

**WEST VIRGINIA  
SECRETARY OF STATE**

**KEN HECHLER**

**ADMINISTRATIVE LAW DIVISION**

Form #6

Do Not Mark In This Box

**FILED**

**APR 3 3 46 PM '98**

OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED  
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Division of Health TITLE NUMBER: 64

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: 69

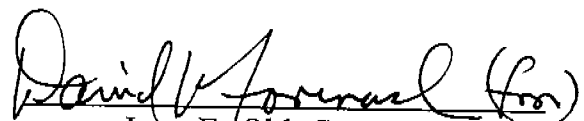
TITLE OF RULE BEING PROPOSED: Breast and Cervical Cancer Treatment Fund

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) Com. Sub. for SB 305

SECTION 64-5-1(b), PASSED ON March 12, 1998

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE  
FOLLOWING DATE: May 4, 1998

  
Joan E. Ohl, Secretary

\$2.80

**DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
RULE PROMULGATION HISTORY ABSTRACT**

**Rule Title:** Breast and Cervical Cancer Treatment Fund

**Series Number:** 69

**Amendment of Existing Rule:**  **New Rule:**

**Responsible Agency:** Division of Health

**Date Filed for Public Hearing or Comment Period:** June 27, 1997

**Date of Public Hearing (if any):**

**Date Public Comment Period Ended:** July 28, 1997

**Date Agency-Approved Rule Filed with the  
Legislative Rule-Making Review Committee:** August 1, 1997

**Date of Filing of Modified Rule as Approved by  
the Legislative Rule-Making Review Committee:** December 16, 1997

**Date of Final Filing:** April 3, 1998

**Effective Date:** May 4, 1998

**Authorized by:** Com. Sub. for SB 305 (With amendments? Yes  No )  
**Passed:** March 12, 1998

**Dates Emergency Rule in Effect (if any):** Filed August 1, 1997

**WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE**

**TITLE 64, SERIES 69**

**BREAST AND CERVICAL CANCER TREATMENT FUND**

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**1998**

WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE  
SERIES 69  
BREAST AND CERVICAL CANCER TREATMENT FUND

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WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULE  
SERIES 69

BREAST AND CERVICAL CANCER TREATMENT FUND

FILED

APR 3 3 46 PM '98

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 § 16-33-8.

1.3. Filing Date. -- April 3, 1998.

1.4. Effective Date. -- May 4, 1998.

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.

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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.

2.4. 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. -- A 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 those provisions 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. Breast cancer related procedures covered by the fund include, but are not limited to:

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. Cervical cancer related procedures covered by the fund include, but are not limited to:
- 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.

**§ 64-69-6. Review and Authorization.**

- 6.1. The medical advisory committee shall entrust the day to day 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. The provider shall apply for and receive reimbursement from the fund on behalf of the patient. The provider shall:

7.1.a. Refer to the list of covered procedures set forth in Section 5 of this rule, and may, if needed, consult with the director of the breast and cervical cancer screening program 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. The provider shall complete only the medical eligibility section of the application for patients who have 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. 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.

8917

64-69

1 Bill-Hea

**H. B. 4168**

2

(By Delegates Hunt, Linch, Compton, Jenkins,  
Faircloth and Riggs)

3

4

[Introduced January 30, 1998; referred to the  
Committee on Finance then the Judiciary.]

5

6

7

8

9

10 A BILL to amend and reenact section one, article five,  
11 chapter sixty-four of the code of West Virginia, one  
12 thousand nine hundred thirty-one, as amended, relating  
13 to authorizing the division of health to promulgate a  
14 legislative rule relating to the breast and cervical  
15 cancer diagnostic and treatment fund.

16 *Be it enacted by the Legislature of West Virginia:*

17 That section one, article five, chapter sixty-four of  
18 the code of West Virginia, one thousand nine hundred  
19 thirty-one, as amended, be amended and reenacted, to read  
20 as follows:

21 **ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND**  
22 **HUMAN RESOURCES TO PROMULGATE LEGISLATIVE RULES.**

23 **§64-5-1. State board of health; division of health.**

4168

1           (a) The legislative rule filed in the state register  
2 on the eighth day of November, one thousand nine hundred  
3 ninety-six, authorized under the authority of section five,  
4 article five-c, chapter sixteen of this code, modified by  
5 the division of health to meet the objections of the  
6 legislative rule-making review committee and refiled in the  
7 state register on the twenty-seventh day of February, one  
8 thousand nine hundred ninety-seven, relating to the  
9 division of health (nursing home licensure, 64 CSR 13), is  
10 authorized.

