Healthcare Council

Tuesday, April 10, 2007
9:00 AM
Morris Hall

Marco Rubio
Speaker

Aaron Bean
Chair

Council Meeting Notice

HOUSE OF REPRESENTATIVES

Speaker Marco Rubio

Healthcare Council

Start Date and Time:	Tuesday, April 10, 2007 09:00 am
End Date and Time:	Tuesday, April 10, 2007 12:00 pm
Location:	Morris Hall (17 HOB)
Duration:	3.00 hrs

Consideration of the following bill(s):

HB 877 Physician Workforce Assessment and Development by Homan
HM 889 State Children's Health Insurance Program by Harrell
HB 977 Primary Care Access Network by Gardiner
HB 1065 Stem Cell Research by Flores
HB 1111 Fiscal Intermediary Services Organizations by Kendrick
HB 1115 Health Care Clinic Act by Kreegel
HB 1361 Emergency Services by Garcia, R.
HB 1477 Forensic Mental Health Services by Ausley

Consideration of the following bill(s) with proposed council substitute(s):

HB 1007 Physician Assistants by Baxley

Consideration of the following proposed council bill(s):

PCB HCC 07-16 -- cardiac care
PCB HCC 07-17 -- home health care

It is the intent of the Council to take up proposed council substitute for HB 1007 which was voted out of its respective committee and was recommended as a council substitute.

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, April 9, 2007.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, April 9, 2007.

NOTICE FINALIZED on 04/06/2007 16:04 by BAI

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 877 Physician Workforce Assessment and Development
SPONSOR(S): Homan
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Quality	8 Y, 0 N	Guy	Lowell
2) Healthcare Council		Guy	Gormley
3) Policy & Budget Council			
4)			
5)			

SUMMARY ANALYSIS

HB 877 creates the Office of Physician Workforce Assessment and Development within the Department of Health. The office is directed to use existing programs in the department to assess Florida's current and future physician workforce needs and develop strategies to addresses those needs.

The bill appears to have an insignificant fiscal impact, which can be absorbed within existing resources.

The effective date of this bill is July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – this bill creates a new office within the department to assess Florida's current and future physician workforce needs.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Workforce Data Collection
The statewide collection of physician data and its analysis is fragmented in Florida and under the purview of different agencies. Currently, there is no centralized physician workforce database that is available to provide objective statewide information on physician practice and manpower needs. Under s. 408.05, F.S., the State Center for Health Statistics within the Agency for Health Care Administration ("AHCA") must collect data on health resources, including physicians, dentists, nurses, and other health care professionals. The Division of Health Access and Tobacco within the Department of Health ("department") administers several programs that relate to physician access. The Florida Medicaid program in AHCA has claims data for physicians participating in the Medicaid program.

During Fiscal Year 2006-07, the department began collection of physician workforce data through a voluntary response survey. The survey was included in the licensure renewal application package for allopathic physicians. As of February 22, 2007, the department has received 22,547 completed surveys. Osteopathic physicians will receive the survey in their licensure renewal application packages this fall.

Medical Education and Residency Programs
Florida ranks 37th nationally in the number of medical school students (both allopathic and osteopathic) per 100,000 state population.[1] Florida has a low number of medical residency positions per 100,000 state population and ranks 41st in the nation.[2] Twenty-six percent of Florida's doctors are over the age of 65.[3]

The Center for Health Workforce Studies and the Council on Graduate Medical Education (COGME) recommend that existing medical schools increase their enrollment by 15 percent by 2015 to contend with the current and projected physician shortage. It is estimated that in order to reach the national ratio of allopathic and medical school students per state population, Florida would need to increase its capacity by 2,700 students.[4]

Research has shown that the location of a physician's practice correlates more closely to the geographic location of the residency, rather than to the medical school from which the physician graduated.[5] A recent nationwide analysis by the National Conference of State Legislatures (NCSL) found that 47 percent of individuals that complete an allopathic medical residency program stay in the same state that they completed their graduate medical education training.[6] CEPRI has projected that 60.5 percent of allopathic medical residency students remain and practice in the state of residency training.

