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 Regulation Committee

BILL:	SB 478
INTRODUCER:	Senator Margolis
SUBJECT:	Department of Health
DATE:	January 9, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

This bill repeals s. 381.00325, F.S., which requires the Department of Health (department) to develop a Hepatitis A awareness program. This program requires the department to work with private businesses and associations to develop the program and disseminate information to educate the public about, and the availability of, the Hepatitis A vaccine.

The bill also repeals s. 381.06015, F.S., which establishes a statewide consortium, known as the Public Cord Blood Tissue Bank. The Public Cord Blood Tissue Bank is a nonprofit legal entity that collects, screens for infectious and genetic diseases, performs tissue typing, cryopreserves, and stores umbilical cord blood as a resource to the public. In addition to other provisions, this section requires a health care facility or health care provider to provide written disclosure of their financial interest in collecting umbilical cord blood prior to harvesting the umbilical cord blood.

This bill repeals the following sections of the Florida Statutes: 381.00325 and 381.06015.

II. Present Situation:

Hepatitis Awareness

The department is required under s. 381.00325, F.S., to develop a Hepatitis A awareness program and work with private businesses and associations to develop the program and disseminate information to educate the public about, and the availability of, the Hepatitis A vaccine. Under s. 381.003, F.S., the department is required to conduct a communicable disease prevention and control program as part of fulfilling its public health mission. The program is

required to include programs for the prevention and control of vaccine-preventable diseases, including Hepatitis A.

To fulfill the requirements of s. 381.00325 and s. 381.003, F.S., the department's Division of Disease Control administers a Hepatitis Prevention Program, which seeks to educate the public about Hepatitis A and Hepatitis B vaccines and recommends such vaccines.[1]

The department's Hepatitis Prevention Program provides on its website a vaccine information statement from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention which provides information about Hepatitis A and the Hepatitis A vaccine. The vaccine information statement explains that Hepatitis A is a serious liver disease caused by the Hepatitis A virus, which is found in the stool of people with hepatitis A and spread by close personal contact or by eating food or drinking water containing the virus. The symptoms of Hepatitis A include "flu-like" illness, jaundice (yellow skin or eyes and dark urine), and severe stomach pains and diarrhea in children. People with Hepatitis A often have to be hospitalized and adults with the virus are often too ill to work for up to a month. Hepatitis A can also cause death, but can be prevented with a vaccine.[2]

Under the department's Hepatitis Prevention Program, the department:

- Provides Hepatitis A and B vaccines each year to over 30,000 at-risk adults who are 18 years of age or older.
- Provides Hepatitis A, B and C panel tests to more than 29,000 at-risk adults each year.
- Provides referrals for treatment for infected individuals.
- Directly funds 15 county health departments for specific Hepatitis prevention programs (Miami-Dade, Collier, Monroe, Pinellas, Polk, Broward, Escambia, Lee, Seminole, Okeechobee, Palm Beach, Bay, Alachua, Duval, and Orange counties).
- Collects and analyzes surveillance data based on reported cases of viral Hepatitis.
- Distributes educational information materials.
- Oversees the Viral Hepatitis Council, which is made up of county health department and non-governmental community members who advise the Hepatitis Prevention Program and write a comprehensive plan.
- Provides technical assistance, training, and quality assurance.
- Provides webinar training to all healthcare providers and any interested groups or individuals.
- Collects and analyzes client risk assessment and other data.[3]

[1] Florida Department of Health, Division of Disease Control, *Hepatitis Prevention Program: Hepatitis Vaccine and Laboratory Testing*, available at: http://www.doh.state.fl.us/disease_ctrl/aids/hep/index.html (Last visited on January 6, 2012).
[2] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement, Hepatitis A Vaccine, *What You Need to* Know, available at: http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-a.pdf (Last visited on January 6, 2012). Additional information about Hepatitis A is provided on the department's website at: http://www.doh.state.fl.us/disease_ctrl/aids/hep/hep_a.htm (Last visited on January 6, 2012).
[3] Department of Health, *Bill Analysis, Economic Statement and Fiscal Note: SB 478*, December 7, 2011, on file with the Health Regulation Committee.

Umbilical Cord Blood Banking[4]

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 without a second thought. But 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. Unfortunately, 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.

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.

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 aren't adequate in quantity to complete an adult's transplant.

[4] 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 on January 6, 2012). 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 on January 6, 2012).