11           (b) The legislative rule filed in the state register  
12 on the thirtieth day of August, one thousand nine hundred  
13 ninety-six, authorized under the authority of section  
14 seven, article one, chapter sixteen of this code, modified  
15 by the division of health to meet the objections of the  
16 legislative rule-making review committee and refiled in the  
17 state register on the twenty-sixth day of February, one  
18 thousand nine hundred ninety-seven, relating to the  
19 division of health (child care centers, 64 CSR 21), is  
20 authorized.

21           (c) The legislative rule filed in the state register  
22 on the thirtieth day of August, one thousand nine hundred  
23 ninety-six, authorized under the authority of section

1 twenty-three, article four-c, chapter sixteen of this code,  
2 modified by the division of health to meet the objections  
3 of the legislative rule-making review committee and refiled  
4 in the state register on the twenty-eighth day of February,  
5 one thousand nine hundred ninety-seven, relating to the  
6 division of health (emergency medical services, 64 CSR 48),  
7 is authorized.

8 (d) The legislative rule filed in the state register  
9 on the twenty-seventh day of November, one thousand nine  
10 hundred ninety-five, authorized under the authority of  
11 section five, article five-c, chapter sixteen of this code,  
12 modified by the division of health to meet the objections  
13 of the legislative rule-making review committee and refiled  
14 in the state register on the twenty-sixth day of February,  
15 one thousand nine hundred ninety-seven, relating to the  
16 division of health (residential board and care homes, 64  
17 CSR 65), is authorized.

18 (e) The legislative rule filed in the state register  
19 on the fifth day of October, one thousand nine hundred  
20 ninety-five, under the authority of section ten, article  
21 five-j, chapter sixteen of this code, modified by the  
22 director of the department of health to meet the objections  
23 of the legislative rule-making review committee and refiled

1 in the state register on the thirty-first day of October,  
2 one thousand nine hundred ninety-six, relating to the  
3 department of health (clinical laboratory technician and  
4 technologist licensure and certification, 64 CSR 57), is  
5 authorized until July 1, 1998: *Provided*, That the director  
6 of the department of health review, revise and propose,  
7 within the statutory deadline and in accordance with the  
8 provisions of article three, chapter twenty-nine-a of this  
9 code, a rule for legislative consideration during the  
10 legislative session of one thousand nine hundred ninety-  
11 eight with the following amendments:

12 "On page one, subsection 2.2.2, following the semi-  
13 colon, by striking the word 'or';

14 On page one, by inserting a new 2.2.3, to read as  
15 follows: '2.2.3. Any respiratory care provider licensed  
16 within the state providing diagnostic testing within the  
17 scope of his or her professional license who performs  
18 moderate complexity testing as defined by CLIA, pursuant to  
19 42 CFR 493.17; or';

20 'On pages one and two, by renumbering the subsequent  
21 subdivision, .'"

22 And,

23 "On page 6, subsection 7.2, after the word

1 'Personnel', by striking the period and inserting in lieu  
2 thereof the following: 'or by the International Society  
3 for Clinical Laboratory Technology.'

4 (f) The legislative rule filed in the state register  
5 on the first day of August, one thousand nine hundred  
6 ninety-seven, authorized under the authority of section  
7 eight, article thirty-three, chapter sixteen, of this code,  
8 modified by the division of health to meet the objections  
9 of the legislative rule-making review committee and refiled  
10 in the state register on the sixteenth day of December, one  
11 thousand nine hundred ninety-seven, relating to the  
12 division of health (breast and cervical cancer diagnostic  
13 and treatment fund, 64 CSR 69), is authorized.

14

15 NOTE: The purpose of this bill is to authorize the  
16 Division of Health to promulgate a legislative rule  
17 relating to the Breast and Cervical Cancer Diagnostic and  
18 Treatment Fund.

19

20 Strike-throughs indicate language that would be  
21 stricken from the present law, and underscoring indicates  
22 new language that would be added.

64-69

**Senate Bill No. 302**

(By Senator(s) Ross, Anderson, Bowman,  
Macnaughtan, Boley and Buckalew)

[Introduced January 30, 1998; referred to the Committee on Health and Human Resources; and then to the Committee on the Judiciary.] *then Finance;*

10 A BILL to amend and reenact section one, article five,  
11 chapter sixty-four of the code of West Virginia, one  
12 thousand nine hundred thirty-one, as amended, relating  
13 to authorizing the division of health to promulgate a  
14 legislative rule relating to the breast and cervical  
15 cancer diagnostic and treatment fund.

