

**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 § 16-33-2

AMENDMENT TO AN EXISTING RULE: YES NO

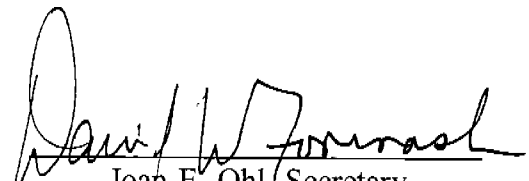
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 69

TITLE OF RULE BEING PROPOSED: Breast and Cervical Cancer Diagnostic and Treatment Fund

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.


Joan E. Ohi, Secretary

4.80



American College of Physicians

Nephrology Associates, Inc.
P.O. Box 6316
Wheeling, WV 26003-0715
Telephone: 304 242 7752 Fax: 304 242 7254

Derrick L. Latos, MD, FACP
Governor for West Virginia

July 7, 1997

RECEIVED

JUL 23 1997

REGULATORY DEVELOPMENT

Nancye Bazzle, MPH, Program Director
Breast and Cervical Cancer Screening Program
Department of Health & Human Resources
Capitol Complex - Building 3, Room 265
Charleston, WV 25301-3013

Dear Ms. Bazzle:

I am happy to respond to your request dealing with the Proposed Rule for Breast and Cervical Cancer Diagnostic and Treatment Fund.

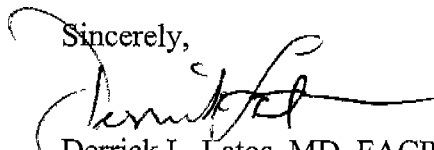
I share your concerns that such a small allocation (\$250,000.00) will leave many West Virginia women without appropriate care for breast and cervical cancer and other pre-cancerous lesions.

The proposed rule eligibility includes individuals whose income is at or below 200% of the federal poverty level. While I understand the intent of the Rule is to provide such services to those most medically needy, it would be helpful to ascertain, at least for breast and cervical cancer, the approximate number of women in that income category as opposed to those up to 300% of federal poverty, who are not covered by Medicare or Medicaid. Too tight a restriction would fail to meet the needs of women with just a little higher income. I am sure that this data is available through past surveillance reports.

I am looking forward to following the implementation of the Rule, particularly since it may serve as a template for future designated programs to cover illnesses in uninsured West Virginians. This approach, while not serving the entire population in need, is a start.

I have taken the liberty of circulating your proposal and covering letter to members of my governing council who may wish to provide comment as well.

Thank you for the opportunity to comment on this important Rule.

Sincerely,

Derrick L. Latos, MD, FACP

DLL/lh

**Discussion of Public Comments Received
Concerning the Proposed Rule
Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69**

The proposed new legislative rule Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69, establishes the procedures and the process for providing financial assistance to medically and financially eligible patients for certain diagnostic and treatment services for breast cancer, cervical cancer or precancerous cervical lesions. Funds for medical assistance are to be distributed from the breast and cervical cancer diagnostic and treatment fund appropriated for this purpose by the State Legislature.

Notice of a public comment period on the proposed rule was filed with the Secretary of State June 27, 1997. The public comment period ended July 28, 1997. One (1) letter of comment was received. The comments are discussed below.

The commenter was favorable towards the rule, but expressed concern about the small allocation of State funds, and remarked that increasing the federal poverty level criterion of 200% is unreasonably restrictive and fails to meet the needs of women with just a little higher income than 200% of poverty level. The commenter suggested using 300%.

While the Department is sympathetic with the commenter's concerns regarding the funding available to provide breast and cervical diagnostic procedures to low-income women not covered by any third party payor, it must be recognized that the Legislature is charged with the responsibility for responsibly allocating funds for many different programs. Furthermore, the 200% of federal poverty level qualifying criterion is set by statute and can only be changed by legislation.

