

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

Form #2

Do Not Mark In This Box

2013 JUN 19 PM 4:59

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

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

RULE TYPE: Legislative CITE AUTHORITY: WV CODE §§ 16-4, 16-1-11(A) and 16-5A-2a(e)

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 68

TITLE OF RULE BEING AMENDED: CANCER REGISTRY

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: \_\_\_\_\_

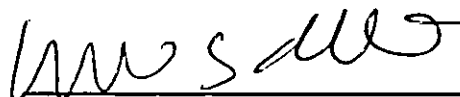
TITLE OF RULE BEING PROPOSED: \_\_\_\_\_

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 19<sup>th</sup> 2013 AT 12 NOON ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

~~LORETTA HADDY, PhD  
DIRECTOR, CEPS, BPH  
350 CAPITOL STREET, RM 125  
CHARLESTON, WV 25301  
LORETTA.E.HADDY@WV.GOV  
(304) 558-5358~~

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

~~ANN GOLDBERG, DIRECTOR  
PUBLIC HEALTH REGULATIONS  
350 CAPITOL STREET, ROOM 702  
CHARLESTON, WV 25301  
ANN.A.GOLDBERG@WV.GOV  
(304) 558-2971~~



Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

## FISCAL NOTE FOR PROPOSED RULES

Rule Title: 64CSR68 Cancer Registry

Type of Rule:                      X      Legislative                              Interpretive                              Procedural

Agency: Health and Human Resources

Address: One Davis Square  
Suite 100, East  
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.

Cancer researchers contact the West Virginia Cancer Registry (WVCR) to request data linkage services. Written informed consents from research study participants are obtained from the cancer researcher prior to data linkage or data release. The researcher provides a dataset containing confidential information on study participants to the WVCR Epidemiologist. The WVCR Epidemiologist "links" the researcher's dataset with the WVCR database to identify study participants who developed cancer. Data from matched or "linked" cases are provided back to the researcher. Datasets provided by Researchers to the WVCR have contained between 30,000 and 90,000 records, and these records are linked with approximately 200,000 cases stored in the cancer registry database which covers the time period of 1995 through 2011. The cancer registry database increases by approximately 12,000 cases each year. Given the number of cases involved in these linkages, a significant portion of the Epidemiologist's time is required to create and manipulate data files, conduct the data linkage and provide data back to the researcher. Additional staff time is required to prepare the necessary Confidentiality and Data Use Agreements.

### 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		
	2013 Increase/Decrease (use "-" )	2014 Increase/Decrease (use "-" )	Fiscal Year (Upon Full Implementation)
<b>1. Estimated Total Cost</b>			
Personal Services			
Current Expenses			
Repairs and Alterations			
Buildings			
Equipment			
Land			
Other Assets			
<b>2. Estimated Total Revenues</b>	0	9,000	9,000

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

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

WVCR proposes charging the following fees for data linkages:

Base fee (for setting up linkage):\$800

Each additional 2,500 records to be linked: \$100

Depending upon the number of links, the WVCR estimates that initially 3 linkages could be performed per year and approximately \$9,000 generated per year.

**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.

[Empty box for memorandum content]

Date 6/11/13

Agency  
Department of Health and Human Resources

Authorized Representative  
[Signature]  
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: June 2013

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* DHHR- Bureau for Public Health  
350 Capitol Street, Room 702  
Charleston, WV 25301  
(304) 558-2971

LEGISLATIVE RULE TITLE: Cancer Registry 64CSR68

1. Authorizing statute(s) citation WV Code §§ 16-1-4, 16-1-11(a), 16-5A-2a(e)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:  
June 2013

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)

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- 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  
ann.a.goldberg@wv.gov

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- 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)

Loretta Haddy, Director  
Bureau for Public Health  
Office of Epidemiology and Prevention Services  
350 Capitol Street, Room 125  
Charleston, WV 25301  
(304) 558-5358  
loretta.e.haddy@wv.gov

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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

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b. Date of hearing or comment period:

May \_\_\_\_\_ June \_\_\_\_\_

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 n/a \_\_\_\_\_

Legislative Rule, 64CSR68  
CANCER REGISTRY  
Office of Epidemiology and Prevention Services  
Bureau for Public Health  
Department of Health and Human Resources

### **BRIEF SUMMARY**

This rule is being amended to allow the West Virginia Cancer Registry (WVCR) to charge a fee for a cancer researcher's request to link the researcher's dataset with the WVCR database. This fee will allow WVCR data to be appropriately used to describe the epidemiology of cancer in WV. There is also an amendment in the rule to require the additional reporting of a cancer patient's physical address, if available, in addition to the patient's mailing address. There is currently no fee being charged for doing cancer registry data linkages.