[1] Council for Education Policy, Research and Improvement (CEPRI). Medical Education Needs Analysis. November 2004.
[2] Florida Department of Health. Annual Report on Graduate Medical Education in Florida. January 2007.
[3] *Id.*
[4] Council for Education Policy, Research and Improvement (CEPRI). Medical Education Needs Analysis. November 2004.
[5] *Id.*
[6] *Id.*

Effect of Proposed Changes

The bill creates the Office of Physician Workforce Assessment and Development ("office") within the department. The office is directed to use existing programs in the department to assess Florida's current and future physician workforce needs and develop strategies to addresses those needs.

In particular, the bill directs the department to maintain a database of physician workforce data and directs the office to:

- Collect and analyze data on physician workforce, medical students, and residents;
- Develop a model of the current and future physician workforce, including demographic factors;
- Develop strategies to address retention of Florida medical school graduates for practice in the state;
- Develop best-practice programs for recruitment of K-12, college, and university students into medical school programs;
- Pursue strategies that target state and federal funding for graduate medical education positions and residency positions towards identified workforce needs areas;
- Target physician recruitment and retention towards identified workforce needs areas; and
- Coordinate stakeholders' efforts to address physician workforce needs.

C. SECTION DIRECTORY:

Section 1. Creates s. 381.4018, F.S., to establish the Office of Physician Workforce Assessment within the Department of Health and specifies duties of the office.

Section 2. Provides for an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   Data analysis can be accomplished within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

Depending on the analysis of the physician workforce data, in the future, there may be a request for additional funding to provide Graduate Medical Education (GME) enhancements.

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:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

"A similar bill by Rep Altman and Homan (HB 1093) was passed out of the House last session but the appropriation got a line-item veto by Gov Bush. The Department of Health began collecting the data anyway with the 2006 physician license renewals and now we have data from 50% of the physicians, but no resources to analyze it. The other 50% of the physicians are coming up for renewal at the end of 2007, and once collected we want to have someone coordinate the data transfer to and analysis by the physician workforce stakeholders.(including, but not limited to: DOH, DOE, AHCA, CMS, medical schools, residency programs, hospitals, specialty societies, and insurance companies)

The Office of Physician Workforce Assessment and Development is set up to be a data collection and clearing house to get information of the physician workforce to the stakeholders to use in making strategic plans to assure accessibility to health care to all Floridians in the near and distant future."

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 13, 2007, the Health Quality Committee adopted one amendment to the bill. The amendment corrects a drafting error by replacing "Office" with "Division" in order to correctly reference the Division of Medical Quality Assurance.

The bill was reported favorably with one amendment.

A bill to be entitled

An act relating to physician workforce assessment and development; creating s. 381.4018, F.S.; providing legislative intent; creating the Office of Physician Workforce Assessment and Development within the Department of Health; proving a purpose; providing functions of the office; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.4018, Florida Statutes, is created to read:

381.4018 Office of Physician Workforce Assessment and Development.--

(1) LEGISLATIVE INTENT.--The Legislature recognizes that physician workforce planning is an essential component in ensuring that there is an adequate and appropriate supply of well-trained physicians to meet the state's future healthcare service needs as both the general population and elderly population of the state increase. The Legislature finds that issues to consider relative to the assessment of physician workforce need may include physician practice status; specialty mix; geographic distribution; demographic information, including, but not limited to, age, gender, race, and cultural considerations; and meeting the needs of current or projected medically underserved areas in the state. Long-term strategic planning is essential, as the period of time from the time of entering medical school to completion of graduate medical

education may range from 7 to 10 years, or longer. The Legislature recognizes that strategies to provide for a well-trained supply of physicians must include ensuring the availability of quality medical schools and graduate medical education capacity in the state as well as utilizing new or existing state or federal programs that might provide incentives for physicians to practice in needed specialties and in underserved areas in a manner that addresses projected physician manpower needs.

