

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

Form #2

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OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**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 §§16-1-4, 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 23, 2010 AT 12:00 Noon ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

|                                      |                                 |
|--------------------------------------|---------------------------------|
| Ann A. Goldberg, Director            | Loretta Haddy, PhD              |
| <del>Public Health Regulations</del> | <del>State Epidemiologist</del> |
| Bureau for Public Health             | Bureau for Public Health        |
| 350 Capitol Street, Rm 702           | 350 Capitol Street, Rm 125      |
| Charleston, WV 25301                 | Charleston, WV 25301            |
| 304 558-0035 Phone                   | 304 558-5358 phone              |
| 304 558-1035 FAX                     | 304 558-1899 FAX                |
| ann.a.goldberg@wv.gov                | loretta.e.haddy@wv.gov          |

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

  
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

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

### **BRIEF SUMMARY**

The proposed rule is to establish 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. This data can provide information relative to the presence of risk factors that place patients at risk for developing cancer. The value of this data can allow researchers under confidential measures to analyze the cancer registry data for purposes of cancer prevention, control and research.

### **STATEMENT OF CIRCUMSTANCES**

West Virginia has had a cancer registry in place since 1993 but currently does not allow for full reimbursement of cancer record abstracting from all facilities in West Virginia. With expansion of the Joint Committee on Cancer requirements for collaborative staging of cancer diagnoses, it is labor intensive and there needs to be equality in setting fees and treating all facilities the same that is shall be based upon the fair market value of the services.

## FISCAL NOTE FOR PROPOSED RULES

Rule Title: 64CSR68 Cancer Registry

Type of Rule:                      X   Legislative                           Interpretive                           Procedural

Agency: Health and Human Resources

Address: 1900 Kanawha Blvd. East  
Bldg. 3, Room 206  
Charleston, WV 25305

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 is to establish 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. The WV Cancer Registry collects and maintains information on cancer cases as outlined in this legislative rule. The proposed revision to the existing rule allows the Bureau for Public Health to assess health care facilities a service fee for accessing and reporting the information regardless of bed capacity. It is estimated that this rule will generate an additional \$22,850 per year 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                             |   |  |
|------------------------------------|---|---|--|
|                                    | 2010<br>Increase/Decrease<br>(use "-" ) | 2011<br>Increase/Decrease<br>(use "-" ) | Fiscal Year<br>(Upon Full<br>Implementation) |
| <b>1. Estimated Total Cost</b>     | 0                                       | 0                                       | 0  |
| <b>Personal Services</b>           |   |   |  |
| <b>Current Expenses</b>            |   |   |  |
| <b>Repairs and Alterations</b>     |   |   |  |
| <b>Equipment</b>                   |   |   |  |
| <b>Other</b>                       |   |   |  |
| <b>2. Estimated Total Revenues</b> |   | 22,850                                  | 22,850                                       |

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

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

The fees collected for abstracting cancer records are estimated to be \$22,850 based on the average number of 457 cases (for facilities with under 50 beds) @ \$50/case abstracted from health care facilities for which such services are provided.

**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.

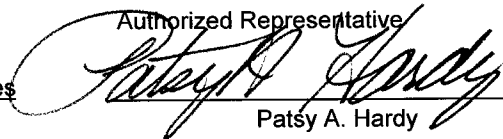
Date

6-23-10

Agency

Department of Health and Human Resources

Authorized Representative



Patsy A. Hardy  
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 2010 \_\_\_\_\_

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Ann A. Goldberg  
Bureau for Public Health  
350 Capitol Street, Rm. 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) and 16-5A-2a(e)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:  
June 2010 \_\_\_\_\_

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:  
\_\_\_\_\_

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)

N/A

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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  
350 Capitol Street, Rm. 702  
Charleston, WV 25301  
304 558-0035 - phone  
~~304 559-1035 - fax~~  
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, PhD  
State Epidemiologist  
Bureau for Public Health  
340 Capitol St. Rm 125  
Charleston, WV  
~~304 558-5358~~  
304 558-1895  
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:

From June 2010 to July 2010

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

TITLE 64

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

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. -- ~~May 8, 2006.~~

1.4. Effective Date. -- ~~May 8, 2006.~~

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

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

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

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

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

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

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

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

3.13. 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. Address at the time of diagnosis, including street, city, county and zip code;

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 ~~Commission~~ 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; ~~and~~
- 4.1.p. Name of patient's health insurance provider;
- 4.1.q. Marital status; and

~~4.1.p.~~ 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, ~~if a health care facility is licensed for fifty beds or more~~ 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 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.

**§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, 64 CSR 1.