

FISCAL NOTE FOR PROPOSED RULES

Rule Title: CANCER REGISTRY, 64CSR68

Type of Rule: X Legislative Interpretive Procedural

Agency: DHHR - BUREAU FOR PUBLIC HEALTH

Address: DHHR - BUREAU FOR PUBLIC HEALTH
350 CAPITOL STREET
CHARLESTON, WV 25301-3715

Phone Number: (304) 558-2971 or 558-0035 Email: annspaner@wvdhhr.org

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 amendment will have no effect on costs or revenues of state government.

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		
	2005 Increase/Decrease (use "-")	2006 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Equipment	0	0	0
Other	0	0	0
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.

There will be no change created in revenue amount by amendment of this rule.

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.

While the proposed rule will not have a fiscal impact in terms of any increase or decrease in costs or revenues, it will permit the Bureau for Public Health to carryover any unexpended fees collected from one state fiscal year to the next. The minor change in section 4.3. of the rule eliminates a reference to "reimbursement of the cost" and adds the requirement for the fees to be deposited in the health services fund account, which was set up in the statute to receive fees such as this one. All fees collected will still be used for the Cancer Registry program.

Date

7/28/05

Agency

Department of Health and Human Resources

Authorized Representative

Martina Yeager Walker

Martina Yeager Walker
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: July 29, 2005

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

LEGISLATIVE RULE TITLE: Cancer Registry

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 29, 2005, rule filed for Public Comment

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:
July 29, 2005 at noon

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)

July 29, 2005

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

<u>Ann A. Spaner</u>	<u>John D. Law</u>
Bureau for Public Health	Secretary's Office, DHHR
350 Capitol Street, Room 702	Building 3, Room 206
Charleston, WV 25301	Charleston, WV 25305
558-0035 Phone, 558-1035 Fax	558-7899 Phone; 558-7075 Fax
<u>annspaner@wvdhhr.org</u>	<u>johnlaw@wvdhhr.org</u>

- 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, State Epidemiologist
Bureau for Public Health
350 Capitol Street, Room 125
Charleston, WV 25301
558-7078 Phone; 558-1553 Fax
lorettahaddy@wvdhhr.org

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:

The comment period ran from June 29 to July 29, 2005.

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

**Department of Health and Human Resources
Bureau for Public Health
Legislative Rule
Title 64, Series 68**

CANCER REGISTRY

BRIEF SUMMARY

Each year the Cancer Registry collects a service fee from some health care facilities to do the mandatory reporting for the facility in accordance with this rule. This amendment is designed to allow the bureau for public health to carryover the fees that are collected by this program by depositing them in the health services fund, in accordance with WV Code §16-1-11(a). This will allow the agency to use those funds to continue to support the Cancer Registry program. All other minor changes are in the nature of clean up and corrections.

FILED

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

2005 JUL 29 P 3:18

SERIES 68
CANCER REGISTRY

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§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 ~~§§16-5A-2a(e), 16-1-21(d) and 16-1-7~~ 16-1-4, 16-1-11(a) and 16-5A-2a(e).

1.3. Filing Date. -- ~~April 13, 2000.~~

1.4. Effective Date. -- ~~July 1, 2000.~~

§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 ~~director~~ commissioner of the ~~division of 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. Commissioner – The commissioner of the bureau for public health in the department of health and human resources or his or her designee.

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

~~3.5.~~ 3.6. Diagnosis - The determination of the nature of a case of disease.

~~3.6. Director – The director of the division of health of the department of health and human resources or his or her lawful designee.~~

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 ~~division of~~ 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 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. 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. 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 (6) 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 ~~director~~ 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 (50) beds or more, the ~~division of~~ bureau for public health shall assess the health care facility a service fee for ~~reimbursement of the cost of~~ accessing and reporting the information. Under the authority of WV 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 ~~division of~~ bureau for public health within sixty (60) 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 (30) 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.

6.1. 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.

7.1. 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 ~~division of~~ bureau for public health Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.