With respect to funding available, the Department notes, however, that it has received donations from various sources, including medical professionals, clinics, and private organizations. A number of fund-raising events have already been scheduled for later this year. The Department gratefully acknowledges the positive support from the private sector.

The Department has made some non-substantive clarifying changes of the rule, which are described below.

1.1. Scope. -- This rule establishes the procedures and the process for providing financial assistance to medically and financially eligible patients for certain diagnostic and treatment services for breast cancer, cervical cancer or precancerous cervical lesions. Funds appropriated by the Legislature, any funds allocated by the federal government, and any other sums designated for deposit in the fund from any other public or private source for medical assistance are to be distributed from the breast and cervical cancer diagnostic and treatment fund appropriated for this purpose established by the State Legislature. In selecting services to be covered, the advisory committee has attempted to maximize the coverage of early diagnostic and treatment procedures in order to maximize the efficient use of funds. The advisory committee believes that in many instances if more extensive procedures are needed in later stages of diagnosis and treatment,

patients are more likely to qualify for coverage under Medicaid.

Section 5.1 has been deleted and subsequent items have been renumbered.

~~5.1. The advisory committee has determined that the procedures listed in subsection 5.2 and 5.3 of this rule shall be covered. Determination is based upon services covered primarily on availability of funds and data which showed the most frequently recommended procedures for patients.~~

ABSTRACT - PROPOSED RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
DIVISION OF HEALTH

**

64 CSR 69

Summary: The proposed new legislative rule Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69, establishes the procedures and the process for providing financial assistance to medically and financially eligible patients for certain diagnostic and treatment services for breast cancer, cervical cancer or precancerous cervical lesions. Funds for medical assistance are to be distributed from the breast and cervical cancer diagnostic and treatment fund appropriated for this purpose by the State Legislature..

The promulgation authority for this rule is W. Va. Code § 16-33-2. The rule is proposed to bring the Division into compliance with the requirements of W. Va. Code §§ 16-33-7 through 12, passed by the 1996 Legislature in House Bill 4181.

The rule contains definitions, provisions related to confidentiality, eligibility, the process to apply for approval and payment, and a list of covered procedure established by the medical advisory committee to the breast and cervical cancer detection and education program coalition.

For further information contact: Nancye Bazzle, M.P.H., Program Director of the Breast and Cervical Cancer Screening Program, Office of Maternal and Child Health, (telephone 304-558-5388), Bureau for Public Health, Department of Health and Human Resources, State Capitol Complex, Building 3, Room 519, Charleston, West Virginia, 25305; or the Office of Regulatory Development, Bureau of Operations, Department of Health and Human Resources, State Capitol Complex, Building 3, Room 265, Charleston, West Virginia, 25305, telephone (304) 558-3223.

Copies of the proposed rule may be obtained from the Office of Maternal and Child Health or the Administrative Law Division of the Office of the Secretary of State, State Capitol Complex, Building 1, Suite 157K, Charleston, WV 25305-0771, phone (304) 558-6000.

6/27/97

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69

Type of Rule: Legislative Interpretive Procedural

Agency: Bureau for Public Health (For the Division of Health)
Department of Health and Human Resources

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

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$ 250,000	\$ 250,000	\$
Personal Services					
Current Expense			250,000	250,000	
Repairs & Alterations					
Equipment					
Other					
Revenue					

2. Explanation of above estimates.

Current Expenses:

Medical bills payable to providers of breast and cervical cancer diagnostic and treatment services for indigent patients	\$250,000
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3. Objectives of this rule:

This rule establishes the procedures and the process for providing financial assistance to medically and financially eligible patients for certain diagnostic and treatment services for breast cancer, cervical cancer or precancerous lesions.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

An estimated \$250,000 will be expended from general revenue funds each year as appropriated by the Legislature.

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


Medical providers will be the recipient of the \$250,000 for treatment to indigent patients. West Virginia indigent citizens with breast cancer, cervical cancer or precancerous lesions will receive treatment.

