



## BRIEF SUMMARY OF THE RULE

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

## **STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE**

This proposed rule change is to ensure that health facilities report cases of cancer to the Division of Health's West Virginia Cancer Registry (WVCR) as required by W. Va. § 16-5A-2a for the compilation of complete, accurate, and timely cancer data for West Virginia. If a health care facility fails to report as required, and if a WVCR abstractor does the reporting for the health care facility, this rule proposes that for health care facilities with fifty (50) or more beds the Division of Health be reimbursed for performing the reporting activities.

When the Division of Health established a cancer registry in 1993, few hospitals had registries in place to report their cancer cases. Instead, most hospitals provided WVCR abstractors access to hospital medical records to both report the hospitals' cancer cases for them and to assist the hospitals to establish their cancer registries. Increasingly, hospitals have discontinued their cancer registries, have not allowed their personnel the time to complete the cancer reporting, and have relied primarily on the WVCR abstractors to obtain and report the data for them.

The proposed rule changes also reflect current cancer registry terminology and data collected by the Division of Health.

## 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: August 4, 1999

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Division of Health

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 265, Charleston, WV 25305

Telephone: (304) 558-5598

LEGISLATIVE RULE TITLE: Cancer Registry, 64CSR68,

1. Authorizing statute(s) citation: WV Code Sections 16-5A-2a(e), 16-1-21(d) & 16-1-7

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:  
June 30, 1999

b. What other notice, including advertising, did you give of the hearing?  
Copies of the proposed rule is distributed to all licensed hospitals in WV, the WV Hospital Association, WV Medical Association, and the WV Society for Osteopathic Medicine.

c. Date of Public Hearing(s) or Public Comment Period ended:  
July 30, 1999

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

Attached  X  No comments received \_\_\_\_\_

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

August 4, 1999

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

Beth Marquart, Director, Office of Regulatory Development

Department of Health and Human Resources

Building 3, Room 265, Capitol Complex

Charleston, West Virginia 25305

(304) 558-5598 FAX: (304) 558-6051 bethmarquart@wvdhhr.org

- 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

Surveillance and Disease Control

Bureau for Public Health

1422 Washington Street, East

Charleston, West Virginia 25301 (304) 558-5358

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:

time and place 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:

N/A

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

N/A

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d. Attach findings and determinations and reasons:

Attached N/A

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**FISCAL NOTE FOR PROPOSED RULES**

**Rule Title:** Cancer Registry, 64 CSR 68

**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
<b>Estimated Total Cost</b>	\$	\$	\$	\$ 5,000	\$ 5,000
<b>Personal Services</b>					
<b>Current Expense</b>	\$			\$ 5,000	\$ 5,000
<b>Repairs &amp; Alterations</b>					
<b>Equipment</b>					
<b>Other</b>					
<b>Revenue</b>					

**2. Explanation of above estimates.**

The above estimate reflects the cost to the Department of Health and Human Resources, West Virginia Cancer Registry, to provide a cancer registry software program. A site license to provide the cancer registry software used by the WVCR to 28 additional hospitals would cost the central registry \$5,000 per year. The above estimate assumes that those hospitals not currently reporting their cancer cases to the West Virginia Cancer Registry would participate in the approach described and would not require the Department to utilize staff to identify and report their cancer cases.

**3. Objectives of this rule:**

- a. To obtain more accurate, complete and timely data regarding trends in cancer incidence, treatment, and survival in West Virginia.
- b. To increase the number of hospitals maintaining cancer registries and reporting newly diagnosed cancer cases to the division of health as required by Chapter 16-5A-2a.
- c. To provide for reimbursement of cancer reporting costs to the division of health.
- d. To increase the number of cancer programs in West Virginia that are approved by the American College of Surgeons. Currently, only 9 of the 55 non-federal hospitals in West Virginia have approved cancer programs. A hospital must have a cancer registry in place for a minimum of two years in order to apply to be an approved cancer program.
- e. To allow WVCR staff to focus on quality control activities, identify more of the growing number of cancer cases diagnosed and treated outside the hospital setting, and perform special studies with the cancer data collected.

**4. Explanation of Overall Economic Impact of Proposed Rule.**

**A. Economic Impact on State Government.**

If hospitals report their own cancer cases as required in Chapter 16-5A-2a, this would have negligible economic impact on state government. WVCR personnel time would be shifted from cancer data collection to quality control activities and data analysis resulting in more accurate data and more cancer information for West Virginia.

