

**DEPARTMENT OF LABOR****Pension and Welfare Benefits Administration****29 CFR Chapter XXV**

RIN 1210-AA75

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Care Financing Administration****45 CFR Subtitle A**

RIN 0938-AJ44

**Coverage for Breast Reconstruction and Related Services After a Mastectomy**

**AGENCIES:** Pension and Welfare Benefits Administration, Department of Labor; and Health Care Financing Administration, Department of Health and Human Services.

**ACTION:** Solicitation of comments.

**SUMMARY:** This document is a request for information regarding issues under the Women's Health and Cancer Rights Act of 1998 (WHCRA). The Department of Labor and the Department of Health and Human Services (collectively, the Departments) have received numerous inquiries from the public on a number of issues arising under WHCRA. Further comments from the public are welcome.

**DATES:** Comments should be submitted on or before June 28, 1999.

**ADDRESSES:** Written comments should be submitted with a signed original and 2 copies to the Pension and Welfare Benefits Administration (PWBA) at the address specified below. PWBA will provide copies to the Department of Health and Human Services for its consideration. All comments will be available for public inspection and copying in their entirety. Comments should be sent to: Health Care Task Force, Pension and Welfare Benefits Administration, Room N-5677, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210, Attn: WHCRA Solicitation of Comments. Written comments may also be sent by Internet to the following address: whcra-comments@pwba.dol.gov.

All comments received will be available for public inspection and copying at the Public Disclosure Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N-5638, 200 Constitution Avenue, NW, Washington, DC 20210, on Monday through Friday of each week from 8:30 a.m. to 4:30 p.m. Comments received timely will also be available for

public inspection approximately 3 weeks after the end of the comment period, in Room 443-G of the Department of Health and Human Services offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone (202) 690-7890).

**FOR FURTHER INFORMATION CONTACT:** Mila Kofman, Department of Labor, Pension and Welfare Benefits Administration, at 202-219-8671 (not a toll-free number); or Suzanne Long, Health Care Financing Administration, at 410-786-1565 (not a toll-free number) for inquiries regarding WHCRA.

*Customer service information.* To assist consumers and the regulated community, the Departments have issued questions and answers concerning the Women's Health and Cancer Rights Act. Individuals interested in obtaining a copy of the Department of Labor's publication may call a toll free number, 800-998-7542, or access the publication on-line at [www.dol.gov/dol/pwba](http://www.dol.gov/dol/pwba), the Department of Labor's website. Questions and answers pertaining to WHCRA are also available on-line at [www.hcfa.gov/hipaa](http://www.hcfa.gov/hipaa), HCFA's website.

**SUPPLEMENTARY INFORMATION:****Background**

The Women's Health and Cancer Rights Act of 1998 (WHCRA) was enacted on October 21, 1998 (Pub. L. 105-277). WHCRA amended the Employee Retirement Income Security Act of 1974, as amended, (ERISA) and the Public Health Service Act (PHS Act) to provide protection for patients who elect breast reconstruction in connection with a mastectomy. WHCRA applies to both employment-based health coverage (group coverage) and individual (non-employment based) health insurance. WHCRA amended ERISA and the PHS Act by adding new requirements to Part 7 of Subtitle B of Title I of ERISA and to Title XXVII of the PHS Act. Part 7 and Title XXVII (health insurance reform provisions) were previously added to ERISA and the PHS Act by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While those HIPAA provisions amended the Internal Revenue Code (Code) as well, WHCRA did not amend the Code.

WHCRA is intended to provide new protections for mastectomy patients. Group health plans and health insurance issuers, e.g., insurance companies or health maintenance

organizations (HMOs),<sup>1</sup> offering medical and surgical benefits for a mastectomy are subject to WHCRA.