(2) CREATION; PURPOSE.--The Office of Physician Workforce Assessment and Development is created in the Department of Health and shall serve as a coordinating and strategic planning body to actively assess the state's current and future physician workforce needs and shall work with multiple stakeholders to develop strategies and alternatives to address the state's current and projected physician workforce needs.

(3) GENERAL FUNCTIONS.--The Office of Physician Workforce Assessment and Development shall maximize the utilization of existing programs under the jurisdiction of the department and other state agencies; coordinate among governmental and nongovernmental stakeholders and resources to determine a state strategic plan; and assess implementation of such strategic plan to:

(a) Monitor, evaluate, and report on the supply and distribution of physicians licensed under chapters 458 and 459. The department shall maintain a database to serve as the official statewide source of valid, objective, and reliable data on the physician workforce.

(b) Develop a model and quantify, on an ongoing basis, the adequacy of the state's current and future physician workforce, as reliable physician workforce data becomes available. Such model shall consider the following factors: demographics, physician practice status, place of education and training, generational changes, population growth, economic indicators, and issues relating to the channeling of students into medical education.

(c) Develop and recommend strategies to determine whether availability of qualified state medical school applicants who might become competent practicing physicians in the state will be sufficient to meet medical school capacity of the state's medical schools. If appropriate, the Office of Physician Workforce Assessment and Development, working with representatives of appropriate governmental and nongovernmental entities, shall develop strategies and recommendations and identify best-practice programs that introduce health care as a profession and strengthen skills needed for medical school admission for elementary, middle, and high school students, and improve premedical education at the K-12 and college level to increase the state's potential pool of medical students.

(d) Assess strategies to ensure that graduates from the state's public and private allopathic and osteopathic medical schools are adequate to meet physician workforce needs, based on the analysis of the physician workforce data, and strategies to ensure that the state's medical schools are adequately funded to provide a high quality medical education to students in a manner that recognizes the uniqueness of each of the state's new and existing medical schools.

(e) Pursue strategies and policies to create, expand, and maintain graduate medical education positions in the state, based on the analysis of the physician workforce data. Such strategies and policies shall consider the impact of federal funding limitations on the expansion and creation of graduate medical education positions and shall develop options to address such federal funding limitations. Options to provide direct state funding for graduate medical education positions shall be considered in a manner that addresses requirements and needs relative to accreditation of graduate medical education programs. Funding for residency positions should be targeted to address needed physician specialty areas, rural and physician shortage areas, areas of ongoing critical need, and otherwise address the physician workforce needs of the state, based on the analysis of ongoing physician workforce data.

(f) Develop strategies to maximize federal and state programs that provide for the use of incentives to attract physicians to the state or retain physicians in the state in order to meet the state's physician workforce needs. Such strategies should explore and maximize federal-state partnerships available to provide for incentives for physicians to practice in federally designated shortage areas. Strategies shall also consider the use of state programs, such as the Florida Health Service Corps established pursuant to s. 381.0302 and the Medical Education Reimbursement and Loan Repayment Program pursuant to s. 1009.65, that provide for education loan repayment or loan forgiveness to provide physicians monetary incentives to relocate to underserved areas of the state.

(g) Coordinate and enhance activities relative to physician workforce needs, undergraduate medical education, and graduate medical education provided by the Office of Medical Quality Assurance, the Community Hospital Education Program and Graduate Medical Education Committee established pursuant to s. 381.0403, the area health education center network established pursuant to s. 381.0402, and other offices and programs within the Department of Health as deemed by the secretary.

