

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 Budget Committee

BILL: SB 702

INTRODUCER: Senator Flores

SUBJECT: Umbilical Cord Blood Banking

DATE: March 21, 2011 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	Favorable
2.	Munroe	Maclure	JU	Favorable
3.	Bradford	Meyer, C.	BC	Pre-meeting
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill requires the Department of Health (DOH) to post on its Internet website resources and an electronic link to materials relating to umbilical cord blood which have been developed by the Parent's Guide to Cord Blood Foundation, Inc., including:

- An explanation of the potential value and uses of umbilical cord blood;
- An explanation of the differences between using one's own cord blood cells or another's in the treatment of disease;
- An explanation of the differences between public and private umbilical cord blood banking;
- The options available to a mother relating to stem cells that are contained in the umbilical cord blood after the delivery of her newborn, including donating, storing, or discarding the stem cells;
- The medical processes involved in the collection of cord blood;
- Criteria for medical or family history that can affect a family's consideration of umbilical cord blood banking;
- Options for ownership and future use of donated umbilical cord blood;
- The average cost of public and private umbilical cord blood banking;
- The availability of public and private cord blood banks to residents of Florida; and
- An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples based on certain medical data.

This bill requires the DOH to encourage health care providers who provide health care services directly related to a woman's pregnancy to make available to the pregnant woman before her third trimester, or at the woman's next scheduled appointment with the provider during her third

trimester, the information required under the bill to be posted by the DOH on its Internet website. This bill also absolves any health care provider or health care facility, including any employee or agent of the provider or facility, of any liability from a civil action, any criminal prosecution, or any disciplinary action if the provider or facility acted in good faith to comply with the provisions of the bill.

This bill has an insignificant fiscal impact on state government which the Department of Health has determined can be absorbed within existing resources. There is no fiscal impact to the private sector.

This bill creates an undesignated section of law.

II. Present Situation:

Umbilical Cord Blood Banking¹

After a baby is delivered, the mother's body releases the placenta, which is the temporary organ that transferred oxygen and nutrients to the baby while in the mother's uterus. Historically, the umbilical cord and placenta were discarded after birth. However, during the 1970s, researchers discovered that umbilical cord blood could supply the same kinds of blood-forming (hematopoietic) stem cells as a bone marrow donor. Consequently, umbilical cord blood began to be collected and stored.

Blood-forming stem cells are primitive cells found primarily in the bone marrow that are capable of developing into the three types of mature blood cells contained in our blood: red blood cells, white blood cells, and platelets. Cord blood stem cells may also have the potential to give rise to other cell types in the body.

Some serious illnesses (such as certain cancers, blood diseases, and immune system disorders) require radiation and chemotherapy treatments to kill diseased cells in the body. These treatments also kill many "good" cells along with the bad, including healthy stem cells that live in the bone marrow. Depending on the type of disease and treatment needed, a patient may need a bone marrow transplant (from a donor whose marrow cells closely match their own). Blood-forming stem cells from a donor are transplanted into the ill person, and those cells then manufacture new, healthy blood cells and enhance the person's blood-producing and immune system capability.

Collection of Cord Blood

Collection of the cord blood takes place shortly after birth in both vaginal and cesarean (C-section) deliveries. The cord blood is collected using a specific kit that parents must order usually at least by the 34th week of pregnancy from their chosen cord blood bank. The kit may

¹ The following information under this subheading is adapted from KidsHealth from Nemours, *Banking Your Newborn's Cord Blood*, available at http://kidshealth.org/parent/cancer_center/treatment/cord_blood.html (last visited Mar. 17, 2011). Nemours is a nonprofit organization established in 1936, which supports several children's health facilities and supports clinical research for children's health needs. See KidsHealth from Nemours, *About Nemours*, available at http://kidshealth.org/parent/kh_misc/nemours.html (last visited Mar. 3, 2011).

include a family medical history questionnaire, a consent form, and the collection materials. The informed consent must be signed prior to the onset of active labor and before the cord blood collection. The consent must contain information pertaining to what tests are to be performed on the cord blood and how the parents will be informed should the test results be abnormal.²

After a vaginal delivery, the umbilical cord is clamped on both sides and cut. In most cases, an experienced obstetrician or nurse collects the cord blood before the placenta is delivered. One side of the umbilical cord is unclamped, and a small tube is passed into the umbilical vein to collect the blood. After blood has been collected from the cord, needles are placed on the side of the surface of the placenta that was connected to the fetus to collect more blood and cells from the large blood vessels that fed the fetus.