Under WHCRA, group health plans and health insurance issuers must provide coverage for reconstructive surgery if an individual who is receiving benefits in connection with a mastectomy elects breast reconstruction. WHCRA requires group health plans and health insurance issuers to provide coverage for—

- Reconstruction of the breast on which the mastectomy has been performed;
  - Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
  - Prostheses and physical complications at all stages of a mastectomy, including lymphedemas.
- WHCRA requires coverage to be provided in a manner determined in consultation with the attending physician and the patient.

WHCRA's requirements apply only to group health plans and health insurance issuers that provide coverage for a mastectomy. However, WHCRA does not require such entities to provide coverage for a mastectomy. WHCRA also does not prohibit group health plans and health insurance issuers from imposing deductibles or coinsurance requirements for health benefits relating to reconstructive surgery in connection with a mastectomy as long as such requirements are consistent with those established for other benefits under the plan or coverage. Additionally, WHCRA does not require mastectomy patients to undergo reconstructive surgery.

WHCRA also prohibits certain compensation arrangements. Specifically, WHCRA prohibits group health plans and health insurance issuers from providing incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual in a manner inconsistent with the law.

<sup>1</sup> WHCRA was added to the existing health insurance reform provisions in Part 7 of Title I of ERISA and Title XXVII of the PHS Act and is subject to the definitions in Part 7 and Title XXVII. The term *group health plan* is defined in 29 CFR 2590.701-2 (1997) and 45 CFR 144.103 (1997) ("\* \* \* an employee welfare benefit plan \* \* \* to the extent that the plan provides medical care \* \* \* to employees or their dependents \* \* \* directly or through insurance, reimbursement, or otherwise."). The term *health insurance issuer* is defined in 29 CFR 2590.701-2 (1997) and 45 CFR 144.103 (1997) ("\* \* \* an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance \* \* \*"). These terms also apply to the Newborns' and Mothers' Health Protection Act and the Mental Health Parity Act and the regulations implementing these laws.

WHCRA also prohibits group health plans and health insurance issuers from penalizing or otherwise reducing or limiting the reimbursement of an attending provider because such provider provided care to an individual in accordance with the law.

Additionally, WHCRA prohibits group health plans and health insurance issuers from denying a patient eligibility or continued eligibility to enroll or renew coverage under the terms of the plan or policy solely to avoid the requirements of WHCRA. WHCRA further requires group health plans and health insurance issuers to notify participants, and in the individual market, policyholders, of their rights under the law upon enrollment and annually thereafter.

The requirements under WHCRA apply to group health plans and health insurance issuers offering coverage in connection with such plans, for plan years beginning on or after October 21, 1998 (the date of enactment of WHCRA). For health insurance issuers in the individual market, the requirements apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after October 21, 1998. Accordingly, the Departments are working actively to develop and promulgate regulations implementing WHCRA.

#### **Economic Analysis/Paperwork Reduction Act Information/Regulatory Flexibility Act Information**

Executive Order 12866 requires that the Departments assess the costs and benefits of a significant rule making action and the alternatives considered, using the guidance provided by the Office of Management and Budget. These costs and benefits are not limited to the Federal government, but pertain to the affected public as a whole. Under Executive Order 12866, the Departments must also determine whether implementation of WHCRA will be economically significant. A rule that has an annual effect on the economy of \$100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act may require the Departments to prepare an analysis of the economic impact on small entities of proposed rules and regulatory alternatives. An analysis under the Regulatory Flexibility Act must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and issuers and, in some contexts small governmental entities), the expense of the reporting and other

compliance requirements (including the expense of using professional expertise), and a description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities. The Departments seek additional information from small entities regarding any special problems they might encounter in implementing the requirements of WHCRA and any regulatory guidance that might minimize those problems.

The Paperwork Reduction Act requires that the Departments estimate how many "respondents" will be required to comply with any "collection of information" aspects of the regulations and how much time and cost will be incurred as a result. A collection of information includes record-keeping, reporting to governmental agencies, and third-party disclosures.

The Departments are requesting comments that may contribute to the analyses that will be performed under these requirements.