If hospitals choose to have the WVCR personnel perform their reporting activities, the central registry will need to hire additional staff (abstractor \$25,000 to \$30,000 including benefits) and additional current expense for travel & vehicle rental.

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


The 28 hospitals licensed for more than 50 beds that are not currently reporting their cancer cases to the division of health as required in Chapter 16-5A-2a would be required to either provide the personnel necessary to report their cancer cases or reimburse the state for providing this service based on the number of cases reported annually from that facility. The 16 hospitals that are currently reporting their cancer cases to the division as required in Chapter 16-5A-2a will not incur any additional costs.

**C. Economic Impact on Citizens/Public at Large.**

None, unless hospitals allocate the costs of reporting their cancer cases to their patients or their insurers.

**Date:**

**Signature of Agency Head or Authorized Representative**

  
\_\_\_\_\_  
**Joan E. Ohl, Secretary**  
**Department of Health and Human Resources**

**TITLE 64  
LEGISLATIVE RULES  
DIVISION OF HEALTH  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 68  
CANCER REGISTRY**

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**FOR REVIEW BY THE  
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

64CSR68

TITLE 64  
LEGISLATIVE RULES  
DIVISION OF HEALTH  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Aug 4 3 35 PM '99

OFFICE OF THE SECRETARY OF STATE

SERIES 68  
CANCER REGISTRY

**§64-68-1. General.**

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

1.2. Authority -- W. Va. Code §§16-5A-2a(e), 16-1-21(d) and 16-1-7.

1.3. Filing Date --

1.4. Effective Date --

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

2.1. Application -- This rule applies to health care providers, and health care facilities and to 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 of the division of 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 - ~~The office within the division of health which collects and maintains information on cancer cases.~~ A registry maintained for the collection of information concerning newly diagnosed cancer cases.

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

3.5. 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.

~~3.9.~~ 3.10. Person - An individual, partnership, corporation or other legal entity.

~~3.10.~~ 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.

~~3.11.~~ 3.12. Reporting Source - A health care facility or provider which diagnoses or provides treatment for cancer.

~~3.12. Tumor Registries - A registry maintained for the collection of information concerning newly diagnosed cancer cases.~~

3.13. West Virginia Cancer Registry - The office within the division of health which collects and maintains information on cancer cases.

### **§64-68-4. Reporting.**

4.1. All reporting sources shall provide the ~~cancer registry office~~ 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:

~~4.1.1~~ 4.1.a. The first name, last name, and middle initial;

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- 4.1.2 4.1.b. Social security number;
- 4.1.3 4.1.c. Sex;
- 4.1.4 4.1.d. Birth date;
- 4.1.5 4.1.e. Maiden name;
- 4.1.6 4.1.f. Race/ethnicity;
- 4.1.7 4.1.g. Address at the time of diagnosis, including street, city, county and zip code;
- 4.1.8 4.1.h. Date of diagnosis;
- 4.1.9 4.1.i. A description of the cancer, including site, type, stage, 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.
- 4.1.10. 4.1.k. The treatment of the cancer and the patient's medical status;
- 4.1.11. 4.1.l. Date of death, if the patient has died;
- 4.1.12. 4.1.m. Cause of death; and
- 4.1.n. Usual occupation;
- 4.1.o. Usual industry of employment; and
- 4.1.13 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 occupation alcohol use.

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4.2. Each cancer case report shall also include:

~~4.2.1~~ 4.2.a. The name of the reporting source; and

~~4.2.2~~ 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. Reporting sources with tumor registries~~ 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 source facility to the cancer registry West Virginia Cancer Registry within six (6) months of diagnosis. 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. If the health care facility fails to report in a format prescribed by the director, 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 health shall assess the health care facility a service fee for reimbursement of the cost of accessing and reporting the information. The fee shall be based upon the fair market value of the services. The health care facility shall pay the division of health within sixty (60) days of assessment of the fee.

~~4.4. Reporting sources without tumor registries~~ Health care facilities shall provide authorized cancer registry 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. The frequency of access shall be related to the number of patients seen and the incidence of reportable cancer cases. Registry staff shall schedule access in advance at reasonable times convenient to the reporting source health care facility and registry staff. West Virginia Cancer Registry staff shall provide notification of a minimum of thirty (30) days to allow for the health care facility to prepare records for review.