C. Economic Impact on Citizens/Public at Large.

A few West Virginian citizens will receive treatment, but due to the minimal amount of dollars appropriated many citizens will still be without needed cancer treatment.

Date: June 25, 1997

Signature of Agency Head or Authorized Representative



Joan E. Ohl, Secretary
Department of Health and Human Resources

PROPOSED RULE
WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE
TITLE 64, SERIES 69
BREAST AND CERVICAL CANCER TREATMENT FUND

**Agency-Approved Rule
For Filing with the
Legislative Rule-Making Review Committee**

August 1, 1997

**PROPOSED - TITLE 64
WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE
SERIES 69
BREAST AND CERVICAL CANCER TREATMENT FUND**

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TITLE 64
PROPOSED

WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE
SERIES 69

Aug 1 12 58 PM '97

BREAST AND CERVICAL CANCER TREATMENT FUND

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§ 64-69-1. General.

1.1. Scope. -- This rule establishes the procedures and the process for providing financial assistance to medically and financially eligible patients for certain diagnostic and treatment services for breast cancer, cervical cancer or precancerous cervical lesions. Funds appropriated by the Legislature, any funds allocated by the federal government, and any other sums designated for deposit in the fund from any other public or private source for medical assistance are to be distributed from the breast and cervical cancer diagnostic and treatment fund established by the State Legislature. In selecting services to be covered, the advisory committee has attempted to maximize the coverage of early diagnostic and treatments procedures in order to maximize the efficient use of funds. The advisory committee believes that in many instances if more extensive procedures are needed in later stages of diagnosis and treatment, patients are likely to qualify for coverage under Medicaid.

1.2. Authority. -- W.Va. Code § 16-33-2.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Applicability. -- This rule applies to providers of, applicants for, and recipients of breast and cervical cancer diagnostic and treatment services.

1.6. Enforcement. -- This rule is administered by the office of maternal and child health within the bureau of public health¹ of the department of health and human resources.

§ 64-69-2. Definitions.

2.1. Advisory Committee. -- The medical advisory committee to the breast and cervical cancer detection and education program coalition.

2.2. Approved Procedure. -- A medical procedure that has been selected by the medical advisory committee to be paid for by the fund.

2.3. Bureau. -- The state bureau for public health of the department of health and human

¹ The Department of Health and Human Resources (DHHR) was created by the Legislature's reorganization of the executive branch of State government in 1989. The Department of Public Health was renamed the Division of Health and made a part of the DHHR (W. Va. Code § 5F-1-1 et seq.). Administratively within the DHHR the Bureau for Public Health through its Commissioner carries out the public health function of the Division of Health.

resources.

2.4. Federal Poverty Level. -- The prevailing national poverty income guidelines established by the federal government and published in the Federal Register.

2.5. Fund. -- The breast and cervical cancer diagnostic and treatment fund.

2.6. Provider. -- Physician, hospital or laboratory currently licensed and operating or practicing in this state.

§ 64-69-3. Confidentiality.

3.1. 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, this rule and any other applicable federal or state law, rule or regulation.

3.2. 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.

§ 64-69-4. Eligibility.

4.1. To be eligible financially for services under the fund, a patient's income shall be at or below two hundred percent (200%) of the federal poverty level. No patient who is covered by medical insurance, Medicaid or Medicare is financially eligible for participation in the fund.

4.2. To be eligible medically for diagnostic services under the fund, a patient shall have a condition strongly suspicious of cancer which requires diagnostic services to confirm the preliminary diagnosis. The bureau shall authorize only those services determined by the advisory committee as established in this rule to be medically necessary to confirm a preliminary diagnosis.

4.3. To be eligible medically for treatment services under the fund, the patient shall have a positive pathology report.

§ 64-69-5. Procedures Covered.

