SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Banking and Insurance Committee

BILL: SB 2052

INTRODUCER: Senator Peaden

SUBJECT: Bone Marrow Transplant/Insurance

DATE: April 19, 2006 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Deffenbaugh	BI	**Favorable**
2.			HE	
3.			HA	
4.				
5.				
6.				

I. Summary:

Currently, insurers and health maintenance organizations are required to provide coverage for bone marrow transplant procedures if certain conditions are met. The bill expands the definition of bone marrow transplant to mean human blood precursor cells administered to a patient to restore hematological and immunological functions following ablative or *nonablative* therapy with curative or *life prolonging* intent. Presently, the law covers ablative therapy with curative intent. These changes in the law will reflect current practices and advances in the practice of transplants. Over the years, nonablative therapies have been associated with less toxicity, improvements in survival, better quality of life, and less hospital costs. The goal of a number of transplants is to offer considerable improvements in both survival rates and quality of life for a number of patients. In other instances, survival is prolonged until a child is old enough to tolerate radiation therapy, and possibly be cured.

This bill substantially amends the following section of the Florida Statutes: 627.4236.

II. Present Situation:

Presently, s. 627.4236, F.S., defines a bone marrow transplant as "…human blood precursor cells administered to a patient to restore normal hematological and immunological functions following ablative therapy with curative intent." In 1992, the Legislature enacted s. 627.4236, F.S., prohibiting an insurer or a health maintenance organization from excluding coverage for bone marrow transplant procedures under policy exclusions for experimental, clinical investigative, educational, or similar procedure, if such procedures are recommended by the referring physician and the treating physician and the particular use of the procedure is accepted within the appropriate specialty and is determined by rule not to be experimental.

Bone marrow transplant 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 or the patient and transplanting (transfusing) it into a patient. The patient receives intensive chemotherapy 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.

The nine-member Bone Marrow Transplant advisory panel created within the AHCA, pursuant to s. 627.4236, F.S., 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. The panel is comprised of six members representing consumers, insurers, physicians, and hospitals.

The Agency for Health Care Administration (AHCA) has adopted a Rule 59B-12, F.A.C., which specifies the particular diseases and conditions for which the bone marrow transplant procedure are acceptable, specifies other conditions and diseases for which bone marrow transplant must be covered as long as the specified procedure is performed as part of a qualified clinical trial; and provides for approval of bone marrow transplant for unspecified diseases and conditions not otherwise addressed by the rule on a case-by-case basis.

Even though the rule requires coverage of a broad range of approved transplant procedures for various bone marrow diseases and conditions, non-myeloablative, or nonablative, stem cell transplantation is not addressed by the current law or rule. The statute defines bone marrow transplantation as "…cells administered to a patient…following *ablative* therapy…" Therefore, by definition, nonablative therapies are not considered bone marrow transplant procedures for which the AHCA or its panel may require insurer coverage.

The difference between myeloablative and non-myeloablative transplant is that ablative procedures require destruction of the patient's existing bone marrow, through high dose chemotherapy or radiation therapy, prior to introduction of donor stem cells. The consequential risks and side effects of ablation are serious, which significantly limits when and for which patients the treatment is recommended. In order to undergo such transplant, the patient must be in relatively good health, because treatment-related toxicity and graft-versus-host disease occur more frequently and with more severity with increased age or concurrent medical conditions.

In 1972, clinical trials of transplants without the myeloablative regimen were initiated, [1] and have recently enjoyed significant success for patients for which ablative therapies are not recommended.[2] A pre-transplantation immunosuppressive chemotherapeutic agent or radiation is used in lower doses than ablative therapy; therefore, it does not fully destroy the patients'

[1] Yonemoto R.H., Terasaki, P.I. Cancer immunotherapy with HLA-compatible thoracic duct lymphocyte transplantation: a preliminary report. *Cancer* 30: 1438-43, 1972.

[2] Giralt, S., Non-Myeloablative stem cell transplantation; Graft versus malignancy effects without myeloablative therapy, *IBMTR,* 1-7, Fall, 1999. American Society for Blood and Marrow Transplantation, Biology of Blood and Marrow Transplantation, *Journal of the American Society for Blood and Marrow Transplantation,* volume 7, number 2, 2001.

existing marrow or immune systems. Because non-myeloablative treatment is less toxic and may therefore be performed on an outpatient basis, perfection of these procedures could possibly lead to increased transplant success for all patients at considerable cost savings over myeloablative procedures. The procedures are sometimes referred to as "mini-transplants." Although varying regimen for mini-transplants have been the subject of clinical trials for several years, no definitive course of treatment can be recommended for any particular bone marrow disease or cancer.

The Bone Marrow Transplant Panel convened on November 22, 2005, to discuss various issues including proposed changes to s. 627.4236, F.S. In past meetings, the panel determined that the current statutory definition is no longer congruent with current practice. The panel noted that many therapy regimens, such as high dose Thytoxin for aplastic anemia, are not ablative. The panel recommended deleting the term, "ablative," to ensure that ablative, as well as nonablative therapy is covered, and adding the phrase "life-prolonging intent." Currently, the statute provides that ablative therapy must have curative intent. Many transplants offer considerable improvements in the both the quality of life and survival, yet do not cure the cancer.

III. Effect of Proposed Changes:

Section 1 amends s. 627.4236, F.S., to revise the definition of bone marrow transplant for purposes of insurance coverage, to include coverage for nonablative therapy as a bone marrow transplant procedure. This section is also revised to provide coverage for such bone marrow transplant procedures with life-prolonging intent. These changes would update the coverage requirements to reflect current practice and advancements in the practice of transplantation. For example, the use of bone marrow transplants is employed in instances where it is not a curative procedure; rather, the treatment has a survival benefit. Also, many therapy regimens currently used are not ablative; instead, they are nonablative. The current law defines bone marrow transplant as, ". . . human blood precursors cells administered to a patient to restore normal hematological and immunological functions following ablative therapy with curative intent."

Section 2 provides that this act will take effect on July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Insurance coverage for nonablative regimen will assist recipients of bone marrow transplants since this type of regimen has been shown to be associated with less toxicity, improvements in survival, better quality of life, and shorter hospital stays and hospital costs.

Nonablative therapy has been used for approximately 10 years and is now the preferred treatment for many bone marrow diseases and cancers. It is indeterminate how many insurers presently provide coverage for nonablative therapy regimens. The major transplant centers in the state have noted that nonablative therapy may result in lower hospital costs for patients than ablative therapy regimens.

C. Government Sector Impact:

Indeterminate. To the extent nonablative therapies are more effective and less costly, medical costs for bone marrow transplants could be reduced.

According to the Agency for Health Care Administration, the bill may have a fiscal impact on Medicaid, but the total cost cannot be determined until the bone marrow transplantation panel amends the existing rule specifying acceptable diagnosis codes for the procedure.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Bone Marrow Transplant Panel recommends revising this law since the current definition of bone marrow transplant is no longer congruent with current practice. The major university transplant centers support the bill (University of Florida, H. Lee Moffitt Cancer Center and Research Center, All Children's Hospital, Mayo Clinic).

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

VIII. Summary of Amendments:

None.

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