

STORAGE NAME: h2337.hcs

DATE: April 10, 2000

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
ANALYSIS**

BILL #: HB 2337 (PCB HCS 00-07)

RELATING TO: Public Cord Blood Tissue Bank

SPONSOR(S): Committee on Health Care Services and Representative Peaden

TIED BILL(S):

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

- (1) HEALTH CARE SERVICES YEAS 14 NAYS 0
 - (2)
 - (3)
 - (4)
 - (5)
-

I. SUMMARY:

HB 2337 creates the Public Cord Blood Tissue Bank, as a nonprofit legal entity formed as a consortium consisting of the University of Florida, the University of South Florida, and the University of Miami. The bill encourages the consortium to do outreach and research for Hispanic, African American, Native American, and other ethnic and racial minorities and requires the consortium to align outreach programs and activities to all geographic areas of the state. The bill requires the Agency for Health Care Administration (agency) to create standardized release forms. The bill requires the agency and the Department of Health to encourage health care providers to disseminate information about the cord blood tissue bank donation program. The bill requires the agency to develop training materials for agencies and state employees working with pregnant women. The bill requires all state funded health care providers to provide information about umbilical cord blood tissue donation to pregnant women using such services. The bill provides an exception for certain religious organizations.

The bill requires health care facilities or providers receiving financial remuneration for the harvesting of umbilical cord blood to provide written disclosure of that status prior to harvesting umbilical cord blood tissue and provides that information about umbilical cord blood donation may be provided to all women upon admission to the hospital or birthing center for obstetrical services. The bill provides that participation in the donor program be voluntary. The bill authorizes the consortium to charge reasonable rates and fees to recipients of cord blood products.

The bill provides for a \$1.9 million appropriation from the General Revenue Fund to the consortium, and for a \$50,000 appropriation from the General Revenue Fund to the Agency for Health Care Administration for the development of the forms and training materials.

The bill provides an effective date of July 1, 2000.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|--|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

HB 2337 creates the Public Cord Blood Tissue Bank, a nonprofit legal entity formed as a consortium consisting of the University of Florida, the University of South Florida, and the University of Miami. The purpose of the consortium is to create a public cord blood tissue bank, conduct outreach and other activities to all geographic areas of the state, and to conduct outreach and research for Hispanic, African American, Native American, and other ethnic and racial minorities in the state.

The Agency for Health Care Administration is directed to develop standardized cord blood tissue bank release forms for use by all health care facilities and providers providing obstetrical services to pregnant women, and to develop cord blood tissue bank program informational training materials for agencies and state employees working with pregnant women. The agency and the Department of Health are required to encourage health care providers to provide information about the Public Cord Blood Tissue Bank program to pregnant women using their services.

B. PRESENT SITUATION:

In clinical practice, organs and tissues are transplanted to treat various conditions that are otherwise untreatable. As medical practices have become more sophisticated, the list of transplantable organs has been extended. However, unless the donor and recipient are genetically identical, the grafted tissues are usually rejected by the host. This rejection is mediated by the host's immune system which recognizes the transplanted tissue as foreign. Central to the immune system's recognition of the graft as foreign, are the more than thirty highly polymorphic molecules that are expressed on the surfaces of virtually all cells. The most important of these molecules are encoded by the Major Histocompatibility Complex (MHC) that 'label' the cells as foreign or self.

Current transplantation protocols rely mainly on sibling or other small pools of allogeneic donors. The chronic lack of suitable donors has led to the formation of bone marrow registries, tissue banks, and social questions of who gets priority for limited organs.

Last year, over 600 children died of leukemia. Approximately, ten to fifteen thousand Americans each year are unable to find suitable bone marrow donors. [*Source: Pregnancy Today, Winter 1998.*]

Umbilical Cord Blood as a Source of Stem and Progenitor Cells

Umbilical cord blood (cord blood) is a rich source of stem and progenitor cells that are present in bone marrow. Stem cells are cells that have not yet specialized; they create red cells (to carry oxygen), white cells (to fight disease), and platelets (to help blood clot).

Bone marrow treatment (BMT) is common for patients with certain blood diseases (e.g. leukemia and lymphoma) and genetic disorders (e.g. osteopetrosis and Fanconi's anemia). However bone marrow for transplants is often in short supply and requires a donor with tightly matched (usually related) tissue and willing to go through the donation process when the donation is needed. Cord blood, because of its high content of stem cells, may be substituted for bone marrow even from unrelated donors and is relatively easy to harvest and store.

