

STORAGE NAME: h0573.hcs

DATE: March 10, 1997

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
BILL ANALYSIS & ECONOMIC IMPACT STATEMENT**

BILL #: HB 573

RELATING TO: Insurance Coverage for Reconstructive Breast Surgery

SPONSOR(S): Rep(s). Murman, Heyman, Argenziano, and others

STATUTE(S) AFFECTED: Sections 627.6417, 627.6612, and 627.6699, F.S.

COMPANION BILL(S): SB 916(i), HB 453(s), SB 1150(s).

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE SERVICES
- (2) GENERAL GOVERNMENT APPROPRIATIONS
- (3)
- (4)
- (5)

I. SUMMARY:

Current law requires all health insurance policies issued in the state which provide coverage for mastectomies to make available to the policyholder coverage for the initial prosthetic device and reconstructive surgery incident to a mastectomy. This is a mandated option, which means the insurer may charge an additional premium for the coverage. Coverage for prosthetic devices and reconstructive surgery is subject to the deductible and coinsurance conditions applied to the mastectomy and all other terms and conditions applicable to other benefits. If a mastectomy is performed and there is no evidence of malignancy, coverage may be limited to the provision of the initial prosthetic device and reconstructive surgery within two years after the date of mastectomy. (see ss. 627.6417 and 627.6612, F.S.)

This bill revises current law to specify that coverage is required for surgical procedures and devices incident to a mastectomy for both the breast that was subject to the mastectomy and the other breast if necessary to achieve symmetry. In addition, the bill deletes the two year statute of limitation restriction on coverage for care incident to a mastectomy when no evidence of malignancy was found. The bill applies these new requirements to individual, group, and small group health insurance policies.

There is no fiscal impact on state government but local governments may experience increased costs associated with providing employee health insurance benefits.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Breast cancer affects a large number of women and their families in Florida. Over 10,000 women will be diagnosed with breast cancer in Florida this year, and more than 2,600 will die from the disease. There are an estimated 150,000 Floridians alive today who have been diagnosed with breast cancer at some point in their lives. Direct health care costs for the treatment of breast cancer in Florida exceed \$160 million annually.

A common treatment for breast cancer is a mastectomy, which is the surgical removal of all or a portion of a woman's breast. Following the mastectomy, the breast is usually reconstructed surgically using a breast implant. Women who have had breast implantation frequently experience local complications during subsequent years. A recent study in the *New England Journal of Medicine* (vol 336, number 10, March 6, 1997, pp 667) studied 749 women who received a first breast implant between 1964 and 1991. During the follow-up period (on average 7.8 years) almost a third (28 percent) of the women underwent additional implant-related surgical procedures. The most frequent problem was capsular contraction (shrinking of scar tissue around the implant that can cause painful hardening of the breasts), followed by implant rupture, hematoma (circumscribed collection of blood in a tissue or organ caused by a break in a blood vessel), and wound infection. Complication rates were significantly lower among women with cosmetic implants than among those who received implants after mastectomy for breast cancer or prophylactic mastectomy.

Since breast implants first came on the market 30 years ago, an estimated 1 million women in the United States have had these devices surgically inserted to enlarge or reshape their breasts, or for reconstruction following breast cancer surgery. Most are filled with a silicone gel; about 10 percent contain saline (salt water). Until recently, both gel-filled and saline implants were available to virtually any woman who wanted them.

In recent years, however, there has been an impassioned debate on the safety of silicone gel-filled breast implants and whether or not the devices should remain on the market. Despite the controversy, there was agreement among manufacturers, physicians, surgeons, consumer advocates, and women with implants on at least one point: Solid clinical research is needed to answer questions that loom large regarding the safety and long-term effects of these devices.

The gel-filled implants came under scrutiny by the Federal Food and Drug Administration as part of an agency review of medical devices in use before 1976, when Congress authorized FDA to regulate devices. In particular, interest in the implants was spurred by reports of adverse effects, including:

- capsular contracture (shrinking of scar tissue around the implant that can cause painful hardening of the breasts);
- claims that the implants could hide some of the breast tissue, interfering with the ability to take and interpret quality mammograms;
- questions about possible effects on the immune system due to migration of small quantities of silicone gel throughout the body; and

- concerns about cancer risk, especially in connection with polyurethane-coated implants.

Another issue involves surgical treatment of the remaining breast. After mastectomy, implantation, and reconstructive surgery, there is often a pronounced difference in the size and shape of the two breasts. Some state laws, such as California, require that insurance policies must cover the cost of treatment of the un-diseased breast in order to achieve symmetry. There is no such provision in Florida's law.

