

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #7

Do Not Mark In This Box

Filing Date

FILED

Aug 1 12 55 PM '97

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Effective Date

Sept 11, 1997

NOTICE OF A EMERGENCY RULE

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code § 16-33-2

EMERGENCY 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 FILED AS AN EMERGENCY: 69

TITLE OF RULE BEING FILED AS AN EMERGENCY: Breast and Cervical Cancer Diagnostic
and Treatment Fund

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

The Division of Health declares that immediate implementation of the proposed new rule, Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69, is necessary in order to prevent substantial harm to the public interest and that the circumstances stated below meet the definition of an emergency rule stated (See next page for continuation.)

Jean E. Ohl

Jean E. Ohl, Secretary

Use additional sheets if necessary

**Statement of Facts and Circumstances
Relating to the Emergency Filing of
Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69
(Continued)**

in W. Va. Code § 29A-3-15(f)(3).

The proposed new legislative rule, Breast and Cervical Cancer Diagnostic and Treatment Fund, 64 CSR 69, establishes the procedures 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 special breast and cervical cancer diagnostic and treatment fund authorized in Code § 16-33-7, and are to be used to reimburse providers for selected services for patients who are not covered by medical insurance, medicare or medicaid (Code § 16-33-9).

In order for the Division to expend moneys from the fund this year, this rule must be in effect. The legislation (House Bill 4181) which established the breast and cervical cancer diagnostic and treatment fund was passed by the 1996 Legislature. The 1996 Legislature appropriated funds for the program, but failed to provide a mechanism for transferring the appropriation into the special fund. Once the Division and the Medical Advisory Committee had developed a process and established a list of procedures to be covered, the Division did proceed to fund some services out from the appropriation that included the funding for the program. The 1997 Legislature provided funding for the current fiscal year (FY '98) which began July 1 and has, in the Budget Digest, provided for the transfer of this year's funding and unexpended funds from the 1997 fiscal year into the special fund.

The program has already funded procedures for approximately 475 individuals. Both public and professional response to the fund has been enthusiastic. In addition to moneys provided by the Legislature, the Division 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.

If this rule does not become effective prior to next spring under the normal process, the Division will not be able to make expenditures from the special fund, and a significant number of individuals will be deprived of needed diagnostic and/or treatment procedures. Failure to provide the needed services on a timely basis will likely result in the need for more costly procedures, or even premature and preventable death.

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #2

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FILED

JUN 27 3 54 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: _____

RECEIVED

JUN 27 1997

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 69

**Legislative Rule Making
Review Committee**

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

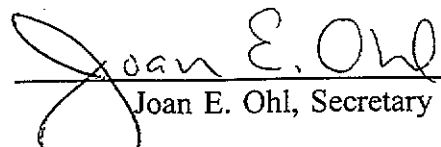
Department of Health & Human Resources

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. Ohi, Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

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: X **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

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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Date: July 31, 1997
To: Legislative Rule-Making Review Committee
From: Kay Howard, Director
Regulatory Development
Re: Emergency Rule - Breast and Cervical Cancer Diagnostic and
Treatment Fund, 64 CSR 69

1. Date of filing: August 1, 1997
2. Statutory authority for promulgating the rule: W. Va. Code §16-33-2.
3. Date of filing of proposed legislative rule: July 26, 1996.
4. Does the emergency rule adopt new language or does it amend or repeal a current legislative rule?

The emergency rule is a new rule.

5. Has the same or similar emergency rule previously been filed and expired?

No.

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the immediate preservation of public peace, health, safety or welfare.

Not applicable.

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

See Emergency Filing Notice.

TITLE 64
PROPOSED

AUG 1 12 55 PM '97

WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE
SERIES 69

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 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 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.

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.

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.