

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #6

Do Not Mark In this Box

FILED

APR 22 1 13 PM '96

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Division of Health TITLE NUMBER: 64

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 RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) HB 4225

SECTION §64-5-1(a), PASSED ON 3-8-96

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON
THE FOLLOWING DATE: 4-22-96



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(Plus all the volunteer
help we can get)

March 12, 1996

Kay Howard
Health
Regulatory Development
Bldg 3 Rm 265
Charleston, WV 25305

HB 4225 authorizing, **Title 64, Series 68, Cancer Registry** passed the Legislature on **March 8, 1996**. It is now awaiting the Governor's signature.

You have sixty (60) days after the Governor signs **HB 4225** to final file the legislative rule with the Secretary of State's office. To final file your legislative rule, fill in the blanks on the enclosed form #6, the "Final Filing" form and file the form with our office with a promulgation history of the rule. Authorization for your legislative rule is cited in **HB 4225 Section 64-5-1(a)**. The agency may set the effective date of the legislative rule up to ninety (90) days from the date the legislative rule is final filed with the Secretary of State's office. Please have an authorized signature on the bottom line.

*****IMPORTANT: IF YOUR AGENCY HAS COMPLETED THE LEGISLATIVE RULE ON A WORD PERFECT OR WORD PERFECT COMPATIBLE COMPUTER SYSTEM THAT USES A 3 1/2" DISK, YOU MUST SUBMIT A CLEAN COPY WITH ALL UNDERLINING AND STRIKE-THROUGHS, HEADERS OR FOOTERS REMOVED, TO OUR OFFICE WHEN FINAL FILING THE RULE. REMEMBER, THE TEXT OF THE COMPUTER FILED RULE MUST BE IDENTICAL - WORD FOR WORD, COMMA FOR COMMA, WITH ALL UNDERLINING, STRIKE-THROUGHS, HEADERS OR FOOTERS REMOVED, AS THE HARD COPY AUTHORIZED BY THE LEGISLATURE. NOTICE: ALL ELECTRONIC FILINGS NOT COMPLYING WITH THIS WILL BE REJECTED AND SENT BACK TO THE AGENCY TO BE RESUBMITTED!**

After the final rule is entered into the data base, the rule will be sent back to the agency for review and proofing. The agency has ten (10) working days to send a confirmation or corrections to the Secretary of States. If the agency fails to return this within ten (10) working days, the rule will be filed in the data base with a disclaimer attached stating that the agency failed to review the rule. Following confirmation, corrections or failure to review, as the case may be, the Secretary of State shall submit to the agency a final version of the rule for their records.

If you have any questions or need any assistance, please do not hesitate to contact our office.

Thank you,
Administrative Law Division

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

Rule Title: Cancer Registry

Series Number: 68

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

Responsible Agency: Division of Health, Department of Health and Human Resources

Date Filed for Public Hearing or Comment Period: 6-23-95

Date of Public Hearing (if any): n/a

Date Public Comment Period Ended: 7-24-95

**Date Agency-Approved Rule Filed with the
Legislative Rule-Making Review Committee:** 7-31-95

**Date of Filing of Modified Rule as Approved by
the Legislative Rule-Making Review Committee:** 10-17-95

Date of Final Filing: 4-22-96

Effective Date: 4-22-96

Authorized by: HB 4225 Section 64-5-1(a) (With amendments? Yes No X),
Passed: 3-8-96

Dates Emergency Rule in Effect (if any): n/a

**TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH
CANCER REGISTRY
SERIES 68**

**Final Rule
Effective April 22, 1996**

**WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH
CANCER REGISTRY
64 CSR 68**

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TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH
SERIES 68
CANCER REGISTRY

FILED

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OFFICE OF 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 cancer registry, maintaining the confidentiality of information in the registry, and disclosing information from the registry.

1.2. **Authority** - W. Va. Code §16-5A-2a(e).

1.3. **Filing Date** - April 22, 1996.

1.4. **Effective Date** - April 22, 1996.

§64-68-2. Application and Enforcement.

2.1. **Application** - This rule applies to health care providers and 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.

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. **Person** - An individual, partnership, corporation or other legal entity.

3.10. **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.

3.11. **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.

§64-68-4. Reporting.