16 *Be it enacted by the Legislature of West Virginia:*

17 That section one, article five, chapter sixty-four of  
18 the code of West Virginia, one thousand nine hundred  
19 thirty-one, as amended, be amended and reenacted, to read  
20 as follows:

21 ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND  
22 HUMAN RESOURCES TO PROMULGATE LEGISLATIVE RULES.

23 §64-5-1. State board of health; division of health.

1           (a) The legislative rule filed in the state register  
2 on the eighth day of November, one thousand nine hundred  
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6 legislative rule-making review committee and refiled in the  
7 state register on the twenty-seventh day of February, one  
8 thousand nine hundred ninety-seven, relating to the  
9 division of health (nursing home licensure, 64 CSR 13), is  
10 authorized.

11           (b) The legislative rule filed in the state register  
12 on the thirtieth day of August, one thousand nine hundred  
13 ninety-six, authorized under the authority of section  
14 seven, article one, chapter sixteen of this code, modified  
15 by the division of health to meet the objections of the  
16 legislative rule-making review committee and refiled in the  
17 state register on the twenty-sixth day of February, one  
18 thousand nine hundred ninety-seven, relating to the  
19 division of health (child care centers, 64 CSR 21), is  
20 authorized.

21           (c) The legislative rule filed in the state register  
22 on the thirtieth day of August, one thousand nine hundred  
23 ninety-six, authorized under the authority of section

1 twenty-three, article four-c, chapter sixteen of this code,  
2 modified by the division of health to meet the objections  
3 of the legislative rule-making review committee and refiled  
4 in the state register on the twenty-eighth day of February,  
5 one thousand nine hundred ninety-seven, relating to the  
6 division of health (emergency medical services, 64 CSR 48),  
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8 (d) The legislative rule filed in the state register  
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13 of the legislative rule-making review committee and refiled  
14 in the state register on the twenty-sixth day of February,  
15 one thousand nine hundred ninety-seven, relating to the  
16 division of health (residential board and care homes, 64  
17 CSR 65), is authorized.

18 (e) The legislative rule filed in the state register  
19 on the fifth day of October, one thousand nine hundred  
20 ninety-five, under the authority of section ten, article  
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22 director of the department of health to meet the objections  
23 of the legislative rule-making review committee and refiled

1 in the state register on the thirty-first day of October,  
2 one thousand nine hundred ninety-six, relating to the  
3 department of health (clinical laboratory technician and  
4 technologist licensure and certification, 64 CSR 57), is  
5 authorized until July 1, 1998: *Provided*, That the director  
6 of the department of health review, revise and propose,  
7 within the statutory deadline and in accordance with the  
8 provisions of article three, chapter twenty-nine-a of this  
9 code, a rule for legislative consideration during the  
10 legislative session of one thousand nine hundred ninety-  
11 eight with the following amendments:

12       "On page one, subsection 2.2.2, following the semi-  
13 colon, by striking the word 'or';

14       On page one, by inserting a new 2.2.3, to read as  
15 follows: '2.2.3. Any respiratory care provider licensed  
16 within the state providing diagnostic testing within the  
17 scope of his or her professional license who performs  
18 moderate complexity testing as defined by CLIA, pursuant to  
19 42 CFR 493.17; or';

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22       And,

23       "On page 6, subsection 7.2, after the word

1 'Personnel', by striking the period and inserting in lieu  
2 thereof the following: 'or by the International Society  
3 for Clinical Laboratory Technology.'"

4 (f) The legislative rule filed in the state register  
5 on the first day of August, one thousand nine hundred  
6 ninety-seven, authorized under the authority of section  
7 eight, article thirty-three, chapter sixteen, of this code,  
8 modified by the division of health to meet the objections  
9 of the legislative rule-making review committee and refiled  
10 in the state register on the sixteenth day of December, one  
11 thousand nine hundred ninety-seven, relating to the  
12 division of health (breast and cervical cancer diagnostic  
13 and treatment fund, 64 CSR 69), is authorized.

14

15 NOTE: The purpose of this bill is to authorize the  
16 Division of Health to promulgate a legislative rule  
17 relating to the Breast and Cervical Cancer Diagnostic and  
18 Treatment Fund.

19

20 Strike-throughs indicate language that would be  
21 stricken from the present law, and underscoring indicates  
22 new language that would be added.