that he or she fully understands the confidentiality of the information and will maintain it.

6.3. Records received and information assembled by the birth defects information system are confidential medical records.

6.4. Reports published with statistical data relating to birth defects and other adverse birth outcomes that do not in any manner identify individual patients or individual sources of information are permissible, provided that the data is not for such small geographic areas or in categories with few entries that together with other publicly available information, the patients could be identified.

§64-81-7. Penalties.

7.1. Anyone who violates the provisions of W.Va. Code §16-40-1 et seq. or this rule is subject to the penalties in W.Va. Code §16-1-17 and -18.