During cesarean births, cord-blood collection is more complicated because the obstetrician's primary focus in the operating room is tending to the surgical concerns of the mother. After the baby has been safely delivered and surgery has concluded, the cord blood can be collected. However, less cord blood is usually collected when delivery is by C-section. The amount collected is critical because the more blood collected, the more stem cells collected. If using the stem cells ever becomes necessary, having more stem cells to implant increases the chances of engraftment, which means a successful transplantation.

After cord blood collection has taken place, the blood is placed into bags or syringes and is usually taken by courier to the cord-blood bank. Once there, it is typed, screened for infectious diseases and for hereditary hematologic diseases, and given an identifying number.³ Then the stem cells are separated from the rest of the blood and are stored cryogenically (frozen in liquid nitrogen) in a collection facility, also known as a cord blood bank.

Storage and Use of Blood-forming Stem Cells

Because cord blood research only began in the 1970s, the maximum time for storage and potential usage for blood-forming stem cells are still being determined. Blood-forming stem cells that have been stored for more than a decade have been used successfully in transplants.

If the blood-forming stem cells are needed, blood-forming stem cells can be taken from storage, thawed, and used in either "autologous" procedures (when someone receives his or her own umbilical cord blood in a transplant) or "allogeneic" procedures (when a person receives umbilical cord blood donated from someone else, such as a sibling, close relative, or anonymous donor).

The primary reason that parents consider banking their newborn's cord blood is because they have a child or close relative with, or a family medical history of, diseases that can be treated with bone marrow transplants. Some diseases that more commonly involve bone marrow transplants include certain kinds of leukemia or lymphoma, aplastic anemia, severe sickle cell anemia, and severe combined immunodeficiency.

² American Academy of Pediatrics, *Frequently Asked Questions about Cord Blood Banking*, available at <http://www.aap.org/advocacy/releases/jan07cordbloodfaq.htm> (last visited Mar. 3, 2011).

³ *Id.*

In most cases, stem cell transplants are performed only on children or young adults. The larger the size of the person, the more blood-forming stem cells are needed for a successful transplant. Umbilical cord blood stem cells are not adequate in quantity to complete an adult's transplant. In addition, it is unknown whether stem cells taken from a relative offer more success than those taken from an unrelated donor. Stem cells from cord blood from both related and unrelated donors have been successful in many transplants, because blood-forming stem cells taken from cord blood are "naïve," which is a medical term for early cells that are still highly adaptable and are less likely to be rejected by the recipient's immune system. Therefore, donor cord-blood stem cells do not need to be a perfect match to create a successful bone marrow transplant.

Physical, Emotional, and Financial Concerns

The physical risks to the health of the mother and baby at the time of collection of the cord blood are low, but they do exist. Clamping the umbilical cord too soon after birth may increase the amount of collected blood, but it could cause the baby to have a lower blood volume and possible anemia soon after birth.

The American Academy of Pediatrics (AAP) has expressed concern that cord blood banks may capitalize on the fears and emotions of vulnerable new parents by providing misleading information about the statistics of bone marrow transplants. Parents of children of ethnic or racial minorities, adopted children, or children conceived through in vitro fertilization may be especially encouraged to bank cord blood because it is statistically harder to find a match in these cases.⁴

In 1999, the AAP stated that the academy does not recommend cord-blood banking for families who do not have a history of disease, because research has not yet determined the likelihood that a child would ever need his or her own stem cells, nor has it confirmed that transplantation using self-donated cells rather than cells from a relative or stranger is safer or more effective. According to the AAP, "private storage of cord blood as 'biological insurance' is unwise. However, banking should be considered if there is a family member with a current or potential need to undergo a stem cell transplantation."⁵

⁴ For a successful transplant, the tissue type of a bone marrow donor or a cord blood unit needs to match the patient's as closely as possible. Tissue types are inherited. Therefore, patients are more likely to match someone who shares their racial or ethnic heritage, and patients from racially or ethnically diverse communities can have a harder time finding a match. Because cord blood does not need to match a patient as closely as donated bone marrow, cord blood transplants may offer hope to these patients. More than 40 percent of minority patients who received a transplant used cord blood. National Marrow Donor Program, *Cord Blood Donation: Frequently Asked Questions*, available at http://www.marrow.org/HELP/Donate_Cord_Blood_Share_Life/Cord_Blood_Donation_FAQs/index.html (last visited Mar. 17, 2011).