4.1. All reporting sources shall provide the cancer registry office 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. The first name, last name, and middle initial;

4.1.2. Social security number;

4.1.3. Sex;

4.1.4. Birth date;

4.1.5. Maiden name;

4.1.6. Race/ethnicity;

4.1.7. Address at the time of diagnosis, including street, city, county and zip code;

4.1.8. Date of diagnosis;

4.1.9. A description of the cancer, including site, type, stage, and any other information needed to describe the case clearly;

4.1.10. The treatment of the cancer and the patient's medical status;

4.1.11. Date of death, if the patient has died;

64 CSR 68

4.1.12. Cause of death; and

4.1.13. Other information relevant for the identification of hazards to the public, i.e., the presence of factors placing the patient at risk for the development of cancer. Risk factor information includes, but is not limited to: tobacco use, familial history of cancer and occupation.

4.2. Each cancer case report shall also include:

4.2.1. The name of the reporting source; and

4.2.2. The name of the diagnosing physician.

4.3. Reporting sources with tumor registries shall submit the required information on all reportable cases of cancer served by that source to the 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 registry.

4.4. Reporting sources without tumor registries shall provide authorized 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. 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 and registry staff.

4.5. The 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.

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 may release information which identifies a specific patient to the reporting source which originally reported the cancer case.

5.4. The 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 shall release the information only to central

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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 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. 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 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.

SENATE BILL NO. 238

(By Senators Ross, Anderson, Boley,
Buckalew, Grubb and Macnaughtan)

[Introduced January 29, 1996; referred
to the Committee on

HEALTH AND HUMAN RESOURCES

THE JUDICIARY

64-68

6
7
8
9

10 A BILL to amend and reenact section one, article five,
11 chapter sixty-four of the code of West Virginia, one
12 thousand nine hundred thirty-one, as amended, relating
13 to authorizing the division of health to promulgate
14 legislative rules relating to the cancer registry.

15 Be it enacted by the Legislature of West Virginia:

16 That section one, article five, chapter sixty-four of
17 the code of West Virginia, one thousand nine hundred
18 thirty-one, as amended, be amended and reenacted, to read
19 as follows:

20 ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND
21 HUMAN RESOURCES TO PROMULGATE LEGISLATIVE RULES.

22 §64-5-1. State board of health; division of health.

23 (a) The legislative rules filed in the state register
24 on the fifteenth day of August, one thousand nine hundred

1 ninety-four, authorized under the authority of section
2 seven, article one, chapter sixteen, of this code, modified
3 by the division of health to meet the objections of the
4 legislative rule-making review committee and refiled in the
5 state register on the twentieth day of October, one
6 thousand nine hundred ninety-four, relating to the division
7 of health (wastewater treatment works and operators, 64 CSR
8 5), are authorized.

9 (b) The legislative rules filed in the state register
10 on the thirty-first day of July, one thousand nine hundred
11 ninety-five, authorized under the authority of section two-
12 a, article five-a, chapter sixteen, of this code, relating
13 to the division of health (cancer registry, 64 CSR 68), are
14 authorized.

15

16 NOTE: The purpose of this bill is to authorize the
17 Division of Health to promulgate legislative rules relating
18 to the cancer registry.

19

20 Strike-throughs indicate language that would be
21 stricken from the present law, and underscoring indicates
22 new language that would be added.

5227

H. B. 4225

(By Delegates Douglas, Gallagher, Faircloth, Compton,
Linch and Riggs)

(Introduced January 29, 1996; referred to the
Committee on ~~Health and Human Resources then the Judiciary~~)

64-68

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RECEIVED

JUN 25 1996

REGULATORY DEVELOPMENT

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(Plus all the volunteer help we can get)

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

AUG 9 2 10 PM '96

FILED

TO: KAY HOWARD

AGENCY: DIVISION OF HEALTH

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: June 24, 1996

THE ATTACHED RULE FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF THE RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 68 TITLE: 64 DIVISION OF HEALTH

* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: _____

TITLE OF PERSON SIGNING: _____

DATE: _____

* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED. *2 minor typos*

SIGNED: Kay Howard

TITLE OF PERSON SIGNING: Director, Office of Regulatory Development

DATE: August 9, 1996

NOTE: IF YOU ARE NOT THE PERSON WHO HANDLES THIS RULE, PLEASE FORWARD TO THE CORRECT PERSON.