

STORAGE NAME: h2037z.hcs
DATE: June 13, 2000

****AS PASSED BY THE LEGISLATURE****
CHAPTER #: 2000-305, Laws of Florida

**HOUSE OF REPRESENTATIVES
AS REVISED BY THE COMMITTEE ON
HEALTH CARE SERVICES
FINAL ANALYSIS**

BILL #: HB 2037 (includes HB 2337, PCB HCS 00-07)

RELATING TO: Health Care

SPONSOR(S): Representative Farkas and others

TIED BILL(S):

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

- (1) HEALTH CARE SERVICES YEAS 16 NAYS 0
- (2) GOVERNMENTAL OPERATIONS YEAS 6 NAYS 0
- (3) HEALTH AND HUMAN SERVICES APPROPRIATIONS (W/D)
- (4)
- (5)

I. SUMMARY:

Passed the Legislature as HB 2037. On June 15, 2000, HB 2037 became chapter 2000-305, Laws of Florida, with the Governor's signature.

HB 2037:

- Provides department status to the Agency for Health Care Administration (AHCA). The bill: designates that the department be known as the Agency for Health Care Administration; provides for Governor appointment, and Senate confirmation, of the Secretary; provides for flexibility in the organization and structure of the new department by eliminating current statutory references to divisions within AHCA; specifies the purpose for the new department, and its substantive areas of responsibility; transfers, via a Type One transfer as specified in s. 20.06(1), F.S., all AHCA resources (staff and funding) from the Department of Business and Professional Regulation to the new department; and incorporates conforming revisions into various sections of the statutes to reflect the new designation of the AHCA Director as a Secretary.
- Provides for the repeal of the Florida Health Care Purchasing Cooperative (s. 408.001, F.S.), effective December 31, 2000, or upon dissolution of the cooperative, whichever occurs first.
- Incorporates the substance of HB 2337 (PCB HCS 00-07), establishing the Cord Blood Tissue Bank, a nonprofit legal entity formed as a consortium consisting of the University of Florida, the University of South Florida, the University of Miami, and the Mayo Clinic, Jacksonville. The bill directs the Agency for Health Care Administration and the Department of Health to encourage all health care providers to provide information regarding umbilical cord blood tissue donation to pregnant women seeking services. The bill provides that information about umbilical cord blood donation may be offered to all women upon admission to a 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 authorizes the consortium participants, the Agency for Health Care Administration, and the Department of Health to seek private or federal funds to initiate program actions for fiscal year 2000-2001. This bill becomes effective on October 1, 2000.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|-----------------------------|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" 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"/> |

B. PRESENT SITUATION:

Agency for Health Care Administration

The Agency for Health Care Administration was created in 1992 within the Department of Business and Professional Regulation, as an independent agency reporting directly to the Governor. Section 20.42, F.S., provides for the creation and organizational structure of the agency. The agency is headed by a director appointed by the Governor.

As specified in subsection (2) of s. 20.42, F.S., the agency consists of: the Division of Health Quality Assurance, the Division of Health Policy and Cost Control, the Division of State Health Purchasing, and the Division of Administrative Services. Responsibilities for each of these divisions are specified, and subsequent subsections specify the appointment of division directors for each of these divisions.

As of a January 10, 2000, internal reorganization, AHCA has three divisions: the Division of Medicaid, which is responsible for the agency's activities related to Medicaid and Kidcare; the Division of Managed Care & Health Quality, which is responsible for the agency's activities related to Managed Care, Facility Licensure and Regulation, Certificate of Need, Plans & Construction, and Practitioner Regulation, Consumer Services, and Investigation; and the Division of Administrative Services, which is responsible for the agency's activities related to Budget, Finance, & Accounting, Human Resources, and Support Services. In addition to these divisions, the following activities report directly to the Executive Director: Inspector General, including Medicaid Program Integrity; General Counsel, including Practitioner Regulation Legal; External Affairs, including Legislative Affairs and Media Relations; Information Technology, including State Center for Health Statistics and Management Information Services; Health Policy; and the Chief Medical Officer.

As of February 29, 2000, AHCA's budget for the current fiscal year was \$7,832,540,059; the Medicaid budget entity was \$7,537,834,690 of that. [NOTE: This does not include Kidcare appropriations which are currently in the Health Care Administration and Regulation budget entity.] The agency has 1,991 FTEs, of which 897 are funded in the Medicaid budget entity.

Under the Division of Managed Care and Health Quality is the Managed Care Bureau. This bureau is responsible for Medicaid prepaid services contracts, health maintenance organization quality assurance under part III of ch. 641, F.S., and quality of care under the workers' compensation managed care arrangement program via s. 440.134, F.S.

