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DATE: April 10, 1999

**HOUSE OF REPRESENTATIVES
AS FURTHER REVISED BY THE COMMITTEE ON
GENERAL GOVERNMENT APPROPRIATIONS
ANALYSIS**

BILL #: CS/HB 377

RELATING TO: Organ Transplants

SPONSOR(S): Committee on Insurance and Representative Bense & others

COMPANION BILL(S): CS/SB 62 (s)

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

- (1) HEALTH CARE SERVICES YEAS 13 NAYS 0
 - (2) INSURANCE YEAS 12 NAYS 0
 - (3) GENERAL GOVERNMENT APPROPRIATIONS YEAS 10 NAYS 0
 - (4)
 - (5)
-

I. SUMMARY:

Section 627.4236, F.S., prohibits an insurer or an HMO from using a policy exclusion for experimental, clinical investigative, educational, or similar treatments to exclude coverage for bone marrow transplant procedures for cancer when such procedures are recommended by the referring physician and the treating physician and the particular use of the procedure is accepted within the appropriate oncological speciality and is determined by rule not to be experimental.

Health insurers and health maintenance organizations (HMOs) would be required under the bill to cover the costs associated with the donor patient to the same extent that the current law requires the insurer or HMO to cover costs associated with the insured for covered bone marrow transplant procedures that are determined to be scientifically acceptable and non-experimental for certain types of cancer. Insurers may limit the reasonable costs of searching for the donor to immediate family members and the National Bone Donor Program.

The membership of the Organ Transplant Advisory Council would be expanded from 8 to 12 members and the term of council would be extended from 1 year to 2 years.

The costs associated with the donor patients are anticipated to be an aggregate of \$2.2 million to the private insurance and HMO industry.

In addition, an estimated \$19,775 cost would be incurred for potential state-employee-related bone marrow donor coverage costs. Expansion of the Organ Transplant Advisory Council would have a projected cost of \$1,768 in fiscal year 1999-2000 and an annualized cost of \$3,536 in the Agency for Health Care Administration.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Section 627.4236, F.S., prohibits an insurer or an HMO from using a policy exclusion for experimental, clinical investigative, educational, or similar treatments to exclude coverage for bone marrow transplant procedures for cancer when such procedures are recommended by the referring physician and the treating physician and the particular use of the procedure is accepted within the appropriate oncological speciality and is determined by rule not to be experimental. The Agency for Health Care Administration (AHCA) has adopted a rule (10D-127.001, Florida Administrative Code) which specifies the particular malignancies for which the bone marrow transplant procedure is acceptable (i.e., non-experimental) after consulting with an advisory panel of medical experts as required by the current law. The nine-member advisory panel must conduct, at least biennially, a review of scientific evidence to ensure that bone marrow transplant procedures are based on current research findings and that insurance policies offer coverage for the latest medically acceptable bone marrow transplant procedures.

Bone marrow transplantation is a highly technical therapy that offers hope to patients with bone marrow failure or various malignancies. It is the process of taking healthy bone marrow (blood stem cells) from a donor and transplanting (transfusing) it into a patient. The patient receives intensive chemotherapy and/or radiation therapy to destroy all cancerous cells in conjunction with the bone marrow transplant procedure. Such transplants are accepted treatments for a variety of cancer types, primarily leukemia, and including breast, ovarian, and lung cancer as well as Hodgkin's, non-Hodgkin's lymphoma, sarcoma and other non-cancerous hematological disorders.

There are two basic types of bone marrow transplant procedures performed. Depending on the disease, blood stem cells can often be taken from the patient him/herself. This is known as *autologous* transplantation and there are obviously no separate donor costs involved because the insured is the donor. The second basic type of transplant, called *allogeneic* transplantation, uses stem cells collected from another person, either a related or unrelated donor, with a closely matched tissue type. Persons undergoing allogeneic transplantation incur donor charges relating to the procurement of stem cells and possible search charges (depending upon whether the donor is a sibling or an unrelated donor) which may or may not be covered under their health policy.

According to the *Organ Transplant Program Utilization Summary* published by AHCA, approximately 2,068 bone marrow transplant procedures were performed in Florida from 1993 to 1997. Sixty percent of the transplants were autologous, while 40 percent were allogeneic. Of the allogeneic procedures, 65 percent (26 percent of the total bone marrow transplants) involved a matched sibling and 35 percent (14 percent of the total bone marrow transplants) involved a matched unrelated donor. Shands Hospital at the University of Florida, along with the H. Lee Moffitt Cancer Center in Tampa and the University of Miami/Jackson Memorial Medical Center perform over 80 percent of all bone marrow transplants in the state. The average cost of a transplant ranges from \$100,000 to \$250,000, depending on whether the procedure is autologous or allogeneic.

