

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 471 Cord Blood Banking

SPONSOR(S): Health & Human Services Quality Subcommittee; Nuñez

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	14 Y, 0 N, As CS	Prater	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

This bill creates section 381.06016, F.S., relating to umbilical cord blood awareness, requiring the Department of Health (DOH) to place on its website resources relating to umbilical cord blood and an internet link to the "Parent's Guide to Cord Blood Foundation" website.

Additionally, the bill requires DOH to encourage health care providers that provide services to pregnant women to make the information listed above available before the woman's third trimester of pregnancy.

Finally, the bill also states that a health care facility or health care provider may not be held liable in any manner or be subject to criminal penalties for providing information regarding umbilical cord blood banking.

This bill appears to have no fiscal impact.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

After a baby is born and the umbilical cord is cut, some blood remains in the blood vessels of the placenta and the portion of the umbilical cord that remains attached to it.¹ After birth, the baby no longer needs this extra blood. This blood is called placental blood or umbilical cord blood.²

Umbilical cord blood contains rich amounts of stem cells known as hematopoietic progenitor cells (HPCs).³ When transplanted, these cells have been shown to be effective in the treatment of blood disorders such as leukemia, lymphoma, and sickle cell anemia.⁴ Although HPCs can also be obtained from bone marrow, obtaining them from umbilical cord blood poses less risk to the donor and carries a lower potential for infectious disease transmission. In addition, umbilical cord blood is more readily available than other HPC sources.⁵

There are several options for handling cord blood available to parents:

1. Donating to a public cord blood bank. The blood can then be used by any patient who needs a transplant. Donating to a public cord blood bank is free.⁶
2. Storing it in a private family cord blood bank. People who use a family cord blood bank to store their baby's cord blood for exclusive use by their family are charged a fee for collection, as well as annual storage fees.⁷ The typical collection fee ranges from \$1,600 to \$2,000, and the typical annual storage fee is \$125.⁸
3. Save it for a sibling that has a medical need. When a biological sibling has a disease that may be treated with a bone marrow or cord blood transplant, parents can choose to save their baby's cord blood for directed donation. Collecting and storing cord blood for directed donation is often offered at little or no cost through some public and family cord blood banks.⁹
4. Donating it for research studies. Laboratories and technology companies conduct studies to help improve the transplant process for future patients. The collection process for research is free.¹⁰

The American Medical Association issued an opinion relating to cord blood stating that the utility of umbilical cord blood stem cells is greater when the donation is to a public rather than private bank and that physicians should encourage women wishing to donate cord blood, to donate to a public bank, if one is available. Further, they suggest that private banking should be considered only in the unusual

¹ National Cord Blood Program, see www.nationalcordbloodprogram.org/qa/ (last viewed on March 25, 2011).

² *Id.*

³ The National Institute of Health, see <http://stemcells.nih.gov/info/scireport/chapter5.asp> (last viewed on March 25, 2011).

⁴ Health Resources and Services Administration, U.S. Department of Health and Human Services, see <http://bloodcell.transplant.hrsa.gov/ABOUT/index.html> (last viewed on March 25, 2011).

⁵ Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program, Executive Summary: Institute of Medicine

⁶ National Marrow Donor Program, Options for Umbilical Cord Blood, see

http://www.marrow.org/HELP/Donate_Cord_Blood_Share_Life/Options_for_Umbilical_Cord_Blo/index.html (last viewed on March 25, 2011).

⁷ *Id.*

⁸ Cyro-Cell, Stem Cell Storage Plans, see <http://www.cryo-cell.com/services/pricing.asp> (last viewed on March 25, 2011);

ViaCord, Pricing & Storage Plans, see <http://www.viacord.com/pricing-storage-plans.htm> (last viewed on March 25, 2011);

Cord Use, Pricing and Payment Plans, see <https://familycordbloodbank.corduse.com/enrollment-cord-use-pricing.php> (last viewed on March 25, 2011); and Cbr cord blood registry, Pricing and Payment Options, see <http://www.cordblood.com/pricing/index.asp> (last viewed on March 25, 2011).