The Florida Health Care Purchasing Cooperative

The Florida Health Care Purchasing Cooperative was created in 1991 to pool the purchasing power for health care services of state and local governmental entities. The statutory authority for the cooperative is contained in s. 408.001, F.S. The cooperative is a nonprofit, private corporation organized under chapter 617, F.S., and received state start-up funding for the first few years of its operation, but has not received state funding since 1994. The cooperative has successfully assisted local governments that have used the services of the cooperative to save money in their employee health benefits purchasing. The reinsurer of the Florida Health Care Purchasing plan has recently made a corporate decision to leave the group health excess risk market and the Board of Directors of the cooperative has decided to not issue any new plans. This has put the cooperative in a position of declining revenues.

Workers' Compensation

As a result of a major restructuring of the workers' compensation program in 1993, workers' compensation came under managed care. As part of this revision, a systematic, self-regulating process was put in place under which employers could be assured of the management of the cost and quality of medical services provided to injured workers. This was accomplished by replacing the non-managed care medical delivery process with physician driven managed care processes and control to ensure that medical decisions are made by appropriately-licensed health care professionals. This is in contrast to the non-managed care medical process under which insurance adjusters made decisions about the necessity of medical care received by injured employees.

Chapter 440, F.S., is the "Workers' Compensation Law." Section 440.134, F.S., empowers an insurer authorized by the Agency for Health Care Administration to offer or utilize a managed care arrangement for service delivery under the workers' compensation program. Under this authority, AHCA currently regulates the quality of medical care for all injured workers in Florida who are under workers' compensation. According to AHCA, as of January 1, 1997, all Florida employers with four or more employees are required to provide medical services to injured workers solely through an AHCA-authorized workers' compensation managed care arrangement. There are currently 552 authorized workers' compensation managed care arrangements serving over 5 million Florida employees.

Method of Reorganization of State Government

Section 20.06, F.S., provides the means for an orderly reorganization of state government. The specific types of transfers are as follows:

Subsection (1) provides for a Type I transfer, wherein an agency or department becomes another agency or department. This can be thought of as an "intact" transfer.

Subsection (2) provides for a Type II transfer, wherein an existing agency, department or program, function, or activity thereof is removed from an existing "location" and merged into another "location."

Umbilical Cord Blood

Introduction

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 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 2037 grants department status to the Agency for Health Care Administration and makes related conforming revisions, repeals the statutory provision relating to the Florida Health Care Purchasing Cooperative, and establishes a statewide consortium to be known as the Public Cord Blood Tissue Bank. Additional details are provided in the SECTION-BY-SECTION ANALYSIS which follows.

D. SECTION-BY-SECTION ANALYSIS:

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

Subsection (1) creates a statewide consortium to be known as the Public Cord Blood Tissue Bank. The consortium is a nonprofit legal entity consisting of the University of Florida, the University of South Florida, the University of Miami, and the Mayo Clinic, Jacksonville. 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. Each of the consortium participants 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 participants are to align their outreach programs and activities to all geographic areas of the state. The consortium is encouraged to conduct outreach and research for the Hispanic, African American, Native American, and other ethnic and racial minorities.

Subsection (2) requires AHCA and the Department of Health to encourage specified health care providers to disseminate information about the Public Cord Blood Tissue Bank program.

Subsection (3) specifies that nothing in this act creates a requirement of 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 (4) provides that any health care facility or health care provider receiving financial remuneration for the collection of umbilical cord blood shall provide written disclosure of this information 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.

Subsection (5) specifies that any 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. A woman may not be required to make such a donation.

Subsection (6) provides that the consortium may charge reasonable rates and fees to recipients of cord blood tissue bank products.

Subsection (7) directs the consortium participants, AHCA, and the Department of Health to seek private or federal funds to initiate program actions for fiscal year 2000-2001

Section 2. Amends s. 20.42, F.S., relating to the creation and organizational structure of the Agency for Health Care Administration, to: create a department that, notwithstanding the provisions of s. 20.04(1), F.S., relating to the organizational structure of state agencies, shall be called the Agency for Health Care Administration; provide for Governor appointment, and for Senate confirmation, of a Secretary of the new department; provide for flexibility in the organization and structure of the new department by eliminating current statutory references to divisions within AHCA; and specify the duties and areas of responsibility of the department.

Section 3. Amends subsection (2) of s. 440.134, F.S., relating to workers' compensation managed care arrangements and AHCA's functions relating to such arrangements, to delete date references which have passed.

