

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §16-5A-2a(e)

AMENDMENT TO AN EXISTING RULE: YES ___ NO X


IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 68

TITLE OF RULE BEING PROPOSED: Cancer Registry

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.



Ruth Ann Panepinto, Ph.D., Secretary
Department of Health and Human Resources

3.40

[PROPOSED]

TITLE 64

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

CANCER REGISTRY

SERIES 68

199_

Modifications Requested by the
Legislative Rule-Making Review Committee

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

CANCER REGISTRY

64 CSR 68

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[PROPOSED]
TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

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SERIES 68
CANCER REGISTRY

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 -

1.4. Effective Date -

§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.

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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. Date of death, if the patient has died;
- 4.1.11. Cause of death; and
- 4.1.12. 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 eight (8) 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 cancer registries in states with 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.

64 CSR 68

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



WEST VIRGINIA LEGISLATURE
 LEGISLATIVE RULE-MAKING REVIEW COMMITTEE
 Room M-152, State Capitol
 Charleston, West Virginia 25305
 (304) 340-3286

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OFFICE OF WEST VIRGINIA
 SECRETARY OF STATE

Senator Joe Manchin III, Co-Chair
 Delegate Brian A. Gallagher, Co-Chair

Debra A. Graham, Counsel
 Marie Nickerson, Admr. Assistant

NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

September 28, 1993

TO: Ken Hechler, Secretary of State, State Register

TO: Ruth Ann Panepinto, PH.D.
 Dept. of Health & Human Resources
 Building 3, Capitol Complex
 Charleston, WV 25305

FROM: Legislative Rule-Making Review Committee

PROPOSED RULE: Cancer Registry

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule
 - (a) as originally filed
 - (b) as modified by the agency X
2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached.
3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached.
4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached.
5. Recommends that the rule be withdrawn; a statement of reasons for such recommendation is attached.

Pursuant to Code 29A-3-11(c), this notice has been filed in the State Register and with the agency proposing the rule.

cc: Kay Howard
 Regulatory Division