

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

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OFFICE WEST VIRGINIA
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Form #6

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

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: _____

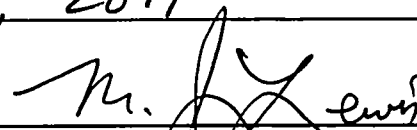
TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) 295

SECTION §64-5-1(f), PASSED ON March 18, 2011

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE
FOLLOWING DATE: April 21, 2011



Authorized Signature

TITLE 64

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

SERIES 68

CANCER REGISTRY

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§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. -- WV Code §§16-1-4, 16-1-11(a) and 16-5A-2a(e).

1.3. Filing Date. --

1.4. Effective Date. -- March 18, 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. 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 WV 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 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 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 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 WV Code §16-5A-2a and this

rule may disclose confidential information to any other person except in strict compliance with WV Code §16-5A-2a and this rule.

5.2. Any person who obtains information protected by the provisions of WV 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 WV 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.