Cancer researchers have recognized the wealth of data in WV's 20-year cancer registry data base which stores close to 200,000 cases and adds approximately 12,000 new cases each year. Requests for data linkages for research projects and special studies have begun to increase since the WVCR hired a Cancer Epidemiologist with analytical skills capable of performing such data linkages. These requests are a time consuming processes. Most other states with state cancer registries have charged fees to cover such analytical work for years. By promulgating a fee in this rule, it will enable a fair compensation to advance cancer research in West Virginia. Most large research projects are well funded and able to cover the cost for performing data linkages.

### **STATEMENT OF CIRCUMSTANCES**

Over the course of the past 20 years of administering this rule the Division of Cancer Epidemiology's Cancer Registry has just begun doing data linkages in 2011-12 to support special research requests. This rule amendment is being promulgated to allow the WVCR to recoup administrative and associated costs to process these special research data requests and the addition of physical address will provide needed information to geographically code the distribution of newly diagnosed cancer cases in WV.

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

2013 JUN 19 PM 4:59

SERIES 68  
CANCER REGISTRY

**§64-68-1. General.**

1.1. Scope. -- This legislative rule establishes standards and procedures for reporting cancer cases to the West Virginia Cancer Registry, maintaining the confidentiality of information in its cancer registry and disclosing information from the cancer registry.

1.2. Authority. -- W. Va. Code §§16-1-4, 16-1-11(a) and 16-5A-2a(e).

1.3. Filing Date. -- April 21, 2011.

1.4. Effective Date. -- April 21, 2011.

**§64-68-2. Application and Enforcement.**

2.1. Application. -- This rule applies to health care providers, health care facilities and persons with access to or in charge of medical records or other sources of cancer-related information.

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

**§64-68-3. Definitions.**

3.1. Abstract -- A summary of information relating to the diagnosis and course of disease of an individual case of cancer.

3.2. Bureau -- The bureau for public health in the department of health and human resources.

~~3.2.~~ 3.3. Cancer -- A cellular tumor, the natural course of which is fatal and usually associated with the formation of secondary tumors.

~~3.3.~~ 3.4. Cancer Registry -- A registry maintained for the collection of information concerning newly diagnosed cancer cases.

~~3.4.~~ 3.5. Commissioner -- The commissioner of the bureau for public health in the department of health and human resources or his or her designee.

~~3.5.~~ 3.6. Confidential Information -- Information which identifies individual cancer patients, health care facilities or health care providers.

3.7. Data linkages -- The service that the Bureau provides to cancer researchers or other qualified individuals or healthcare facilities that involves the linkage of an external data file to individual level data maintained in the West Virginia Cancer Registry.

~~3.6.~~ 3.8. Diagnosis -- The determination of the nature of a case of disease.

~~3.7.~~ 3.9. Health Care Facility -- Any hospital, nursing home, clinic, cancer treatment center, laboratory, or any other facility or institution which provides health care or diagnostic services to individuals.

~~3.8.~~ 3.10 Health Care Provider -- Any physician, dentist, nurse, or other individual who provides to individuals medical, dental, nursing, or other health care services of any kind.

~~3.9.~~ 3.11. Hospital -- An entity subject to licensure as a hospital under W. Va. Code §16-5B-1.

~~3.10.~~ 3.12. Person -- An individual, partnership, corporation or other legal entity.

~~3.11.~~ 3.13. Reportable Cancer Case -- Any case of cancer diagnosed after December 31, 1992, where the primary tumor is determined to be malignant or carcinoma in situ, with the exception of basal cell or squamous cell carcinomas of the skin and carcinoma in situ of the cervix.

~~3.12.~~ 3.14. Reporting Source -- A health care facility or provider which diagnoses or provides treatment for cancer.

~~3.13.~~ 3.15. West Virginia Cancer Registry -- The office within the bureau for public health which collects and maintains information on cancer cases.

**§64-68-4. Reporting.**

4.1. All reporting sources shall provide the West Virginia Cancer Registry with the following patient-related information on all reportable cancer cases to the extent that the information would be routinely available at a particular type of reporting source:

4.1.a. The last name, first name, and middle initial;

4.1.b. Social security number;

4.1.c. Sex;

4.1.d. Birth date;

4.1.e. Maiden name;

4.1.f. Race/ethnicity;

4.1.g. Physical address at the time of diagnosis, including street, city, county and zip code or the mailing address at the time of diagnosis if physical address is unavailable;

4.1.h. Date of diagnosis;

4.1.i. A description of the cancer, including site, type, and any other information needed to describe the case clearly;

4.1.j. Stage of disease at diagnosis using:

4.1.j.1. Surveillance, Epidemiology, and End Results (SEER) system; and

4.1.j.2. American Joint Committee on Cancer (AJCC) system if maintained by the reporting source.