Sections 4-25. Amend several statutory provisions to conform references to the head of AHCA made necessary by designation of AHCA as a department headed by a secretary. References to *director* and *Director of Health Care Administration* are replaced with references to *secretary* and *Secretary of Health Care Administration*. References to the Division of State Health Purchasing and Deputy Director for State Health Purchasing are also deleted to conform to changes made in section 2 of the bill. The specific sections of statute which are amended are as follows:

Bill Statute

<u>Section</u>	<u>Section</u>	<u>Subject</u>
4.	120.80 (15)	Exceptions and special requirements; agencies
5.	215.5601(4)(d)	Lawton Chiles Endowment Fund; creation; purpose; and uses
6.	381.0602	Organ Transplant Advisory Council; membership; responsibilities
7.	381.6023(1)	Organ and Tissue Procurement and Transplantation Advisory Board; creation; duties
8.	381.90(3)	Health Information Systems Council; legislative intent; creation; appointment; duties
9.	395.0163(1)(a)	Construction inspections; plan submission and approval; fees
10.	395.10972	Health Care Risk Manager Advisory Council
11.	400.0067	Establishment of State Long Term Care Ombudsman Council; duties; membership
12.	400.235(3)(a)	Nursing home quality and licensure status; Gold Seal Program
13.	400.4415(1)	Assisted Living Facilities Advisory Committee
14.	400.967(5)	Rules and classification of deficiencies
15.	408.036(3)	Projects subject to review
16.	408.05(8)(a)	State Center for Health Statistics
17.	408.902(1)	MedAccess program; creation; program title
18.	409.8132(2)	Medikids program component
19.	430.710(1)	Long-Term Care Interagency Advisory Council
20.	478.44(4)(c)	Electrolysis Council; creation; function; powers and duties
21.	627.4236(3)	Coverage for bone marrow transplant procedures
22.	641.454	Civil action to enforce prepaid health clinic contract; attorney's fees; court costs
23.	641.60(6)(f)	Statewide Managed Care Ombudsman Committee
24.	641.70(3)	Agency duties relating to the Statewide Managed Care Ombudsman Committee and the district managed care ombudsman committees
25.	732.9216	Organ and Tissue Donor Education Panel

Section 26. Repeals s. 408.001, F.S., relating to the Health Care Purchasing Cooperative, effective December 31, 2000, or upon dissolution of the cooperative, whichever occurs first.

Section 27. Provides for the transfer, via a Type One transfer as specified in s. 20.06(1), F.S., of all AHCA powers, duties and functions and rules, records, personnel, property, and unexpended balances of appropriations, allocations, or other funds from the Department of Business and Professional Regulation to the new department.

Section 28. Provides for an effective date of October 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:

N/A

D. FISCAL COMMENTS:

The Agency for Health Care Administration indicates the redesignation of the agency as a department will be revenue neutral.

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:

The 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:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

When the Committee on Health Care Services heard the bill on April 5, 2000, the committee adopted a "strike-everything" amendment, as well as a substantive amendment and technical

amendment to the main amendment. The amendment, as amended, incorporated the following revisions:

- Clarified the designation of the name of the department as the “Agency for Health Care Administration.”
- Deleted as unnecessary date of appointment relative to Senate confirmation.
- Specified the purpose for the new department, and its substantive areas of responsibility; and deleted reference to the Secretary’s general authority to transfer positions and resources internally.
- Clarified the wording of the language that is added to s. 440.134, F.S., relating to the Agency for Health Care Administration’s duties specific to workers’ compensation managed care arrangements and quality of medical care rendered under such arrangements. Changed the placement of this added language from subsection (18) to subsection (2) of that section.
- Amended various sections of the statutes to reflect the new designation of the AHCA Director as a Secretary.
- Provided for the repeal of the Florida Health Care Purchasing Cooperative (s. 408.001, F.S.), effective December 31, 2000, or upon dissolution of the cooperative, whichever occurs first.
- Deleted an unnecessary date reference regarding the transfer of positions and related budget for the workers’ compensation managed care arrangements from the Department of Labor and Employment Security to the Agency for Health Care Administration, and deleted reference to a specific trust fund within Labor.

On April 12, 2000, the Committee on Governmental Operations heard this bill and adopted five amendments to the strike-everything amendment traveling with the bill. All five amendments were technical in nature, amending a grammatical problem, clarifying statutory references, and reflecting the new designation of the AHCA Director as a Secretary and removing references to the Division of State Health Purchasing. The bill was reported favorably as amended.

On April 27, 2000, the bill was taken up on second reading by the full House of Representatives. A strike-everything amendment was adopted which incorporated the previously explained amendments, as well as clarified the language relating to the transfer of functions and positions associated with workers’ compensation managed care arrangements.

On May 2, 2000, the bill was taken up on third reading by the full House of Representatives. The bill was amended to delete reference to the transfer of functions and positions relating to workers’ compensation managed care arrangements, and to include a modified version of the substance of HB 2337 (PCB HCS 00-07), relating to the Public Cord Blood Tissue Bank consortium.

When take up in the Senate on May 3, 2000, the bill as amended was approved by the Senate.

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VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

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Staff Director:

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AS REVISED BY THE COMMITTEE ON GOVERNMENTAL OPERATIONS:

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