Donors are a necessary part of all allogeneic bone marrow transplant procedures and such costs which involve searching for a donor and procuring or harvesting the donor blood stem material can amount to thousands of dollars. These donor related costs are not required to be covered by insurers and HMOs under current law. Representatives with Shands Hospital estimate donor costs range between \$10,000 and \$30,000 and may be higher depending upon whether the donor is a sibling or an unrelated donor. (See Fiscal Analysis and Economic Impact Statement below.) According to representatives with Shands Hospital, in 85 percent of their allogeneic bone marrow transplant cases, donor search costs are covered by the patient's insurance. Additionally, once the donor is identified, the medical evaluation and bone marrow procurement procedure is covered by the patient's insurance in 90 percent to 95 percent of the cases.

The current law does not apply to a "standard" or a "basic" benefit plan that small group carriers must offer to small employers (with 50 or fewer employees) because s. 627.6699(15)(a), F.S., provides that unless a law is made *expressly applicable* to such plans, a law requiring coverage for a health care benefit does not apply to standard or basic benefit plans. However, current law applies to any major medical policy issued to a small employer that provides benefits different from the standard or basic policies. According to representatives with the Department of Insurance, the current standard group policy which was developed by a health benefit plan committee appointed by the Insurance

Commissioner, does provide cancer coverage for both the patient and donor costs for several bone marrow transplant procedures.

Organ Transplant Advisory Council consists of 8 members, the council exists within the AHCA. Its responsibilities are to recommend indications to ACHA for adult and pediatric organ transplant, and form guidelines for certain organ transplants.

B. EFFECT OF PROPOSED CHANGES:

Health insurers and health maintenance organizations (HMOs) would be required to cover the costs associated with the donor patient to the same extent that the current law requires the insurer to cover costs associated with the insured for covered bone marrow transplant procedures for the treatment of cancers when bone marrow transplant procedures are recommended by the referring physician and the particular use of the procedure is accepted within the appropriate oncological specialty and is determined by rule not to be experimental. Reasonable donor search costs could be limited to immediate family members and the National Bone Marrow Donor Program.

The advisory council would be expanded from 8 members to 12 members and the term of the council chair would increase from 1 year to 2 years.

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?

N/A

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

Insurers will be required to provide coverage for services that they may not be covering today.

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

N/A

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?

N/A

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

N/A

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

N/A

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

N/A

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

N/A

3. Personal Responsibility:

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

N/A

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

Beneficiaries may pay slightly higher insurance costs as impacted insurers pass costs on to covered persons.

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 may decrease insurers' options since the bill requires insurers to cover donor-patient costs to the same extent they cover costs associated with the insured.

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

N/A

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?

N/A

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. STATUTE(S) AFFECTED:

Sections 381.0602 and 627.4236(2), F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Names this act the "Pat Thomas Bone Marrow Transplant Act"

Section 2. Amends s. 381.0602, F.S., relating to the Organ Transplant Advisory Council. This section expands council membership from 8 to 12 members and increases the term of the council chair.

Section 3. Amends s. 627.4236(2), F.S., relating to insurer and HMO coverage requirements for bone marrow transplant procedures, to require health insurers and HMOs to cover the costs associated with the donor patient to the same extent that the current law requires the insurer to cover costs associated with the insured for covered bone marrow transplant procedures that are determined to be scientifically acceptable and non-experimental for certain types of cancer.

Section 4. Provides legislative finding of important state interest.

Section 5. Provides an effective date of January 1, 2000.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

No increased administrative cost anticipated.

2. Recurring Effects:

Under the State Employees' Preferred Provider Organization (PPO) health insurance plan and its contracted HMO providers, donor costs associated with covered bone marrow transplant procedures are covered to the same extent and limitation as those costs associated with the insured. However, donor search costs are not covered and state officials estimate such costs would be \$19,775 annually. This estimate is based on the fact that during 1998, the PPO plan paid for three allogeneic transplants (two were siblings and one an unrelated donor) and the average search costs were \$1,025 (per sibling) and \$7,837 (per unrelated donor). Assuming the PPO plan pays for the same number of related and unrelated transplants in 1999, such search costs would add approximately \$9,887 to plan costs. Lacking any information on the number of bone marrow transplant procedures for HMOs, the state plan assumes that HMO donor search costs are similar. Thus, total annualized fiscal impact is \$19,775 (\$9,887 x 2). Anticipated cost for 1999/2000 is \$9,887.

The Department of Insurance would have the responsibility to verify bone marrow transplant donor coverage in all health insurance policies.

Increasing the membership of the Organ Transplant Advisors Council from 8 to 12 members will result in additional per diem and travel expenses incurred by the AHCA. According to the AHCA, the annualized recurring impact would be \$3,536 per year, half of which would be from the General Revenue Fund and half would be from ACHA's Administrative Trust Fund. The increased cost for 1999/2000 would be \$1,768, half from General Revenue and half from the Administrative Trust Fund.