(h) Work in conjunction with and act as a coordinating body for governmental and nongovernmental stakeholders to address matters relating to the state's physician workforce assessment and development for the purpose of ensuring an adequate supply of well-trained physicians to meet the state's future needs. Such governmental stakeholders shall include, but may not be limited to, the secretaries or designees of the Department of Health, Department of Education, and Agency for Healthcare Administration, the Chancellor or designee of the Board of Governors, and, at the discretion of the department, other representatives of state and local agencies involved in the assessment, education, training, or provision of the state's current or future physician workforce. Other stakeholders shall include, but may not be limited to, organizations representing the state's public and private allopathic and osteopathic medical schools; organizations representing hospitals and other healthcare-providing institutions, particularly those that currently provide or have an interest in providing accredited medical education and graduate medical education to medical students and medical residents in the state; organizations representing allopathic and osteopathic practicing physicians; and, at the discretion of the department, representatives of other organizations or entities involved in the assessment, education, training, or provision of the state's current or future physician workforce.

(i) Serve as a state liaison with other states and federal agencies and programs to enhance resources available to the state's physician workforce and medical education continuum.

(j) Act as a clearinghouse for collecting and disseminating information of physician workforce and medical education continuum issues in the state.

Section 2. This act shall take effect July 1, 2007.

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	______	

Council/Committee hearing bill: Healthcare Council
Representative(s) Homan offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 381.4018, Florida Statutes, is created to read:

381.4018 Office of Physician Workforce Assessment and Development.--

(1) LEGISLATIVE INTENT.--The Legislature recognizes that physician workforce planning is an essential component in ensuring that there is an adequate and appropriate supply of well-trained physicians to meet the state's future healthcare service needs as both the general population and elderly population of the state increase. The Legislature finds that issues to consider relative to the assessment of physician workforce need may include physician practice status; specialty mix; geographic distribution; demographic information, including, but not limited to, age, gender, race, and cultural considerations; and meeting the needs of current or projected medically underserved areas in the state. Long-term strategic planning is essential, as the period of time from the time of

entering medical school to completion of graduate medical education may range from 7 to 10 years, or longer. The Legislature recognizes that strategies to provide for a well-trained supply of physicians must include ensuring the availability of quality medical schools and graduate medical education capacity in the state as well as utilizing new or existing state or federal programs that might provide incentives for physicians to practice in needed specialties and in underserved areas in a manner that addresses projected physician manpower needs.

(2) CREATION; PURPOSE.--The Office of Physician Workforce Assessment and Development is created in the Department of Health and shall serve as a coordinating and strategic planning body to actively assess the state's current and future physician workforce needs and shall work with multiple stakeholders to develop strategies and alternatives to address the state's current and projected physician workforce needs.

(3) GENERAL FUNCTIONS.--The Office of Physician Workforce Assessment and Development shall maximize the utilization of existing programs under the jurisdiction of the department and other state agencies; coordinate among governmental and nongovernmental stakeholders and resources to determine a state strategic plan; and assess implementation of such strategic plan to:

(a) Monitor, evaluate, and report on the supply and distribution of physicians licensed under chapters 458 and 459. The department shall maintain a database to serve as the official statewide source of valid, objective, and reliable data on the physician workforce.

(b) Develop a model and quantify, on an ongoing basis, the adequacy of the state's current and future physician workforce, as reliable physician workforce data becomes available. Such model shall consider the following factors: demographics, physician practice status, place of education and training, generational changes, population growth, economic indicators, and issues relating to the channeling of students into medical education.

(c) Develop and recommend strategies to determine whether availability of qualified state medical school applicants who might become competent practicing physicians in the state will be sufficient to meet medical school capacity of the state's medical schools. If appropriate, the Office of Physician Workforce Assessment and Development, working with representatives of appropriate governmental and nongovernmental entities, shall develop strategies and recommendations and identify best-practice programs that introduce health care as a profession and strengthen skills needed for medical school admission for elementary, middle, and high school students, and improve premedical education at the K-12 and college level to increase the state's potential pool of medical students.

