

STORAGE NAME: h0453.hcs
DATE: March 10, 1997

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

BILL #: HB 453
RELATING TO: Insurance Coverage for Procedures Incident to Mastectomies
SPONSOR(S): Rep. Mackey
STATUTE(S) AFFECTED: Section 627.6417, F.S.
COMPANION BILL(S): SB 1150(l), HB 573(s), SB 916(s)
ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:
(1) HEALTH CARE SERVICES
(2)
(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 s. 627.6417, F.S.)

This bill revises current law relating to individual health insurance policies to specify that coverage for surgical procedures and devices incident to a mastectomy is not subject to an additional deductible. 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. Finally, the bill clarifies that the term "mastectomy" applies to prophylactic mastectomies, procedures necessitated by complication caused by implants, and includes a variety of listed reconstructive procedures.

Since the provisions of this bill apply only to individual health insurance policies, there is no fiscal impact on state or local government.

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 purchases an individual health insurance policy and who selects optional coverage for surgical procedures and devices incident to a mastectomy will receive expanded benefits, including not being required to meet a separate deductible for implants and reconstructive surgery, no time limit on coverage for prosthetic devices when no malignancy is found, and coverage for an expanded list of medical procedures related to complications, including coverage for prophylactic mastectomies, or a mastectomy performed on a high risk woman to prevent the occurrence of breast cancer.

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?

No.

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

No.

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

No.

- 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, persons who select the expanded coverage pay through increased 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?

N/A

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

N/A

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 insurance coverage for procedures incident to mastectomies, to:

- (1) Specify that coverage for surgical procedures and devices incident to a mastectomy is not subject to an additional deductible;
- (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; and
- (3) Clarify that the term "mastectomy" applies to prophylactic mastectomies, procedures necessitated by complications caused by implants, and includes certain reconstructive procedures.

Section 2. 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:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

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 who select the optional coverage will receive enhanced benefits.

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

None.

D. FISCAL COMMENTS:

Since this bill applies to individual policies only, it has no impact on local government.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not 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:

The provisions of this bill apply to individual health insurance policies only. The bill does not apply to group health policies, small group health policies, out of state group health policies, multiple employer warfare arrangements, or health maintenance organizations.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

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