

WEST VIRGINIA

SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #4

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Jan 22 9 55 AM '99

OFFICE OF THE SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

Division of Health

AGENCY: Department of Health and Human Resources TITLE NUMBER: 64

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

AMENDMENT TO AN EXISTING RULE: YES X NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 68

TITLE OF RULE BEING AMENDED: Cancer Registry

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED:

TITLE OF RULE BEING PROPOSED:

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Handwritten signature of Joan E. Ohl, Secretary

Joan E. Ohl, Secretary

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

**SERIES 68  
CANCER REGISTRY**

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**MODIFIED PROPOSED RULE  
APPROVED BY THE  
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

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

**SERIES 68  
CANCER REGISTRY**

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**64CSR68**  
**TITLE 64**  
**LEGISLATIVE RULES**  
**DIVISION OF HEALTH**  
**DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 68**  
**CANCER REGISTRY**

OFFICE OF THE ATTORNEY GENERAL  
STATE OF WEST VIRGINIA  
LEGISLATIVE COUNSEL  
Jan 22 3 55 AM '99

**§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. The Surveillance, Epidemiology, and End Results (SEER) system; and
- 4.1.j.2. The 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 fee to 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. 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 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.~~