

**WEST VIRGINIA  
SECRETARY OF STATE  
KEN HECHLER**

**ADMINISTRATIVE LAW DIVISION**

Form #6

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APR 13 2 51 PM '00

OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

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

Division of Health

AGENCY: Department of Health and Human Resources 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 NEW RULE BEING PROPOSED: \_\_\_\_\_

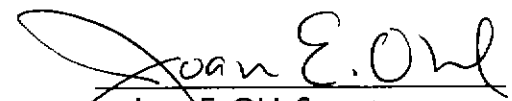
TITLE OF RULE BEING PROPOSED: \_\_\_\_\_

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

AUTHORIZATION IS CITED IN (house or senate bill number) HB 4250

SECTION 64-5-2(f), PASSED ON March 10, 2000

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE  
FOLLOWING DATE: July 1, 2000

  
Joan E. Ohi, Secretary

**DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
RULE PROMULGATION HISTORY ABSTRACT**

**Rule Title:** 64 Cancer Registry

**Series Number:** 68

**Amendment of Existing Rule:**  X  **New Rule:**   

**Responsible Agency:** Division of Health

**Date Filed for Public Hearing or Comment Period:** June 30, 1999

**Date of Public Hearing (if any):**

**Date Public Comment Period Ended:** July 30, 1999

**Date Agency-Approved Rule Filed with the  
Legislative Rule-Making Review Committee:** August 4, 1999

**Date of Filing of Modified Rule as Approved by  
the Legislative Rule-Making Review Committee:** October 22, 1999

**Date of Final Filing:** April 13, 2000

**Effective Date:** July 1, 2000

**Authorized by:** H.B.  4250  (With amendments? **Yes**  X  **No**   ),  
**Passed:** March 10, 2000

**Dates Emergency Rule in Effect (if any):**

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

**SERIES 68  
CANCER REGISTRY**

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**FINAL FILING**

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

**SERIES 68  
CANCER REGISTRY**

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FILED

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

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OFFICE OF WEST VIRGINIA  
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 West Virginia Cancer Registry, maintaining the confidentiality of information in 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 -- 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 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 - A registry maintained for the collection of information concerning newly diagnosed cancer cases.

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.

3.10. 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 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 first name, last 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. 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. 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. 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 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 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 health Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

70 5.10.a. The number shall be answered on a twenty-four-  
71 hour basis.

72 5.10.b. Exception. Any fire department rapid response  
73 system that, according to its written policy, does not respond to  
74 calls from the general public but responds only to calls from a  
75 unique population, such as the population of a state institution,  
76 an industrial plant, between specified health care facilities, or  
77 a university, is not required to provide a publicly listed tele-  
78 phone number. The agency shall provide for a telephone  
79 number and shall make that number known to the unique  
80 population it services. The number shall be required to be  
81 answered during all periods when that population may require  
82 service.”

83 (e) The legislative rule filed in the state register on the first  
84 day of December, one thousand nine hundred ninety-eight,  
85 authorized under the authority of section eight, article three-c,  
86 chapter sixteen, of this code, modified by the division of health  
87 to meet the objections of the legislative rule-making review  
88 committee and refiled in the state register on the twenty-ninth  
89 day of April, one thousand nine hundred ninety-nine, relating  
90 to the division of health (AIDS-related medical testing and  
91 confidentiality, 64 CSR 64), is authorized with the following  
92 amendment:

93 “On page six, subsection 5.1, following the words ‘initial  
94 period of time’, by striking the words ‘not to exceed three (3)  
95 months’.”

96 (f) The legislative rule filed in the state register on the  
97 fourth day of August, one thousand nine hundred ninety-nine,  
98 authorized under the authority of section two-a, article five-a,  
99 chapter sixteen, of this code, modified by the division of health  
100 to meet the objections of the legislative rule-making review  
101 committee and refiled in the state register on the twenty-second

102 day of October, one thousand nine hundred ninety-nine, relating  
103 to the division of health (cancer registry, 64 CSR 68), is  
104 authorized with the following amendment:

105 "On page five, immediately following subsection 5.4, by  
106 adding a new subsection, designated subsection 5.5, to read as  
107 follows:

108 '5.5. The West Virginia Cancer Registry may release case  
109 data to cancer researchers for the purposes of cancer prevention,  
110 control and research.'"

111 (g) The legislative rule filed in the state register on the  
112 fourth day of August, one thousand nine hundred ninety-nine,  
113 authorized under the authority of section nine, article one,  
114 chapter sixteen, of this code, modified by the division of health  
115 to meet the objections of the legislative rule-making review  
116 committee and refiled in the state register on the twenty-ninth  
117 day of December, one thousand nine hundred ninety-nine,  
118 relating to the division of health (behavioral health consumer  
119 rights, 64 CSR 74), is authorized.

120 (h) The legislative rule filed in the state register on the fifth  
121 day of August, one thousand nine hundred ninety-nine, autho-  
122 rized under the authority of section nine-a, article one, chapter  
123 sixteen, of this code, modified by the division of health to meet  
124 the objections of the legislative rule-making review committee  
125 and refiled in the state register on the nineteenth day of January,  
126 two thousand, relating to the division of health (public water  
127 systems design standards, 64 CSR 77), is authorized.

**§64-5-3. Child support enforcement division.**

1 (a) The legislative rule filed in the state register on the sixth  
2 day of August, one thousand nine hundred ninety-nine, under  
3 the authority of section nine, article two, chapter forty-eight-a,  
4 of this code, relating to the bureau for child support enforce-