

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

Form #2

Do Not Mark In This Box

**FILED**

**JUN 27 3 53 PM '97**

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 § 16-33-2

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

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 July 28, 1997 AT 4:30 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

Regulatory Development

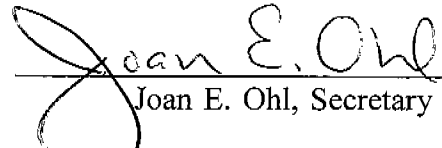
Department of Health & Human Resources

Capitol Complex - Building 3, Room 265

Charleston, WV 25305

ATTN: Kay Howard

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

  
Joan E. Ohl, Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

\$4.00

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

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**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
<b>Estimated Total Cost</b>	\$	\$	\$ 250,000	\$ 250,000	\$
<b>Personal Services</b>					
<b>Current Expense</b>			250,000	250,000	
<b>Repairs &amp; Alterations</b>					
<b>Equipment</b>					
<b>Other</b>					
<b>Revenue</b>					

**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**

  
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Joan E. Ohi, 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**

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**For Public Comment**

**June 27, 1997 through July 28, 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

JUN 27 3 53 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 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.

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 health<sup>1</sup> 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 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.

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<sup>1</sup> 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.

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 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.

5.2. The following breast cancer related procedures are covered:

5.2.a. Breast biopsy-needle core;

5.2.b. Breast biopsy-incisional;

5.2.c. Breast biopsy-excisional;

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

5.2.d.1. Each additional lesion;

5.2.e. Pre-op placement of needle localization wire;

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

5.4. 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.