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.

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.[5]

Umbilical Cord Blood Awareness in Florida

In 2011, the Legislature enacted SB 702[6] to require the department to make available to the public on its website resources and a link to materials relating to umbilical cord blood which have been developed by the Parent's Guide to Cord Blood Foundation, Inc.

The department is required to provide on its website:

- An explanation of the potential value and uses of umbilical cord blood, including cord blood cells and stem cells, for individuals who are, as well as individuals 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 and using biologically related or biologically unrelated 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.
- 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 Florida.
- An explanation of which racial and ethnic groups are in particular need of publicly donated cord blood samples based upon medical data developed by the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

[5] American Pregnancy Association, *Cord Blood Banking*, available at: http://www.americanpregnancy.org/labornbirth/cordbloodbanking.html (Last visited on January 6, 2012).
[6] Chapter 2011-154, L.O.F.

The department is also required to encourage health care providers who provide services to pregnant women to make available to a pregnant patient before her third trimester of pregnancy information relating to the patient's options regarding umbilical cord blood banking.

Section 381.06015, F.S., enacted in 2000, establishes a statewide consortium, known as the Public Cord Blood Tissue Bank. The Public Cord Blood Tissue Bank is a nonprofit legal entity that collects, screens for infectious and genetic diseases, performs tissue typing, cryopreserves, and stores umbilical cord blood as a resource to the public. The consortium may charge reasonable rates and fees to recipients of cord blood tissue bank products.

Section 381.06015, F.S., also requires the University of Florida, the University of South Florida, the University of Miami, and the Mayo Clinic (Jacksonville) to jointly form a collaborative consortium, each working with community resources such as regional blood banks, hospitals, and other health care providers to develop local and regional coalitions for the purposes of encouraging dissemination of information about the Public Cord Blood Tissue Bank and donating umbilical cord blood. The consortium participants are required to provide statewide outreach programs and activities and are encouraged to conduct outreach and research for Hispanics, African Americans, Native Americans, and other ethnic and racial minorities.

Additionally, s. 381.06015, F.S., requires the AHCA and the department to encourage health care providers, including, but not limited to, hospitals, birthing facilities, county health departments, physicians, midwives, and nurses, to disseminate information about the Public Cord Blood Tissue Bank. Section 381.06015, F.S., provides that a woman admitted to a hospital or birthing facility for obstetrical services may be offered the opportunity to donate umbilical cord blood to the Public Cord Blood Tissue Bank, but the woman may not be required to make a donation.

Section 381.06015, F.S., also provides that the section does not impose any requirement on any health care or services program that is 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 principles the denomination considers to be an essential part of its beliefs.

III. Effect of Proposed Changes:

This bill repeals s. 381.00325, F.S., which requires the department to develop a Hepatitis A awareness program. This program requires the department to work with private businesses and associations to develop the program and disseminate information to educate the public about, and the availability of, the Hepatitis A vaccine.

The bill also repeals s. 381.06015, F.S., which:

- Establishes the Public Cord Blood Tissue Bank.
- Requires the AHCA and the department to encourage health care providers, including, but not limited to, hospitals, birthing facilities, county health departments, physicians, midwives, and nurses, to disseminate information about the Public Cord Blood Tissue Bank.
- Requires any health care facility or health care provider receiving financial remuneration for the collection of umbilical cord blood to provide written disclosure of their financial interest

to any woman postpartum or parent of a newborn from whom the umbilical cord blood is collected prior to the harvesting of the umbilical cord blood.
- Contains an obsolete provision requiring the AHCA and the department to seek private or federal funds to initiate program actions for fiscal year 2000-2001.

The effective date of the bill is July 1, 2012.

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:

None.

C. Government Sector Impact:

The universities in the consortium required under s. 381.06015, F.S., may realize cost-savings once the consortium is disbanded upon the repeal of s. 381.06015, F.S.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The department reports that, even if the Hepatitis A awareness program under s. 381.00325, F.S., is repealed, the department will continue to provide education and outreach of the Hepatitis A

vaccine under the authority of s. 381.003(1)(e), F.S. Therefore, the repeal of s. 381.00325, F.S., will have minimal impact on the department.[7]

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.

[7] Department of Health, *Bill Analysis, Economic Statement and Fiscal Note: SB 478*, December 7, 2011, on file with the Health Regulation Committee.