⁵ American Academy of Pediatrics, News Release, *Cord Blood Banking For Future Transplantation Not Recommended*, July 6, 1999, available at <http://www.nationalcordbloodprogram.org/AAP%20News%20Release%20-%20AAP%20CORD%20BLOOD%20BANKING%20FOR%20FUTURE%20TRANSPLANTATION%20NOT%20RECOMMENDED.htm> (last visited Mar. 17, 2011). See also American Academy of Pediatrics, News Release, *AAP Encourages Public Cord Blood Banking*, January 2, 2007, available at <http://www.aap.org/advocacy/releases/jan07cordblood.htm> (last visited Mar. 18, 2011), wherein the AAP stated, "Storing cord blood at private banks for later personal or family use as a general 'insurance policy' is discouraged."

Although typically there is no cost or a nominal cost for donating cord blood to a public cord blood bank, the price of banking cord blood with a private cord blood bank can be quite expensive. There are usually two fees associated with cord blood banking with a private cord blood bank. The first is the initial fee, which pays for enrollment and the collection and storage of the cord blood for at least the first year, and the second is an annual storage fee. Some facilities offer a variety of options for the initial fee with predetermined periods of storage. The initial fee ranges from \$900 to \$2,100 depending on the predetermined period of storage. Annual storage fees beyond the initial storage fee are approximately \$100.⁶

Parent's Guide to Cord Blood Foundation, Inc.

The Parent's Guide to Cord Blood Foundation, Inc. (Foundation), is a nonprofit foundation, which was incorporated in 2007.⁷

The primary mission of the Foundation is to educate parents with accurate and current information about cord blood medical research and cord blood storage options.⁸ The second mission of the Foundation is to conduct and publish statistical analyses on medical research or policy developments that could expand the likelihood of cord blood usage.⁹

The Foundation's website, which has been operational since 1998, explains the medical motivations for banking umbilical cord blood, and the difference between public bank donations versus paying for private storage of umbilical cord blood. In addition, the Foundation's website contains:¹⁰

- A list of all public cord blood banks that collect donations in the United States, irrespective of their business model or accreditations.¹¹
- A compilation of private United States cord blood banks.¹²
- An international list of private/family cord blood banks, which is sorted by geographic region.
- An international list of private cord blood banks.
- A table of private banks, which compares their prices and accreditations at a glance.¹³

⁶ American Pregnancy Association, *Cord Blood Banking*, available at <http://www.americanpregnancy.org/labornbirth/cordbloodbanking.html> (last visited Mar. 18, 2011).

⁷ Parent's Guide to Cord Blood Foundation, Inc., *Parent's Guide to Cord Blood Foundation*, available at <http://parentsguidecordblood.org/content/usa/aboutus/index.shtml?navid=1> (last visited Mar. 18, 2011).

⁸ Parent's Guide to Cord Blood Foundation, Inc., *Mission Statement*, available at <http://parentsguidecordblood.org/index.shtml> (last visited Mar 18, 2011).

⁹ *Id.*

¹⁰ *Id.*

¹¹ Parent's Guide to Cord Blood Foundation, Inc., *Public Cord Blood Banks in the USA*, available at http://parentsguidecordblood.org/content/usa/banklists/publicbanks_new.shtml?navid=15 (last visited Mar. 4, 2011).

According to the Foundation's website, there are 38 public cord blood banks in the U.S. and only 2 provide banking services specifically in Florida. However, 8 cord blood banks provide banking services in all states.

¹² Parent's Guide to Cord Blood Foundation, Inc., *Family Cord Blood Banks in the USA*, available at <http://parentsguidecordblood.org/content/usa/banklists/listusa.shtml?navid=16> (last visited Mar. 4, 2011). The Foundation's website lists 32 private cord blood banks, 6 of which provide services in Florida.

¹³ The table is available at: <http://parentsguidecordblood.org/content/usa/banklists/summary.shtml?navid=17#us> (last visited Mar. 4, 2011).

- A consumer questionnaire that provides a guide to evaluate the services of private banks.
- A summary of diseases that have been treated by blood stem cells.¹⁴

The Foundation reports¹⁵ that its website has been accredited by the international standard for medical websites, Health on the Net Foundation (HONF), since 2001.¹⁶

III. Effect of Proposed Changes:

This bill requires the Department of Health (DOH) to post on its Internet website resources and an electronic link to materials relating to umbilical cord blood which have been developed by the Parent's Guide to Cord Blood Foundation, Inc., including:

- An explanation of the potential value and uses of umbilical cord blood, including cord blood cells and stem cells, for individuals who are, or who are not, biologically related to a mother or her newborn child;
- An explanation of the differences between using one's own cord blood cells, a biologically related person's cord blood stem cells, or a biologically unrelated person's cord blood stem cells in the treatment of disease;
- An explanation of the differences between public and private umbilical cord blood banking;
- The options available to a mother relating to stem cells that are contained in the umbilical cord blood after the delivery of her newborn, including donating to a public umbilical cord blood bank, storing the stem cells in a private umbilical cord blood bank for use by immediate and extended family members, storing the stem cells for use by family members through a program that provides free services if there is an existing medical need, or discarding the stem cells;
- The medical processes involved in the collection of cord blood;
- Criteria for medical or family history that can affect a family's consideration of umbilical cord blood banking, including the likelihood of using a baby's cord blood to serve as a match for a family member who has a medical condition;
- Options for ownership and future use of donated umbilical cord blood;
- The average cost of public and private umbilical cord blood banking;
- The availability of public and private cord blood banks to residents of Florida, including a list of public cord blood banks and the hospitals they serve, a list of private cord blood banks, and the availability of free family banking and sibling donor programs if there is an existing medical need by a family member; and

¹⁴ The summary of diseases that have been treated by blood stem cells, is available at: <http://parentsguidecordblood.org/content/usa/medical/diseases.shtml?navid=37> (last visited Mar. 4, 2011).

¹⁵ *Supra* note 8.

¹⁶ "The Health On the Net Foundation (HONF) promotes and guides the deployment of useful and reliable online health information, and its appropriate and efficient use. Created in 1995, HONF is a non-profit, non-governmental organization, accredited to the Economic and Social Council of the United Nations. For 15 years, HONF has focused on the essential question of the provision of health information to citizens, information that respects ethical standards. To cope with the unprecedented volume of healthcare information available on the Net, the HONF code of conduct offers a multi-stakeholder consensus on standards to protect citizens from misleading health information." Health On the Net Foundation, Home Page, <http://www.hon.ch/> (last visited Mar. 18, 2011).

- An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples based on medical data developed by the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

This bill requires the DOH to encourage health care providers who provide health care services directly related to a woman's pregnancy to make available to the pregnant woman before her third trimester, or at the woman's next scheduled appointment with the provider during her third trimester, the information required under the bill to be posted by the DOH on its Internet website.

This bill also absolves any health care provider or health care facility, including any employee or agent of the provider or facility, of any liability from a civil action, any criminal prosecution, or any disciplinary action if the provider or facility acted in good faith to comply with the provisions of the bill.

The bill provides an effective date of July 1, 2011.

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.

D. Other Constitutional Issues:

The bill absolves a health care provider or health care facility, including any employee or agent of the provider or facility, of any liability from a civil action, any criminal prosecution, or any disciplinary action if the provider or facility acted in good faith to comply with the provisions of the bill. If immunity from civil liability is legislatively accorded to a private entity, a potential constitutional challenge would be that the law violates the right of access to the courts. Section 21, Article I of the State Constitution, provides that the courts shall be open to all for redress for an injury. To impose a barrier or limitation on a litigant's right to file certain actions, the immunity from liability would have to meet the test announced by the Florida Supreme Court in *Kluger v. White*.¹⁷ Under the test, the Legislature would have to provide a reasonable alternative remedy or commensurate benefit, or make a legislative showing of overpowering public necessity

¹⁷ See *Kluger v. White*, 281 So. 2d 1 (Fla. 1973).

for the abolishment of the right and no alternative method of meeting such public necessity. When the Legislature restructures a cause of action, such as limiting a civil action to situations where providers or facilities did not act in good faith when providing certain information to pregnant women, the cause of action is not constitutionally suspect as a violation of the access to courts provision of the State Constitution because the cause of action is not completely destroyed, although recovery for negligence may be more difficult.¹⁸

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DOH reports that they will absorb any costs associated with implementing the bill and that the time required for periodic updates to the DOH's website and encouragement of providers to disseminate information on cord blood banking can be accomplished with existing staff and by using the existing network of maternal and child health partners.¹⁹

VI. Technical Deficiencies:

None.

VII. Related Issues:

The DOH reports that the Foundation's website is copyrighted and requires permission from the copyright owner to repeat the information contained on the website. Therefore, the DOH reports that it will need to include a disclaimer on its website advertising the Foundation's link that access to the website through the DOH does not give the viewer of the information on the website or the DOH permission to copy or redistribute any information from the Foundation's website.²⁰

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

¹⁸ *Id.* at 4.

¹⁹ Florida Department of Health, *Bill Analysis, Economic Statement, and Fiscal Note for SB 702*, dated Feb. 11, 2011. A copy of this analysis is on file with the Senate Health Regulation Committee.

²⁰ *Id.*

B. Amendments:

None.

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