Cord blood transplantation was first performed in 1988. Initially, it was used among relatives because of the tight tissue match (called Human Leukocyte Antigens (HLA) matching). Cord blood transplantation from unrelated donors has been performed since at least 1992. The New York Blood Center, under a grant from the National Institutes of Health since 1992, found that cord blood is a useful substitute for bone marrow. [Source: New England Journal of Medicine 1998;339:1565-77: <http://www.nejm.org/content/1998/0339/0022/1565.asp>]

Advantages and Disadvantages of Umbilical Cord Blood Harvesting

The advantages of cord blood harvesting has made it an attractive alternative to bone marrow as a source of stem cell rescue for allogeneic (from sibling) and unrelated bone marrow transplantation. Some advantages of using cord blood instead of bone marrow are that cord blood is: less likely to transmit infectious diseases; less likely to cause severe graft-versus-host disease; and is plentiful. In addition, because newborns exhibit naive/immature immune systems, cord blood transplants allow for greater human lymphocyte antigen (HLA) mismatch between donor and recipient. This allows for cord blood transplants between recipients and unrelated donors who would be rejected as suitable bone marrow donors.

With cord blood transplants, the size of the recipient is an issue because the volume of the cord blood from any one donor can be as little as 40 ml, and the total number of nucleated cells infused is important for engraftment.

Umbilical Cord Blood Harvesting and Storage

Cord blood donation occurs at the time of delivery; it is non-invasive and does not create any apparent risk for the donor. The donation process does not change the routine of maternity or newborn care.

Traditionally, after the normal delivery of a healthy full term baby and placenta, the placenta and umbilical cord are discarded as medical waste. If the cord blood is to be donated the cord is clamped after delivery and the blood is removed with a syringe. Typically between 40 and 100 ml of blood is collected (much smaller than the pint of traditional blood donations). The collection process takes about five minutes and is not performed if other complications occur.

The blood may then be sampled for HLA markers and tested for infectious diseases such as hepatitis, syphilis, and AIDS. Within 48-72 hours it must be frozen and stored under

liquid nitrogen. Once the blood is frozen, it may be shipped in special containers to another location, thawed, and transplanted.

Patients interested in harvesting cord blood have two general alternatives: (1) donation to a common bank, or (2) storage through a private company for their family's potential future use.

The New York Blood Center Study

The New York Blood Center, under a grant from the National Institutes of Health, studied the outcomes of 562 patients that received cord blood transplants from unrelated donors between August 24, 1992, and January 30, 1998. The study, published in the November 26, 1998, issue of the *New England Journal of Medicine*, concluded that cord blood from unrelated donors can restore bone marrow function even if there is not a complete HLA match.

The study encompassed most of the cord blood transplants from unrelated donors performed in the world to date. The New York Blood Center collected the blood from volunteer donors and stored it until it could be matched with patients around the world. The study provides evidence that the transplants: (1) regularly engraft (are successful), (2) cause graft-versus-host disease at a low rate relative to bone marrow transplants, and (3) produce survival rates similar to bone marrow transplants.

According to Cord Blood News, a publication of the Cord Blood Registry, third party coverage of cord blood as a stem cell source is becoming more common. They report that a number of managed care organizations cover cord blood banking.

C. EFFECT OF PROPOSED CHANGES:

HB 2337 creates a statewide consortium Public Cord Blood Tissue Bank ("consortium"), as a nonprofit legal entity consisting of the University of Florida, the University of South Florida, and the University of Miami. A series of "WHEREAS" clauses provide some background on the subject. The bill encourages the consortium to do outreach and research for Hispanic, African American, Native American, and other ethnic and racial minorities. The bill requires the consortium to align outreach programs and activities to all geographic areas of the state.

The bill requires the Agency for Health Care Administration to create standardized release forms. The bill requires the agency and the Department of Health to encourage health care providers to disseminate information about the Public Cord Blood Tissue Bank program. The bill requires the agency to develop training materials for agencies and state employees working with pregnant women.

The bill requires all state funded health care providers to provide information about umbilical cord blood tissue donation to pregnant women utilizing such services. The bill provides an exception for certain religious organizations.