Florida's law related to coverage for surgical procedures and devices incident to mastectomy is contained in s. 627.6417, F.S., for individual health insurance policies, and s. 627.6612, F.S., for group health insurance policies. The law requires that companies offer coverage for an additional premium. It is up to the policyholder to select the additional coverage. As such, it is referred to as a mandated option, as opposed to a mandated benefit, which would require that the insurance policy automatically provide the coverage as a part of the overall premium.

The law specifies that the coverage for prosthetic devices and reconstructive surgery is subject to the deductible and coinsurance conditions applied to the mastectomy. If mastectomy is performed and no evidence of malignancy is found, coverage may be limited to the initial prosthetic device and reconstructive surgery within 2 years of the date of the mastectomy.

B. EFFECT OF PROPOSED CHANGES:

A person who is an individual, group, or small group policyholder will receive expanded benefits for surgical procedures and devices incident to a mastectomy, including coverage for surgical procedures and devices incident to a mastectomy for both the breast that was subject to the mastectomy and the other breast if necessary to achieve symmetry. In addition, there will no longer be a two year statute of limitation restriction on coverage for care incident to a mastectomy when no evidence of malignancy was found.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

- a. Does the bill create, increase or reduce, either directly or indirectly:

- (1) any authority to make rules or adjudicate disputes?

Yes, the bill gives the Department of Insurance authority to enforce additional standards on health insurers.

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- (2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Yes, health insurers will be required to abide by the new standards established in the bill.

- (3) any entitlement to a government service or benefit?

No.

- b. If an agency or program is eliminated or reduced:

- (1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

- (2) what is the cost of such responsibility at the new level/agency?

N/A

- (3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

- a. Does the bill increase anyone's taxes?

No.

- b. Does the bill require or authorize an increase in any fees?

Health insurance premiums may increase.

- c. Does the bill reduce total taxes, both rates and revenues?

No.

- d. Does the bill reduce total fees, both rates and revenues?

No.

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e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

- a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

- b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

Yes, through higher health insurance premiums.

4. Individual Freedom:

- a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No, the bill increases government regulation of health insurance.

- b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

Yes, the bill imposes additional standards on health insurers.

5. Family Empowerment:

- a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

No.

(5) Are families penalized for not participating in a program?

No.

b. Does the bill directly affect the legal rights and obligations between family members?

No.

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 627.6417, F.S., relating to optional individual insurance coverage for procedures incident to mastectomies, to make coverage a mandated benefit instead of a mandated option and:

- (1) Mandate coverage for prosthetic devices and reconstructive surgery to both the breast that was subject to the mastectomy and the other breast if necessary to achieve symmetry; and
- (2) Delete the two-year statute of limitation restriction on coverage for care incident to a mastectomy in which no evidence of malignancy was found.

Section 2. Amends s. 627.6612, F.S., relating to optional group, blanket, or franchise insurance coverage for procedures incident to mastectomies, to make coverage a mandated benefit instead of a mandated option and:

- (1) Mandate coverage for prosthetic devices and reconstructive surgery to both the breast that was subject to the mastectomy and the other breast if necessary to achieve symmetry; and

- (2) Delete the two-year statute of limitation restriction on coverage for care incident to a mastectomy in which no evidence of malignancy was found.

Section 3. Amends s. 627.6699, F.S., relating to the Employee Health Care Access Act, to require the standard health benefit plan applicable to small employers to include reconstructive breast surgery as mandated by s. 627.6612, F.S.

Section 4. Provides an effective date of October 1, 1997.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

Indeterminate.

2. Recurring Effects:

Indeterminate

3. Long Run Effects Other Than Normal Growth:

Indeterminate.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

Health insurers will be required to cover enhanced benefits related to breast implants surgical reconstruction following mastectomy.

2. Direct Private Sector Benefits:

Policyholders will receive enhanced benefits for breast implants and reconstructive surgery related to a mastectomy.

3. Effects on Competition, Private Enterprise and Employment Markets:

None.

D. FISCAL COMMENTS:

Since most local governments provide employee health insurance benefits, local governments will experience increased costs to the extent that the benefits required by this bill exceed current benefits. It is not possible to assign a dollar amount to the potential increased costs.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

Yes, this bill does require counties or municipalities to expend funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority of counties or municipalities to raise revenues.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

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VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

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