#### **Comments**

Comments have been received from the public on a number of issues arising under WHCRA. These comments include questions about the notice requirements under WHCRA. More specifically, the Departments have been asked what information must be included in the annual notice and the enrollment notice required by WHCRA. To assist the regulated community and individuals, the Departments are considering whether to include in the regulation a model notice which will describe the information that must be included in these notices. The model notice would include information on the benefits required by WHCRA and permitted deductibles and coinsurance limitations. Comments are invited on whether a model notice would be helpful.

In addition to the questions relating to the notice requirements, the Departments have received questions regarding the timing of the requirements under WHCRA. For example, the Departments have received questions on whether, to what extent, and how WHCRA applies if an individual had a mastectomy, but not breast reconstruction, before changing health plans or coverage. Similarly, questions have been raised about whether there is a specific time period following a mastectomy after which WHCRA requirements no longer apply. Additional comments are welcome.

The Departments have also received questions concerning how WHCRA

would interact with State law. Under WHCRA, State law protections continue to apply to certain health coverage if the State law in effect on October 21, 1998 (date of enactment of WHCRA)

"requires coverage of at least the coverage of reconstructive breast surgery otherwise required" by the federal requirements under WHCRA. The Departments have been asked which State laws would continue to apply. Additional questions are invited, and in particular, the Departments are interested in comments from State regulators on the scope of specific State laws.

The Departments welcome any and all comments related to WHCRA. However, the Departments are particularly interested in receiving comments on the aforementioned questions and those related to the following specific topics. While the information supplied by the public related to these specific topics will be used to formulate overall policy, it will also be used for analyses under Executive Order 12866, Paperwork Reduction Act, and Regulatory Flexibility Act.

*Specific areas with respect to the Departments' responsibilities and analysis under Executive Order 12866, Paperwork Reduction Act, and Regulatory Flexibility Act in which the Departments are interested include:*

1(a). Prior to WHCRA's enactment, what proportion of group health plans and/or health insurance issuers had excluded, restricted, or limited coverage of reconstructive surgery following mastectomies?

1(b). What specific exclusions, restrictions, or limits applied?

1(c). Did patient cost sharing for such surgery differ from that for other covered benefits?

1(d). Did coverage for such surgeries vary depending on whether they were performed immediately following mastectomies or later as a separate procedure?

2. How did group health plans and health insurance issuers covering such surgery compensate providers for their related services?

3. Were small group health plans more or less likely than large group health plans to exclude, restrict, or limit coverage for such surgery?

4(a). Among group health plans and health insurance issuers covering such surgery at a level consistent with WHCRA, what was the incidence and cost of such surgery?

4(b). Do group health plans and health insurance issuers currently notify participants and beneficiaries of their coverage consistent with WHCRA's notification requirements?

5(a). Among group health plans and health insurance issuers that must increase coverage of such surgery to comply with WHCRA, what are the anticipated claims or premium cost associated with that increase?

5(b). What is the anticipated administrative cost to amend plan documents and/or insurance contracts?

5(c). Will some group health plans and health insurance issuers make other amendments to offset WHCRA's cost?

5(d). Will plans' costs and responses vary with plans' size?

6. Does the extent and nature of coverage for such surgery affect the

likelihood that patients will elect it and/or the timing of such surgery?

7. What are the benefits of coverage for reconstructive surgery following mastectomy?

The purpose of this announcement is to advise the public that further comments and suggestions concerning any area or issue pertinent to the assessment and development of regulatory guidance regarding WHCRA are welcome.

All submitted comments will be made part of the official record and will be available for public inspection.

Signed at Washington, DC this 17th day of March 1999.

**Richard M. McGahey,**

*Assistant Secretary, Pension and Welfare Benefits Administration, Department of Labor.*

Signed at Washington, DC this 22nd day of March 1999.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration, Department of Health and Human Services.*

[FR Doc. 99-13625 Filed 5-27-99; 8:45 am]

BILLING CODE 4510-29-P; 4120-01-P