4.1.k. The treatment of the cancer and the patient's medical status;

4.1.l. Date of death, if the patient has died;

4.1.m. Cause of death;

4.1.n. Usual occupation;

4.1.o. Usual industry of employment;

4.1.p. Name of patient's health insurance provider;

4.1.q. Marital status; and

4.1.r. Other information relevant for the identification of hazards to the public, i.e., the presence of factors placing the patient at risk for development of cancer. Risk factor information includes, but is not limited to: tobacco use, familial history of cancer and alcohol use.

4.2. Each cancer case report shall also include:

4.2.a. The name of the reporting source;

4.2.b. The name of the diagnosing physician; and

4.2.c. Sufficient narrative to determine the accuracy of coding and information.

4.3. Features of Health care facility reporting.

4.3.a. Any health care facility diagnosing or treating cancer patients within the state of West Virginia shall submit the required information on all reportable cases of cancer served by that facility to the West Virginia Cancer Registry within six months of diagnosis.

4.3.b. Reports shall be submitted monthly via electronic information transfer or paper copy of case abstracts, in a manner or on forms acceptable to the West Virginia Cancer Registry.

4.3.c. If the health care facility fails to report in a format prescribed by the commissioner, authorized West Virginia Cancer Registry personnel may enter the health care facility, access the information and report it in the appropriate format. In these cases the bureau for public health shall assess the health care facility a service fee for accessing and reporting the information. In accordance with W. Va. Code §16-1-11(a) and this rule, the fee collected shall be deposited into the health services fund. The fee shall be based upon the fair market value of the services. The health care facility shall pay the bureau for public health within sixty days of assessment of the fee.

4.4. Health care facilities shall provide authorized West Virginia Cancer Registry personnel access to all medical records which would identify cases of cancer or establish characteristics of cancer to collect the required information on reportable cases of cancer for the purposes of assuring the accuracy and completeness of reported data. Registry staff shall schedule access at reasonable times convenient to the health care facility and registry staff. The West Virginia Cancer Registry staff shall notify the health care

4.4. Health care facilities shall provide authorized West Virginia Cancer Registry personnel access to all medical records which would identify cases of cancer or establish characteristics of cancer to collect the required information on reportable cases of cancer for the purposes of assuring the accuracy and completeness of reported data. Registry staff shall schedule access at reasonable times convenient to the health care facility and registry staff. The West Virginia Cancer Registry staff shall notify the health care facility a minimum of thirty days in advance of its need to access medical records to allow for the health care facility to prepare records for review.

4.5. The West Virginia Cancer Registry shall collect standardized data usable for research purposes.

**§64-68-5. Confidentiality; Disclosure.**

5.1. No person who obtains information protected by the provisions of W. Va. Code §16-5A-2a and this rule may disclose confidential information to any other person except in strict compliance with W. Va. Code §16-5A-2a and this rule.

5.2. Any person who obtains information protected by the provisions of W. Va. Code §16-5A-2a and this rule shall sign a statement that he or she fully understands and will maintain the confidentiality of the information.

5.3. The West Virginia Cancer Registry may release information which identifies a specific patient to the reporting source which originally reported the cancer case.

5.4. The West Virginia Cancer Registry may release information which identifies a specific patient whose address at the time of diagnosis was outside West Virginia to the central cancer registry in the state where the patient resides. The West Virginia Cancer Registry shall release the information only to central cancer registries in states which have confidentiality standards equivalent to those of West Virginia and which establish reciprocal reporting with West Virginia. The West Virginia Cancer Registry shall have a written agreement with other state cancer registries to which it releases information which specifically addresses provisions for maintaining confidentiality.

5.5. The West Virginia Cancer Registry may release case data to cancer researchers for the purposes of cancer prevention, control and research.

5.5.a. Identifying data may be released for research purposes provided:

5.5.a.1. The researcher supplies the West Virginia Cancer Registry with written consent of the patient, physician, health care provider or personal representative of a deceased case, whichever is appropriate; and

5.5.a.2. The researcher assures that the data received from the West Virginia Cancer Registry will be maintained by the researcher with the same level of confidentiality as that maintained by the West Virginia Cancer Registry.

5.5.b. The West Virginia Cancer Registry may contact individual patients who have cancer and are in the West Virginia Cancer Registry for the purpose of patient recruitment for a research study.

5.5.c. The West Virginia Cancer Registry may provide data linkages to appropriate researchers or institutions to allow for the meaningful use of cancer registry data for a fee. The fee shall be assessed and collected by the Office of Epidemiology and Prevention Services of the bureau and shall be deposited into the health services fund.

**§64-68-6. Violations and Sanctions.**

Failure to comply with this rule as required subjects a person to the criminal penalties prescribed in W. Va. Code §16-1-18.

**§64-68-7. Administrative Due Process.**

Those 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 Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.