

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

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

Prepared By: The Professional Staff of the Health Policy Committee

BILL: SB 1968

INTRODUCER: Senator Posey

SUBJECT: Health Insurance

DATE: March 14, 2008                      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Deffenbaugh	BI	<b>Favorable</b>
2.	Garner	Wilson	HP	<b>Favorable</b>
3.			GA	
4.				
5.				
6.				

**I. Summary:**

This bill expands the definition of bone marrow transplant for purposes of required health insurance coverage to include nonablative therapy and authorizes coverage for bone marrow transplants for life-prolonging intent, not just for curative purposes. These changes in the law would update coverage requirements to reflect current practice and advancements in the area of bone marrow transplants.

The bill also requires health insurance companies and health maintenance organizations to provide identification cards to policyholders and subscribers, which contain specified information that can be used to estimate the financial responsibility of the covered person, in compliance with the federal Health Insurance Portability and Accountability Act of 1996, and contact information for the insurer or health maintenance organization. This information will assist hospitals and other providers in determining coverage and the financial responsibility of the covered person.

This bill amends ss. 627.4236, 627.642, 627.657, and 641.31, Florida Statutes.

**II. Present Situation:**

**Bone Marrow Transplants**

A bone marrow transplant (BMT) 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 the patient, or a donor, and transplanting the marrow through a transfusion into the patient. Bone marrow transplants are accepted treatments for a variety of

cancer types including: leukemia; breast, ovarian, and lung cancers; Hodgkin's and non-Hodgkin's lymphoma; sarcoma; and other non-cancerous hematological disorders.

There are two types of BMTs: ablative and nonablative (also called non-myeloablative). In an ablative BMT, the patient receives intensive chemotherapy or radiation therapy before receiving the transplant (called conditioning), which serves two purposes. First, it destroys the patient's abnormal blood cells or cancer. Second, it slows the patient's immune response against the donor bone marrow (graft rejection).<sup>1</sup>

The other type of BMT is called a mini-BMT, or a nonablative BMT. A nonablative BMT uses just enough chemotherapy to create room for the transplant. The transplanted stem cells then partner with existing bone marrow cells to fight cancer. This procedure has proven more effective in treating certain types of cancer than the traditional, ablative BMT.<sup>2</sup>

### **Health Insurance Coverage for Bone Marrow Transplants**

Presently, Florida law 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."<sup>3</sup> The Legislature enacted s. 627.4236, F.S., in 1992, which has been amended several times over the years to reflect technology advances and medical practices.<sup>4</sup> The law, as currently stated, prohibits an insurer or a health maintenance organization (HMO) 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 Advisory Panel*

Section 627.4236, F.S., also requires the Agency for Health Care Administration (agency or AHCA) to adopt rules specifying the bone marrow transplant procedures that are accepted within the appropriate oncological specialty and are not experimental for purposes of this law. The rules must be established based on the recommendations of a nine-member advisory panel. The panel is appointed by the secretary and is composed of:

- One adult oncologist, selected from a list of three names recommended by the Florida Medical Association;
- One pediatric oncologist, selected from a list of three names recommended by the Florida Pediatric Society;
- One representative of the J. Hillis Miller Health Center at the University of Florida;
- One representative of the H. Lee Moffitt Cancer Center and Research Institute, Inc.;
- One consumer representative, selected from a list of three names recommended by the Chief Financial Officer;

<sup>1</sup> <http://www.nlm.nih.gov/medlineplus/ency/article/003009.htm> - see bone marrow transplant (last visited on March 14, 2008).

<sup>2</sup> <http://www.webmd.com/cancer/news/20071210/mini-bmt-nonhodgkins-lymphoma-cure> (last visited on March 14, 2008).

<sup>3</sup> S. 627.4236, F.S.

<sup>4</sup> Ch. 92-318, L.O.F.

- One representative of the Health Insurance Association of America;
- Two representatives of health insurers, one of whom represents the insurer with the largest Florida health insurance premium volume and one of whom represents the insurer with the second largest Florida health insurance premium volume; and,
- One representative of the insurer with the largest Florida small group health insurance premium volume.

The 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.

In compliance with this law, the agency has adopted rule 59B-12.001, 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.<sup>5</sup>

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 agency or its panel may require insurer coverage.

The bone marrow transplant advisory panel convened on November 22, 2005, to discuss various issues including proposed changes to s. 627.4236, F.S. The panel determined that the current statutory definition is no longer congruent with current medical practice. Currently, the law 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. The panel noted that many therapy regimens, such as high dose Thytoxin for aplastic anemia, are not ablative. 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. 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" to the current law.

### **Insurance Cards**

Currently, laws governing health insurers do not require insurers to provide an insurance card to policyholders or subscribers. The laws generally require health insurers to provide policyholders either with an outline of benefits and coverage or a handbook.<sup>6</sup> Many health insurers and HMOs

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<sup>5</sup> [https://www.flrules.org/Gateway/View\\_notice.asp?id=3414029](https://www.flrules.org/Gateway/View_notice.asp?id=3414029) (last visited on March 14, 2008).

<sup>6</sup> See s. 627.642, F.S., relating to the outline of coverage for individual health insurance policies. Similarly, see s. 627.657, F.S., prescribing the provisions and form of group health insurance policies. See also ss. 627.64725 and 641.185, F.S.,

currently issue cards to their policyholders or subscribers; however, each insurer or HMO determines the type of information to be printed on the card.

Laws governing automobile insurance in Florida require insurers to provide policyholders with proof of insurance.<sup>7</sup> Such proof generally is provided through an insurance card. Proof of insurance typically contains: the policyholder's and insurer's name, a telephone number for the insurer, the policy number; and a brief description of the covered auto(s), including manufacturer, model, and vehicle identification number.