5.1. The following breast cancer related procedures are covered:

5.1.a. Breast biopsy-needle core;

5.1.b. Breast biopsy-incisional;

5.1.c. Breast biopsy-excisional;

5.1.d. Breast biopsy-identified by radiological marker;

- 5.1.d.1. Each additional lesion;
 - 5.1.e. Pre-op placement of needle localization wire;
 - 5.1.f. Breast biopsy-stereotactic localization;
 - 5.1.g. Needle localization-radiologic supervision/interpretation;
 - 5.1.h. Radiological examination, surgical specimen;
 - 5.1.i. Ultrasound guided biopsy;
 - 5.1.j. Lab-needle biopsy;
 - 5.1.k. Lab-surgical pathology breast tissue biopsy;
 - 5.1.l. Stereotactic biopsy supplies;
 - 5.1.m. Follow-up after procedure-outpatient;
 - 5.1.n. Follow-up consultation-post-op outpatient; and
 - 5.1.o. General anesthesia.
- 5.2. The following cervical cancer related procedures are covered:
- 5.2.a. Loop electrode excision procedure;
 - 5.2.b. Biopsy or local excision of lesion;
 - 5.2.c. Endocervical curettage;
 - 5.2.d. Cryocautery of the cervix;
 - 5.2.e. Laser surgery of the cervix;
 - 5.2.f. Conization of the cervix;
 - 5.2.g. Dilation and curettage-diagnostic and/or therapeutic;
 - 5.2.h. Lab-cervical biopsy;
 - 5.2.i. Follow-up after procedure-outpatient; and
 - 5.2.j. General anesthesia.
- 5.3. The commissioner of the bureau may, on behalf of the committee, by order filed with

the Secretary of State, add or delete a diagnostic or treatment procedure as authorized and approved by the committee.

§ 64-69-6. Review and Authorization.

6.1. The medical advisory committee shall entrust the day to day enactment of review and authorization for payment as authorized by this rule to the director of the breast and cervical cancer screening program of the office of office of maternal and child health within the bureau.

§ 64-69-7. Application and Process.

7.1. In order to apply for and receive reimbursement from the fund, the applicant shall follow the following steps:

7.1.a. Refer to list of covered procedures shown in Section 5 of this rule to determine if the procedure to be performed is covered;

7.1.b. Complete the fund application form approved by and available from the division and submit it to the director of the breast and cervical cancer screening program for approval, except as specified in subsection 7.2 of this rule;

7.1.c. Provide the services; and

7.1.d. Submit an invoice to the director of the breast and cervical cancer screening program listing procedures and CPT codes, accompanied by a pathology report when appropriate, within ninety (90) days of the date the service was provided.

7.2. Only the medical eligibility section of the application is required to be completed for patients who have been already been screened and determined to meet the financial eligibility criteria through the breast and cervical cancer screening program.

7.3. The division shall use the current rate established by Medicare to determine the amount of payment.

7.4. Physicians and other health care providers performing procedures to be covered by the fund shall accept the Medicare-determined payment amount as full payment.

§64-69-8. 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 as prescribed in the division of health's administrative rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

Date: August 1, 1997

To: Legislative Rule-Making Review Committee

From: Kay Howard, Director
Regulatory Development
Department of Health and Human Resources

Re: Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69

1. Authorizing statute(s) citation: § 16-33-2
2.
 - a. Date filed in State Register with Notice of Hearing: 6/27/97
 - b. Other notice, including advertising, given of the hearing: Notice of the opportunity to comment was sent to representatives of the following: Marshall University School of Medicine, WV State Medical Association, WV Chapter - American Academy of Family Physicians, WV Chapter American College of Physicians, American College of Surgeons, WV Association of Pathologists, and WV Radiological Society, Inc.
 - c. Date of public comment period ended: 7/28/97
 - d. List of persons who commented, amendments, reasons for amendments.
Attached X No comments received _____
 - e. Date of filing in State Register the Agency-Approved proposed Legislative Rule following public hearing: August 1, 1997
 - f. Name and phone number of agency contact person: 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: Not applicable.
 - 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.
 - 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: