

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #2

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JUL 13 10 30 AM '93

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Division of Health TITLE NUMBER: 64

RULE TYPE: Legislative; CITE AUTHORITY W. Va. Code §16-5A-2a

AMENDMENT TO AN EXISTING RULE: YES NO

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

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON August 12, 1993 AT 4:30 p.m.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS. Comments may be hand delivered up to 4:30 p.m. or must be post marked no later than midnight.

Regulatory Development

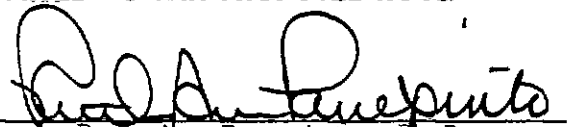
Building 3, Room 204

Capitol Complex

Charleston, WV 25305

ATTN: Kay Howard

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.


Ruth Ann Panepinto, Ph.D.
Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

3-60

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Cancer Registry, 64 CSR 68

Type of Rule: X Legislative Interpretive Procedural

Agency Department of Health Address Building 3, Capitol Complex
and Human Resources Charleston, W. Va. 25305

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$	\$
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Other					

2. Explanation of above estimates.

The West Virginia Cancer Registry is already in operation on a voluntary basis. Funds totaling \$186,632 were allocated by the Legislature for Fiscal Year 1994. These funds include salary (\$120,000) and employee benefits (\$50,012) for a registry director, 3 professional technical staff and 1 secretary, an additional \$11,620 for other current expense; and \$5,000 for office and communication equipment. Funds for continuation at the same level will be a part of the Department's budget request.

3. Objectives of these rules:

To establish rules for the collection of information by the West Virginia Cancer Registry concerning the incidence of cancer which might indicate hazards to public health. The rule defines terms, lists information to be reported, specifies reporting formats, and includes standards for confidentiality and disclosure of information included in the registry.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

The operation of the Registry will be supported by general revenue funds.

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

No direct impact.

C. Economic Impact on Citizens/Public at Large.

No direct impact.

Date July 6, 1993

Signature of Agency Head or Authorized Representative



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

RULE ABSTRACT

FILED

JUL 13 10 30 AM '93

Agency: Department of Health and Human Resources

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Rule Title: Cancer Registry

CSR Title and Series: 64 CSR 68

Type: Legislative

Summary: In 1992, S.B. 272 established a cancer registry within the Department of Health and Human Resources to collect and analyze information concerning the incidence of cancer which might indicate hazards to public health. The rule defines terms, lists information to be reported, specifies reporting formats, and includes standards for confidentiality and disclosure of information in the registry. The registry is presently operating on a voluntary basis.

For further information contact: Beverly Keener, Cancer Surveillance Coordinator, Cancer Registry, Bureau of Public Health, Department of Health and Human Resources, Building 3, Capitol Complex, Charleston, West Virginia, 25305, telephone (304) 558-5358 or Loretta Haddy, Director, Division of Surveillance and Disease Control, Bureau of Public Health, Department of Health and Human Resources, telephone (304) 558-5358, or the Regulatory Development Unit, Bureau of Administration and Finance, Department of Health and Human Resources, telephone (304) 558-3223.

7/6/93

FILED

JUN 13 10 31 AM '93

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

[PROPOSED]

TITLE 64

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

CANCER REGISTRY

SERIES 68

199_

For Public Comment
July 13, 1993 to August 12, 1993

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

FILED

CANCER REGISTRY

JUL 13 10 31 AM '93

64 CSR 68

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

INDEX

\$64-68-1.	General	1
\$64-68-2.	Application and Enforcement	1
\$64-68-3.	Definitions	1
\$64-68-4.	Reporting	2
\$64-68-5.	Confidentiality; Disclosure	3
\$64-68.6.	Administrative Due Process	3
\$64-68-7.	Severability	3

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

SERIES 68
CANCER REGISTRY

FILED

JUL 13 10 31 AM '93

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.

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

7/1/93

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 - 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 - 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 cancer cases.

§64-68-4. Reporting.

4.1. All reporting sources shall provide the cancer registry office with the following information on all reportable cancer cases:

- 4.1.1. The patient's 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. Description of cancer, including site, type, stage, and any other information needed to describe the case clearly;
- 4.1.10. Name of the reporting source;
- 4.1.11. Name of the diagnosing physician;
- 4.1.12. Date of death, if the patient has died;
- 4.1.13. Cause of death; and
- 4.1.14. 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. 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.

4.3. 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. Access shall be scheduled by advance notice to the source by registry staff and shall occur at reasonable times convenient to the reporting source and registry staff.

§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. 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.



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Gaston Caperton
Governor

Date: July 6, 1993
To: Ruth Ann Panepinto, Ph.D.
Secretary
From: Nancy J. Tolliver, Commissioner
Bureau of Administration and Finance
Re: Cancer Registry, 64 CSR 68

A handwritten signature in cursive script, appearing to read "Nancy J. Tolliver", written over the typed name in the "From:" field.

The following materials related to the proposed new rule Cancer Registry, 64 CSR 68, are enclosed for your review and signature:

1. Notice of Public Comment Period (Please sign. The public comment period ending date will be filled in after the Notice is signed.)
2. Abstract
3. Fiscal Note (Please sign.)
4. Rule text.

The cancer registry is already operating successfully. We anticipate no controversy regarding this new rule. These materials have been approved by Dr. Wallace.

Please return this package to Regulatory Development for scheduling and filing.

NJT:ksm

Attachments