⁹ National Marrow Donor Program, Options for Umbilical Cord Blood, see

http://www.marrow.org/HELP/Donate_Cord_Blood_Share_Life/Options_for_Umbilical_Cord_Blo/index.html (last viewed on March 25, 2011).

¹⁰ *Id.*

circumstance when there is a family predisposition to a condition in which umbilical cord stem cells are needed and that private banking should not be recommended to low-risk families.¹¹

Cord blood is collected by clamping the baby's umbilical cord after birth and collecting blood from the umbilical cord and placenta into a sterile bag. With public donation, the blood sample is given an identification number and stored temporarily. A sample of the mother's blood is then tested for infectious diseases, and within one or two days, the cord blood unit is delivered to the public cord blood bank.¹² ViaCord, a private cord blood banking company, provides a kit to the parents. The kit is then given to the medical staff that is delivering the baby and the cord blood is collected and given back to the parents. ViaCord then arranges a medical courier to come to the hospital and pick up the cord blood. The cord blood is then transported to a ViaCord processing laboratory where it is tested and stored.¹³

While private cord blood banking can be done from anywhere in the country, public cord blood donation can only occur in participating hospitals.¹⁴ Public cord blood banks cover the costs to collect, test and store umbilical cord blood. However, because of funding limitations, cord blood cannot be donated at every hospital.¹⁵ There are less than 200 hospitals that collect cord blood donations in the US.¹⁶ In Florida, there are only 6 hospitals that participate in public cord blood banking.¹⁷ However, in some circumstances, public cord blood banks can collect donations from non-participating hospitals, although only limited donations of this kind are accepted.¹⁸ Public cord blood banks are funded through the sale of their samples, which are used for transplants, often paid for by the insurance company of the person receiving the transplant.¹⁹

The U.S. Congress passed, and President Bush approved, the Stem Cell Therapeutic and Research Act of 2005.²⁰ The act is administered by the U.S. Department of Health and Human Services and consists of 2 components. The first is to increase the number of bone marrow and cord blood donors and to serve patients in need of a bone marrow or cord blood transplant. The other component is the National Cord Blood Inventory which collects and stores cord blood units to treat patients and to provide cord blood units for research.²¹

¹¹ American Medical Association, Code of Medical Ethics, Opinion 2.165, *see* <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2165.page> (last viewed on March 25, 2011).

¹² National Marrow Donor Program, Options for Umbilical Cord Blood, *see* http://www.marrows.org/HELP/Donate_Cord_Blood_Share_Life/Options_for_Umbilical_Cord_Blo/index.html (last viewed on March 25, 2011).

¹³ ViaCord, Our Services, Frequently Asked Questions, *see* <http://www.viacord.com/general-faq.htm#Does%20the%20hospital%20need%20to%20provide%20any%20materials%20for%20collection?> (last viewed on March 25, 2011).

¹⁴ National Marrow Donor Program, Where to donate cord blood, *see* http://www.marrows.org/HELP/Donate_Cord_Blood_Share_Life/How_to_Donate_Cord_Blood/CB_Participating_Hospitals/nmdp_cord_blood_hospitals.pl (last viewed on March 25, 2011).

¹⁵ *Id.*

¹⁶ Parents Guide to Cord Blood Foundation, Public Cord Blood Banks in the U.S., *see* http://www.parentsguidecordblood.com/content/usa/banklists/publicbanks_new.shtml (last viewed on March 25, 2011).

¹⁷ North Florida Regional Medical Center, Gainesville; Shands Teaching Hospital at University of Florida, Gainesville; Memorial Regional Hospital, Hollywood; Winnie Palmer Hospital for Women and Babies, Orlando; Memorial Hospital West, Pembroke Pines; South Miami Hospital, Miami, *see* http://www.marrows.org/HELP/Donate_Cord_Blood_Share_Life/How_to_Donate_Cord_Blood/CB_Participating_Hospitals/nmdp_cord_blood_hospitals.pl (last viewed on March 25, 2011).

