

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #3

Do Not Mark In this Box

FILED

AUG 16 3 29 PM '93

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

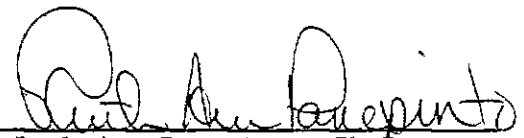
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

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 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.



Ruth Ann Panepinto, Ph.D.
Secretary

5.00

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.

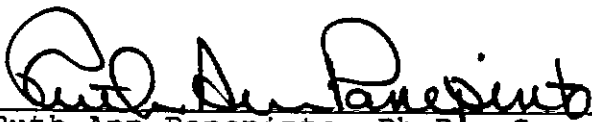
No direct impact.

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

DATE: August 13, 1993

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: Division of Health

LEGISLATIVE RULE TITLE: Cancer Registry, 64 CSR 68

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

2. a. Date filed in State Register with Notice of Public Comment Period:

July 13, 1993

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

Copies circulated to the Cancer Advisory Committee, various providers and provider associations - physicians, dentists, hospitals, laboratories, nursing homes - and local health departments.

c. Date of hearing(s): Comment period ended

August 12, 1993.

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

Attached X No comments received

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

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: _____

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

d. Attach findings and determinations and reasons:

Attached _____

RULE ABSTRACT

Agency: Department of Health and Human Resources

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

[PROPOSED]

TITLE 64

WEST VIRGINIA ADMINISTRATIVE RULES
DIVISION OF HEALTH

CANCER REGISTRY

SERIES 68

199_

Filing with 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

FILED

AUG 16 3 29 PM '93

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.

8/13/93

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 newly diagnosed 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 to the extent that the information would be routinely available at a particular type of reporting source:

- 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 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.

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

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 proposed rule, Cancer Registry, 64 CSR 68, 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 within the Division of Health on a voluntary basis. Promulgation authority for this rule is found at W. Va. Code §16-5A-2a(e).

A public comment period was held, beginning July 13, 1993 and ending August 12, 1993. Comments (copies attached) were received from Dr. John Pearson, M.B., M.P.H., Chairman, Department of Community Medicine, West Virginia University, Dr. Josefina M. Orteza, and the Veterans Hospital at Clarksburg. The Veterans Hospital had no comments. Other comments are summarized and discussed below.

1. Comment (Dr. Pearson): Section 3.1. Delete "and course."

Response: "Course" includes information such as the extent of the disease and the survival time after initial diagnosis, all of which are important pieces of information in the study of cancer.

2. Comment (Dr. Pearson): Section 3.12. Insert "newly diagnosed" in front of "cancer."

Response: Agreed.

3. Comment (Dr. Orteza): Section 4.1. It will not be possible for all of the providers listed in Section 3.8 to provide you with all of the information listed in Section 4.1.

Response: The Division of Health does not expect that all providers would have all of the information and has added clarifying language to Section 4.1.

4. Comment (Dr. Pearson): Section 4.1.14. Insert "a full listing of all" preceding "occupation," and an "s" to "occupation," and add "with dates" following "occupations."

Response: This information is not routinely available, and it is beyond the current capacity of the program to collect it.

5. Comment (Dr. Pearson): Section 5.4. At the end of the last sentence, change the period to a comma, and add "which establishes reciprocal reporting of West Virginia residents diagnosed out of state."

Response: The Division agrees that establishing reciprocal reporting relationships is important and has added language to that effect to Section 5.4.

Comments from Dr. John Pearson

Dr. John Pearson, M.B., M.P.H., Chairman, Department of Community Medicine, West Virginia University made the following suggestions in the form of notes on a copy of the rule:

3.1. Delete "and course."

3.12. Insert "newly diagnosed" in front of "cancer."

4.1.14. Insert "a full listing of all" preceding "occupation," and an "s" to "occupation," and add "with dates" following "occupations."

5.4. At the end of the last sentence, change the period to a comma, and add "which establishes reciprocal reporting of West Virginia residents diagnosed out of state."

JOSEFINA M. ORTEZA, M.D.
P. O. Box 913
Morgantown WV 26507
(304) 599-4630

RECEIVED

AUG - 6 1993

**REGULATORY DEVELOPMENT
SECTION**

August 3, 1993

Regulatory Development
Bldg. 3, Room 204
Capitol Complex
Charleston WV 25305
Attn: Kay Howard

Dear Ms. Howard:

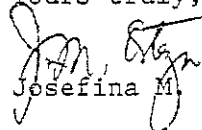
This is in regard to the Cancer Registry, comments about which you welcome from interested persons.

My comment will be confined to sections 3.8 (Health Care Provider) and the section on Reporting.

It will not be possible for all the health care providers you have enumerated in section 3.8 to provide you with all the information you need under 4.1 and following. The only health care providers who will be able to provide you with the full information requested under the section on Reporting will be the physicians who have the full responsibility for the care of the cancer patient whether the patient is first seen in a physician's office or in a clinic or hospital. A patient who may be transferred from one facility to another is always under the care of a physician. As a pathologist, the information I obtain on a requisition slip for a tissue biopsy or a Pap smear examination are: patient's name, date of birth, sex, address, telephone number, relevant clinical information, physician's clinical impression or diagnosis, nature of tissue or other specimen sent for examination, site from where specimen was obtained, date when specimen was obtained and by whom (name of referring M.D.). It would be too much to expect a physician's office to furnish me with all the information listed under Reporting (due to the time involved in passing such information to me). Pathologists' reports always give the referring physician enough information about the specimen examined. Pathologists will not be able to inform you on the cancer stage, follow-up, treatment, etc. Obtaining information for the Cancer Registry from laboratories and pathologists will result in needless duplication and paper work.

I retired from medical practice on July 1, 1993. You need not keep my name in your directory.

Yours truly,



Josefina M. Orteza, M.D.



DEPARTMENT OF VETERANS AFFAIRS
Louis A. Johnson
Medical Center
Clarksburg WV 26301

RECEIVED

JUL 26 1993

REGULATORY DEVELOPMENT
SECTION

In Reply Refer To: 540/136

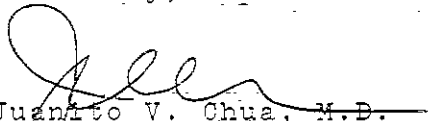
July 22, 1993

Regulatory Department
ATTN: Kay Howard
Building 3, Room 204
Capitol Complex
Charleston, WV 25305

Dear Kay:

The notice of a comment period on the proposed rule for Cancer Registry has been received. This VA Medical Center has no additional comments at this time.

Sincerely,


Juanito V. Chua, M.D.
Chief, Surgical Service
Chairman, Cancer Committee