

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Division of Health TITLE NUMBER: 64

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

AMENDMENT TO AN EXISTING RULE: YES NO

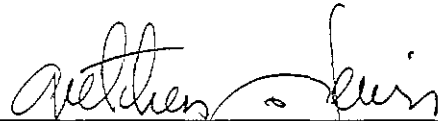
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 68

TITLE OF RULE BEING AMENDED: Cancer Registry

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

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.



Gretchen O. Lewis, Secretary

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Cancer Registry, 64 CSR 68

Type of Rule: Legislative Interpretive Procedural

Agency: Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$ 0	\$ 0	\$ 0
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Other					

2. Explanation of above estimates.

The proposed amendments will not increase State costs.

3. Objectives of this rule:

The rule which is being amended applies to the operation of the West Virginia Cancer Registry. The proposed amendments: 1) change the timing of reporting a newly diagnosed case of cancer from within eight (8) months to within six (6) months of the diagnosis; and 2) add treatment and medical status of individual patients to the data required to be reported. These changes are needed to conform to the national reporting standards of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Program of Cancer Registries.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None. However, if the proposed change is not authorized, the State may lose at least \$236,500 in federal funding. The proposed changes are needed to continue the Department's eligibility to receive financial assistance from the CDC for the state cancer data collection program, which, for the current year (Federal fiscal year '94-'95) is \$236,500, approximately half of the state cost for maintaining this program. The federal funds are used in part to support operating costs, training and equipment, and also to fund part of the program's staff and associated employee benefits.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

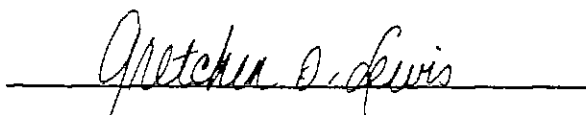
Hospital registries have been advised of the need to report within six (6) months; most cases were already being reported within this time frame. Registries presently collect treatment and status data. There should not be additional costs to hospitals for complying with the new requirement. Data from other sources is routinely collected by the Department.

C. Economic Impact on Citizens/Public at Large.

None.

Date: April 13, 1995

Signature of Agency Head or Authorized Representative



Gretchen O. Lewis, Secretary
Department of Health and Human Resources

DATE: July 31, 1995

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: Division of Health

LEGISLATIVE RULE TITLE: Cancer Registry

1. Authorizing statute(s) citation W. Va. Code § 16-5A-2a(e)

2. a. Date filed in State Register with Notice of Hearing:

June 23, 1995

b. What other notice, including advertising, did you give of the hearing?

Copies circulated to: WV Hospital Association, hospitals, 2 cancer treatment centers, free-standing pathology laboratories, WV Health Care Association, WV Medical Association, and WV Osteopath Association.

c. Date of hearing(s): Comment period 6-23-95 to 7-24-95

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached

No comments received X

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

June 23, 1995

f. Name and phone number of agency person to contact for additional information:

Kay Howard, 558-3223

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing: N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

Discussion of Public Comments Received
Concerning the Proposed Rule,
Cancer Registry, 64 CSR 68

The rule which is being amended applies to the operation of the West Virginia Cancer Registry. The proposed amendments: 1) change the timing of reporting a newly diagnosed case of cancer from within eight (8) months to within six (6) months of the diagnosis; and 2) add treatment and medical status of individual patients to the data required to be reported. These changes are needed to conform to the national reporting standards of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Program of Cancer Registries.

The proposed changes are needed to continue the Department's eligibility to receive financial assistance from the CDC for the state cancer data collection program, which, for the current year (Federal fiscal year '94-'95) is \$236,500, approximately half of the state cost for maintaining this program. The federal funds are used in part to support operating costs, training and equipment, and also to fund part of the program's staff and associated employee benefits.

A public comment period was held, beginning June 23, 1995 and ending July 24, 1995. No comments were received. No changes have been made to the rule.

RULE ABSTRACT

Agency: Department of Health and Human Resources

Rule Title: Cancer Registry

CSR Title and Series: 64 CSR 68

Type: Legislative

Summary: The rule which is being amended applies to the operation of the West Virginia Cancer Registry. The proposed amendments: 1) change the timing of reporting a newly diagnosed case of cancer from within eight (8) months to within six (6) months of the diagnosis; and 2) add treatment and medical status of individual patients to the data required to be reported. These changes are needed to conform to the national reporting standards of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Program of Cancer Registries.

The proposed changes are needed to continue the Department's eligibility to receive financial assistance from the CDC for the state cancer data collection program, which, for the current year (Federal fiscal year '94-'95) is \$236,500, approximately half of the state cost for maintaining this program. The federal funds are used in part to support operating costs, training and equipment, and also to fund part of the program's staff and associated employee benefits.

The proposed changes will be filed on an emergency basis in order to comply with a federal deadline of September 29, 1995.

For further information contact:

Beverly Keener, Cancer Surveillance Coordinator, or
Loretta Haddy, Director, Division of Surveillance and Disease Control, telephone (304) 558-5358, Bureau for Public Health, Department of Health and Human Resources, 1422 Washington Street, East, Charleston, West Virginia, 25301; or

Office of Regulatory Development, Operations, Department of Health and Human Resources, Capitol Complex, Building 3, Room 265, Capitol Complex, Charleston, West Virginia, 25305, telephone (304) 558-3223.

7/31/95

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

For Filing with the Legislative
Rule-Making Review Committee

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

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FILED
Jul 31 4 53 PM '95
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.

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;
- ~~4.1.10~~ 4.1.11. Date of death, if the patient has died;
- ~~4.1.11~~ 4.1.12. Cause of death; and

~~4.1.12~~ 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 ~~eight (8)~~ 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 cancer registries in states with 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.