¹⁸ *See* http://www.marrows.org/HELP/Donate_Cord_Blood_Share_Life/How_to_Donate_Cord_Blood/CB_Participating_Hospitals/nmdp_cord_blood_hospitals.pl (last viewed on March 25, 2011).

¹⁹ The Parent's Guide to Cord Blood Foundation, *see* <http://www.parentsguidecordblood.com/content/usa/society/cost.shtml> (last viewed on March 25, 2011).

²⁰ Pub. L. No. 109-129 (2005).

²¹ Health Resources and Services Administration, U.S. Department of Health and Human Services, *see* <http://bloodcell.transplant.hrsa.gov/ABOUT/index.html> (last viewed on March 25, 2011).

Effect of Proposed Changes

This bill requires DOH to place on its website resources relating to umbilical cord blood and an internet link to the "Parent's Guide to Cord Blood Foundation" website. The primary mission of the Parent's Guide to Cord Blood Foundation is to educate parents with accurate and current information about cord blood medical research and cord blood storage options.²² The bill requires DOH to provide, on its website, the following information:

- An explanation of the potential value and use of umbilical cord blood for those that are related and not related to the donor;
- An explanation of the difference between using one's own cord blood cells and using related and unrelated cord blood 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;
- The medical processes involved in the collection of cord blood;
- Criteria for medical or family history that can impact 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 this state; and
- An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples.

Some of the required information listed above is either not found on the Parent's Guide to Cord Blood Foundation website or is difficult to find. Therefore, DOH would be required to research and provide the missing or unclear information which are required by the provisions of the bill. According to DOH, it will be able to accomplish the additional work within existing resources.²³

Additionally, the bill requires DOH to encourage health care providers that provide services to pregnant women to make the information listed above available before the woman's third trimester of pregnancy. If the provider does not see the patient until after the third trimester of pregnancy, this information can be made available at the patient's first visit. According to DOH, it does not currently provide information to clients or providers regarding umbilical cord blood, but that this requirement could be accomplished within existing resources.²⁴

The bill provides that a health care provider or health care facility cannot be held liable for damages in civil action or subject to criminal penalties for complying with the provisions listed above.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.06016, F.S., relating to umbilical cord blood awareness.

Section 2: Provides an effective date of July 1, 2011.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

²² Parent's Guide to Cord Blood Foundation, *see* <http://www.parentsguidecordblood.org/> (last viewed on March 30, 2011).

²³ Department of Health, Bill Analysis, HB 471, 2011

²⁴ *Id.*

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill requires DOH to provide an internet link on their website to the Parent's Guide to Cord Blood Foundation website. The bill provides specific detailed information regarding umbilical cord blood that is to be made available and appears to imply that all of this information is contained within the Parent's Guide to Cord Blood Foundation website. However, some of the information required is difficult to find, unclear, or missing from the Parent's Guide to Cord Blood Foundation website.

The DOH analysis indicates that the Foundation's website is copyrighted and requires permission from the copyright owner to repeat the information contained on the website. DOH will need to include a disclaimer on its website stating that access to the website through DOH does not give the viewer of the information permission to copy or redistribute any information from the Foundation's website.²⁵

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 6, 2011, the Health and Human Services Quality Subcommittee adopted one amendment to HB 471.

²⁵ Department of Health, Bill Analysis, HB 471, 2011

The strike-all amendment conforms the bill to the Senate companion. The original House Bill required the Agency for Health Care Administration (AHCA) and DOH to encourage health care providers and health care facilities to disseminate information regarding umbilical cord blood banking. The strike-all requires only DOH to disseminate this information to health care providers. The amendment placed the bill language in a new statutory section, s. 381.06016, F.S.

The bill was reported favorable as a Committee Substitute. The analysis reflects the Committee Substitute.