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

~~4.6. The cancer registry shall work toward the use of the cancer stage classifications of the American Joint Committee on Cancer.~~

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

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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 ~~cancer registry~~ 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 ~~cancer registry~~ 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 ~~cancer registry~~ 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 ~~cancer registry~~ 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.

### §64-68-6. Distribution of Rule.

6.1. The division and health care professional licensing boards and agencies may distribute this rule to any health care facility that has a duty under this rule.

### §64-68-7. Violations and Sanctions.

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

### ~~§64-68-6:~~ §64-68-8. Administrative Due Process.

8.1. 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 health Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

### ~~§64-68-7 Severability.~~

~~The provisions of this rule are severable. If any provisions of this rule are held invalid, the remaining provisions shall remain in effect.~~

## PUBLIC COMMENTS AND DEPARTMENT RESPONSES

### CANCER REGISTRY, 64CSR68

A public comment period on the proposed amendments to the rule, Cancer Registry, 64CSR68 was held beginning on June 30, 1999 and ending July 30, 1999. There were only two commenters. Comments are summarized below, and the Department's responses and changes to the rule are detailed.

**Comment:** The simple and incredibly important step of gathering accurate cancer data is critically important to cancer care. These proposed amendments allow the West Virginia Cancer Registry to address its obligation to the citizens of West Virginia.

**Response:** The Department agrees that accurate cancer data is essential to proper cancer care. The proposed amendments will ensure that health facilities report cases of cancer to the West Virginia Cancer Registry for the compilation of complete, accurate, and timely cancer data for West Virginia.

**§4.1.n. and §4.1.o. Comment:** Usual occupation and employment are likely to offer no useful indication of an occupation-cancer connection. A complete history of occupations and exposures is needed to find possible connections. Such data is very difficult to collect.

**Response:** The Department agrees that information regarding usual occupation and usual industry of employment available in patient medical records rarely offers sufficient data to develop an occupation-cancer connection. However, the National Program of Cancer Registries/Centers for Disease Control and Prevention requires that such data be collected. Occupation and industry remain important cancer risk factors, and the Department will continue to try to collect any available data.

#### **§64-68-6. Distribution of Rule.**

**6.1. The division and health care professional licensing boards and agencies may distribute this rule to any health care facility that has a duty under this rule.**

**Explanation of Change:** The proposed amendments to Cancer Registry 64CSR68, change some reporting procedures and guidelines for health care facilities that have a duty under this rule. As a result, the Department wishes to distribute this rule to inform these health care facilities of the changes, and to ensure that the guidelines of the rule are properly and consistently followed.



RECEIVED

July 13, 1999

99 JUL 15 2:11:10

STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Department of Health and Human Services  
Regulatory Development  
Capitol Complex – Building 3, Room 265  
Charleston, WV 25305  
Attn: Beth Marquart

Gentlemen:

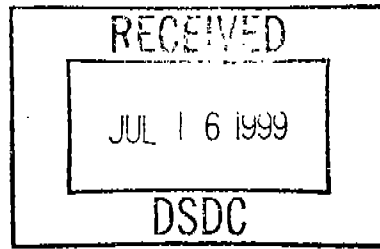
The purpose of this letter is to voice strong support for the intent and content of the proposed legislative rule regarding the West Virginia State Cancer Registry (WV Code 16-5A-2a), Administrative Rule, Title 64, Series 68.

West Virginia has a serious cancer problem, and it ***needs*** a working Cancer Registry in order to address the problem. Hospitals and other settings, which provide cancer care, are obligated to provide their data in order to address public health issues of concern to the citizens of this state. Our cancer problem is just such a concern.

Cancer care is a public obligation with extremely important public health implications. One of those implications is the simple and terribly important step of gathering accurate data. This simple step is critically important for all subsequent activities. This proposed rule permits an important state agency to address its obligation to the citizens of our state.

Sincerely,

Alan M. Ducatman, MD, MSc  
Chair, Department of Community Medicine



7-14-99

Dear Loretta,

Thank you for sending me a copy of your new Cancer Registry rules.

They look fine to me.

Of course the questions on usual occupation and industry are all you can probably get (if at all) but are more than likely to give you no useful clues as to an occupation - cancer connection as West Virginians often do a multiplicity of jobs — and the induction time is usually so long. A complete history of occupations and exposures is needed to find possible connections — and it's no doubt too much to ask to expect to get such data.

Best wishes