3. Long Run Effects Other Than Normal Growth:

N/A

4. Total Revenues and Expenditures:

	<u>FY 1999 - 2000</u>	<u>Annualized</u>
Coverage Claim Costs for donor search:	\$9,887	\$19,775
Travel/Per Diem Reimbursement for Advisory Council (AHCA):	\$1,768	\$3,536

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

N/A

2. Recurring Effects:

N/A

3. Long Run Effects Other Than Normal Growth:

N/A

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

The Agency for Health Care Administration's hospital discharge data indicates that a total of 429 bone marrow transplants were performed in Florida in calendar year 1996 (the most recent complete year of information available). Of the 429 transplants, 294 were paid by commercial insurance, 118 were paid by the public sector, i.e., Medicaid, Medicare, and CHAMPUS, and 17 were self-pay. Of the 294 procedures paid by commercial insurance, it is estimated that 118 were allogeneic transplants which involved searching for a donor and the procurement of donor bone marrow. It is estimated that the total cost of coverage of these *donor related* costs associated with these 118 procedures would be \$2,231,000, or an average of \$18,907 per patient. This figure is based on the assumption that of the 118 allogeneic procedures, 77 involved siblings while 41 involved unrelated donors. The average sibling related donor cost was \$13,000 while the average costs for an unrelated donor was \$30,000, based on the information provided by Shands Hospital.

Donor costs associated with bone marrow transplant procedures are covered by many of the larger insurance companies and HMOs, however, sometimes the search costs are not covered. As reported by the Florida Association of Health Maintenance Organizations, the smaller plans do not routinely provide either donor coverage or donor search coverage. Several of Florida's larger insurance companies and HMOs and these companies' HMO and PPO policies cover donor procurement charges once the donor is identified. Officials with Shands Hospital state that in 85 percent of their allogeneic bone marrow transplant cases, donor search costs are covered by the patient's insurance. Additionally, once the donor is identified, the medical evaluation and bone marrow procurement procedure is covered by the patient's insurance in 90 percent to 95 percent of the cases. Therefore, the bill's fiscal impact would appear to be relatively minor.

Shands Hospital has prepared an impact study in response to s. 624.215, F.S., which requires organizations seeking consideration of a legislative proposal that would mandate a health benefit to prepare a report to the legislative committee with jurisdiction over the proposal to assess its financial and social impact. The study estimates the charges associated with the donor search, the evaluation of the donor and the procurement of bone marrow for allogeneic sibling transplants and allogeneic matched unrelated transplants.

2. Direct Private Sector Benefits:

Individuals in need of a bone marrow transplant would have fewer out-of-pocket expenses and possibly a shorter waiting period for a bone marrow transplant procedure if the donor costs are covered under their health insurance policies.

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

N/A

D. FISCAL COMMENTS:

The bill does not include the Florida Medicaid Program in its mandate and therefore does not create a direct fiscal impact for that program. However, to the extent that the bill results in a standard by which health care payers provide reimbursement for donor costs, the pressure will mount for the state to consider including this coverage as part of Medicaid as part of a uniform coverage and payment scheme across all payers.

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

A. **APPLICABILITY OF THE MANDATES PROVISION:**

The health insurance benefits required by this bill would apply to local government health insurance plans. To the extent this bill requires local governments to incur expenses, i.e., to pay additional health insurance costs, the bill falls within the purview of Article VII, Section 18 of the Florida Constitution, which provides that cities and counties are not bound by general laws requiring them to spend funds or to take action which requires the expenditure of funds unless certain specified exemptions or exceptions are met.

This bill may qualify for an exemption for bills having an insignificant fiscal impact.

The bill contains a legislative finding that the bill fulfills an important state interest.

B. **REDUCTION OF REVENUE RAISING AUTHORITY:**

The bill does not reduce the ability of local governments to raise revenue.

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

The bill does not reduce state tax shared with counties and municipalities.

V. **COMMENTS:**

The National Marrow Donor Program, a Congressionally authorized bone marrow donor registry established to identify donors for patients who need allogeneic matched bone marrow transplants, maintains a national registry of approximately 3.8 million volunteers willing to be bone marrow donors. (This issue is addressed as part of the Fiscal Analysis and Economic Impact Statement portion of this analysis.)

VI. **AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:**

On March 22, 1999 the Committee on Insurance adopted the bill as a committee substitute. The CS incorporates amendments adopted by the Committee on Health Care Services and Committee on Insurance.

The CS differs from the original bill in that the CS:

- 1) Includes a legislative finding that the bill fulfills an important state interest;
- 2) Expands the membership of the Organ Transplant Advisory Council from 8 to 12 members and increases the term for the council chair from 1 year to 2 years.
- 3) Names this act the "Senator Pat Thomas Bone Marrow Transplant Act"
- 4) Broadens the title to reflect the addition of provisions related to the Organ Transplant Advisory Council.
- 5) Changes effective date from July 1, 1999, to January 1, 2000.

VII. **SIGNATURES:**

COMMITTEE ON HEALTH CARE SERVICES:

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