(d) Assess strategies to ensure that graduates from the state's public and private allopathic and osteopathic medical schools are adequate to meet physician workforce needs, based on the analysis of the physician workforce data, and strategies to ensure that the state's medical schools are adequately funded to provide a high quality medical education to students in a manner that recognizes the uniqueness of each of the state's new and existing medical schools.

(e) Pursue strategies and policies to create, expand, and maintain graduate medical education positions in the state, based on the analysis of the physician workforce data. Such strategies and policies shall consider the impact of federal funding limitations on the expansion and creation of graduate medical education positions and shall develop options to address such federal funding limitations. Options to provide direct state funding for graduate medical education positions shall be considered in a manner that addresses requirements and needs relative to accreditation of graduate medical education programs. Funding for residency positions should be targeted to address needed physician specialty areas, rural and physician shortage areas, areas of ongoing critical need, and otherwise address the physician workforce needs of the state, based on the analysis of ongoing physician workforce data.

(f) Develop strategies to maximize federal and state programs that provide for the use of incentives to attract physicians to the state or retain physicians in the state in order to meet the state's physician workforce needs. Such strategies should explore and maximize federal-state partnerships available to provide for incentives for physicians to practice in federally designated shortage areas. Strategies shall also consider the use of state programs, such as the Florida Health Service Corps established pursuant to s. 381.0302 and the Medical Education Reimbursement and Loan Repayment Program pursuant to s. 1009.65, that provide for education loan repayment or loan forgiveness to provide physicians monetary incentives to relocate to underserved areas of the state.

(g) Coordinate and enhance activities relative to physician workforce needs, undergraduate medical education, and graduate medical education provided by the Division of Medical Quality Assurance, the Community Hospital Education Program and the Graduate Medical Education Committee established pursuant to s. 381.0403, the area health education center network established pursuant to s. 381.0402, and other offices and programs within the department as deemed by the secretary.

(h) Monitor, evaluate and quantify, on an ongoing basis, the availability of critical physician services statewide and by geographic area. Such critical physician services shall include, but are not limited to, availability of and trends relating to obstetric care and services, particularly delivery of babies; radiological services, particularly performance of mammograms and breast-imaging services; physician specialty services for hospital emergency departments and trauma centers; and additional items as may be determined by the department.

(i) Work in conjunction with and act as a coordinating body for governmental and nongovernmental stakeholders to develop strategies and recommendations regarding assessment and development of Florida's physician workforce. The Office of Physician Workforce Assessment and Development must report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1 of each year. The report shall include, at a minimum, a description of the status of each item in this section, recommendations of strategies needed to address each item, assessment of the implementation of previous recommendations, and recommendations relative to other alternative strategies or matters deemed important by the department to ensure that Florida has an adequate supply of well-trained physicians to meet the state's future health care needs. Stakeholders that may serve as resources may include, but are not limited to, the secretaries or designees of the Department of Health, Department of Education, and Agency for Healthcare Administration; the Chancellor or designee of the Board of Governors; and, at the discretion of the department, other representatives of state and local agencies involved in the assessment, education, training, or provision of the state's current or future physician workforce. Other stakeholders shall include, but are not limited to, organizations representing the state's public and private allopathic and osteopathic medical schools; organizations representing hospitals and other healthcare-providing institutions, particularly those that currently provide or have an interest in providing accredited medical education and graduate medical education to medical students and medical residents in the state; organizations representing allopathic and osteopathic practicing physicians, including organizations representing physician specialties as needed to address items requiring specific physician specialist expertise; and, at the discretion of the department, representatives of other organizations or entities involved in the assessment, education, training, or provision of the state's current or future physician workforce.

(j) Serve as a state liaison with other states and federal agencies and programs to enhance resources available to the state's physician workforce and medical education continuum.

(k) Act as a clearinghouse for collecting and disseminating information regarding physician workforce and medical education continuum issues in the state.

(4) DATA COLLECTION.--In order to collect the physician workforce data described in subsection (3), the department must develop a physician workforce survey instrument that must be provided to each person who applies for licensure renewal as a physician under chapter 458 or chapter 459 in conjunction with the renewal of such license, under procedures adopted by the department. Completion of the physician workforce survey instrument shall be voluntary.