### **Privacy and Security of Health Information**

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted in 1996. The law requires the Department of Health and Human Services (HHS) to publicize standards for the electronic exchange, privacy and security of health information. Collectively these sections are known as the Administrative Simplification provisions. The HHS adopted privacy regulations governing individually identifiable health information, known as the Privacy Rule, on December 28, 2000.

The Privacy Rule, as well as the Administrative Simplification rules, applies to health plans and any health care provider who transmits health information in electronic form in connection with transactions for which the HHS has adopted standards under HIPAA (the "covered entities"). The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information, "*protected health information*."<sup>8</sup> "Individually identifiable health information" is information, including demographic data, that relates to the:

- Individual's past, present or future physical or mental health or condition;
- Provision of health care to the individual; or
- Past, present or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

A major purpose of the Privacy Rule is to define and limit the circumstances in which an individual's protected health information may be used or disclosed by covered entities. A covered entity may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.<sup>9</sup>

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outlining the requirements for HMO plans to provide the conditions of their respective plans either on the policy or in a member handbook.

<sup>7</sup> Ss. 320.02 and 627.733(3)(a), F.S., respectively, require insurance coverage for motor vehicles; require the provision of uniform proof-of-purchase cards in a form that includes the name of the insured, the insured carrier's name, the year, make and model of vehicle, and the vehicle identification number; and require auto insurers to provide notice to the Department of Highway Safety and Motor Vehicles regarding issuance, non-renewal, and cancellation of auto coverage.

<sup>8</sup> 45 C.F.R. s. 160.103.

<sup>9</sup> 45 C.F.R. s. 164.502(a).

A covered entity must disclose protected health information in only two situations: 1) to individuals (or their personal representatives) specifically when they request access to, or an accounting of disclosures of, their protected health information; and 2) to HHS when it is undertaking a compliance investigation or review or enforcement action.

A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: 1) to the individual (unless required for access or accounting of disclosures); 2) treatment, payment, and health care operations; 3) opportunity to agree or object; 4) incidental to an otherwise permitted use and disclosure; 5) public interest and benefit activities; and 6) limited data sets for the purposes of research, public health or health care operations. Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.

### III. Effect of Proposed Changes:

**Section 1.** Amends s. 627.4236, F.S., expanding the definition of bone marrow transplant for purposes of insurance coverage, to include coverage for nonablative therapy as a bone marrow transplant procedure, as well as ablative therapy. This section is also revised to provide coverage for such bone marrow transplant procedures with life-prolonging intent, not just as a curative procedure.

**Sections 2 and 3.** Amend ss. 627.642 and 627.657, F.S., respectively, to require an insurer to provide an identification card to a person with group or individual health insurance coverage that contains the following applicable information, at a minimum:

- The name of the organization issuing the policy or the name of the organization administering the policy.
- The name of the contract or certificate holder.
- The type of plan only if the plan is filed in the state, an indication that the plan is self-funded, or the name of the network.
- The member identification number, contract number, and policy or group number, if applicable.
- A contact phone number or electronic address for authorizations.
- A phone number or electronic address that can be used by the covered person or hospital, physician, or other providers that may obtain information necessary to verify benefits and to estimate patient financial responsibility, in compliance with privacy rules under federal HIPAA.
- The national plan identifier, in accordance with the compliance date set forth by HHS.

The identification card must present the information in a readily identifiable manner or, alternatively, the information may be embedded on the card and available through magnetic stripe or smart card. The information may also be provided through other electronic technology. This provision also applies to HMOs, which are addressed in Section 4 of the bill.

**Section 4.** Amends s. 641.31, F.S., requiring the contract, certificate, or member handbook of the HMO to be accompanied by an identification card that contains, at a minimum the following information:

- The name of the organization offering the contract or the name of the organization administering the contract.
- The name of the subscriber.
- A statement that the health plan is a health maintenance organization. Only a health plan with a certificate of authority issued under this chapter may be identified as a health maintenance organization.
- The member identification number, contract number, and group number, if applicable.
- A contact phone number or electronic address for authorizations.
- A telephone number or electronic address that can be used by the covered person or hospital, physician, or other providers to obtain information necessary to verify benefits and to estimate patient financial responsibility, in compliance with privacy rules under the federal HIPAA.
- The national plan identifier, in accordance with the compliance date set forth by HHS.

**Section 5.** Provides that this act will take effect on January 1, 2009, and will apply to policies or certificates issued or renewed on or after that date.

#### **IV. Constitutional Issues:**

##### **A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

##### **B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

##### **C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

#### **V. Fiscal Impact Statement:**

##### **A. Tax/Fee Issues:**

None.

##### **B. Private Sector Impact:**

Insurance coverage for nonablative therapy regimens will assist recipients of bone marrow transplants since this type of regimen is now the preferred treatment for many

bone marrow diseases and cancers and has been shown to be associated with less toxicity, improvements in survival, better quality of life, and shorter hospital stays and hospital costs. 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.

Insurers that do not presently provide an identification card or do not currently provide all of the required information on the identification card will incur indeterminate administrative costs to comply with the requirements of the bill. The information required on the identification card will assist hospitals and other health care providers in determining the financial responsibility of the policyholder or subscriber.

**C. Government Sector Impact:**

Changes in the bone marrow mandated coverage will have an indeterminate impact on the Division of State Group Health Insurance Program. To the extent nonablative therapies are more effective and less costly, medical costs for bone marrow transplants could be reduced.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

**A. Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.