The bill requires health care facilities or providers receiving financial remuneration for the harvesting of umbilical cord blood to provide written disclosure of that status prior to harvesting umbilical cord blood tissue.

The bill provides that information about umbilical cord blood tissue donation may be provided to all women upon admission to the hospital or birthing center for obstetrical services. The bill provides that participation in the donor program is voluntary.

The bill authorizes the consortium to charge reasonable rates and fees to recipients of cord blood products.

The bill provides for a \$1.9 million appropriation from the General Revenue Fund for the consortium and \$50,000 from the General Revenue Fund for the Agency for Health Care Administration for development of forms and training materials on the Public Cord Blood Tissue Bank program.

The bill provides an effective date of July 1, 2000.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Provides for a Public Cord Blood Tissue Bank.

Subsection (1) creates a statewide consortium known as the Public Cord Tissue Bank. The consortium is a nonprofit legal entity consisting of the University of Florida, the University of South Florida, and the University of Miami. The purpose of the consortium is to collect, screen for infectious and genetic diseases, perform tissue typing, cryopreserve, and store cord blood as a resource to the public. The consortium is directed to work with community resources such as regional blood banks, hospitals, and other health care providers to develop local and regional coalitions. The three universities are to align their outreach programs and activities to all geographic areas of the state. The consortium is encouraged to do outreach and research for the Hispanic, African American, Native American, and other ethnic and racial minorities.

Subsection (2) requires the Agency for Health Care Administration (agency), to develop and make available to all health care providers, information and standard release forms for the donation of umbilical cord blood. Requires the agency and the Department of Health to encourage all health care providers to disseminate information about the Public Cord Blood Tissue Bank program.

Subsection (3) requires the agency to develop training materials for agencies and state employees working with pregnant women to educate and inform them about the Public Cord Blood Tissue Bank program.

Subsection (4) requires all state funded health care programs providing education or services to pregnant women to provide information on the Public Cord Blood Tissue Bank program. Provides that information on the Public Cord Blood Tissue Bank program must be provided to, but not limited to, the following programs: Healthy Start, county health departments, Medicaid, and MediPass.

Subsection (5) specifies that nothing in this act creates a requirement to any health care or services program directly affiliated with a bona fide religious denomination that includes as an integral part of its beliefs and practices the tenet that blood transfer is contrary to the moral principals that the religious denomination considers to be an essential part of its beliefs.

Subsection (6) provides that any health care facility or health care provider receiving financial remuneration for the collection of umbilical cord blood must provide a written

statement of disclosure of this information to any woman post-partum or parent of a newborn from whom the umbilical cord blood is collected prior to the harvesting of the cord.

Subsection (7) provides that all women admitted to a hospital or birthing facility for obstetrical services may be offered the opportunity to donate the cord blood to the Public Cord Blood Tissue Bank. Provides that no woman may be required to donate the cord blood to the Public Cord Blood Tissue Bank.

Subsection (8) provides that the consortium may charge reasonable rates and fees to recipients of cord blood tissue bank products.

Section 2. Provides a \$1.9 million appropriation from the General Revenue Fund to the University of Florida, the University of South Florida, and the University of Miami to fund the statewide consortium Public Cord Blood Tissue Bank.

Section 3. Provides a \$50,000 appropriation from the General Revenue Fund to the Agency for Health Care Administration to develop standardized release forms, and training and educational materials.

Section 4. Provides that the act shall take effect July 1, 2000.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

N/A

2. Expenditures:

N/A

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

N/A

2. Expenditures:

N/A

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill requires health care facilities and providers who receive financial remuneration for the collection of cord blood to provide written disclosure of that information prior to harvesting of the cord blood.

D. FISCAL COMMENTS:

N/A

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 spend funds or to take action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that counties or municipalities have to raise revenues in the aggregate.

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:

A. CONSTITUTIONAL ISSUES:

N/A

B. RULE-MAKING AUTHORITY:

N/A

C. OTHER COMMENTS:

INSURANCE COVERAGE

Staff contacted the Department of Management Services, Division of State Group Health Insurance. According to the division, it does not appear that the state PPO or HMO plans cover cord blood as a stem cell transplant resource.

Staff has contacted several managed care plans and asked whether they regularly cover the cost of providing umbilical cord blood as a stem cell transplant resource. As of the date of publication of this analysis, a response has not been received.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

N/A

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VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

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