(5) RULEMAKING.--The department shall adopt rules, pursuant to ss. 120.536(1) and 120.54, necessary to implement this section.

Section 2. This act shall take effect July 1, 2007.

================ T I T L E A M E N D M E N T ================

Remove the entire title and insert:

A bill to be entitled

An act relating to physician workforce assessment and development; creating s. 381.4018, F.S.; providing legislative intent; creating the Office of Physician Workforce Assessment and Development within the Department of Health; providing a purpose; providing for functions of the office; requiring the department to collect physician workforce data; providing rule-making authority; providing an effective date.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **877**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

Council/Committee hearing bill: Healthcare Council

Committee on Health Quality offered the following:

Amendment

Remove line 116 and insert:

graduate medical education provided by the Division of Medical

This amendment was adopted in HQ on 03/13/07 and is traveling with the bill and requires no further action. However, the new strike all will supercede the traveling amendment which is encompassed in the strike all.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HM 889 State Children's Health Insurance Program
SPONSOR(S): Harrell
TIED BILLS: **IDEN./SIM. BILLS:** SB 1506

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Healthy Families	9 Y, 0 N	Mitchell	Mitchell
2) Healthcare Council		Mitchell	Gormley
3) Rules & Calendar Council			
4)			
5)			

SUMMARY ANALYSIS

House Memorial 889 is a resolution to encourage federal reauthorization of funding for the Healthy Kids component of the Florida KidCare Program that provides health care to low-income children who are uninsured and not eligible for Medicaid.

The memorial requests the Florida delegation to Congress to work to ensure that the Congress reauthorizes the State Children's Health Insurance Program (SCHIP). The memorial requests the Governor to work with the Florida delegation to ensure that SCHIP is reauthorized in a timely manner.

The memorial also requests the Governor to provide the assistance necessary to identify and enroll children who qualify for Medicaid or the Florida KidCare program. It proclaims that all components of state government should work together with educators, health care providers, social workers, and parents to ensure that to the maximum extent possible all available public and private assistance is used to provide health benefits to uninsured children.

Copies of the memorial are to be sent to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Empower Families--The bill requests Congress to reauthorize and continue federal funding for the State Children's Health Insurance Program (SCHIP) that supports Florida's KidCare program of health coverage to low-income children. Health care coverage helps children succeed in life and helps families avoid crisis due to lack of insurance.

B. EFFECT OF PROPOSED CHANGES:

House Memorial 889 requests the members of the Florida Congressional delegation to ensure Congress reauthorizes the State Children's Health Insurance Program (SCHIP) to provide federal funding for the Healthy Kids component of the Florida KidCare program. The memorial requests the Governor to work with the Florida delegation to ensure that SCHIP is reauthorized in a timely manner.

The memorial also requests the Governor to provide the assistance necessary to identify and enroll children who qualify for Medicaid or the Florida KidCare program. It proclaims that all components of state government should work together with educators, health care providers, social workers, and parents to ensure the maximum use of available public and private assistance to provide health benefits to uninsured children in Florida.

CURRENT SITUATION

The purpose of the resolution is to get federal reauthorization of funding for Florida's Healthy Kids program by September 1, 2007. Healthy Kids provides health care to low-income children who are uninsured and ineligible for Medicaid under federal rules. The federal government provides a more than two to one (71/29) ratio of federal matching funds to the state program. Federal funding has permitted Florida to cover children up to 200% of the federal poverty level and reduce the number of uninsured children. Additional federal funding for the Healthy Kids program is due to expire in August of this year.

Background Information on the State Children's Health Insurance Program and Florida's KidCare Program

The State Children's Health Insurance Program (SCHIP) was established as Title XXI of the Social Security Act as part of the Balanced Budget Act of 1997 (BBA). The goal of SCHIP is to expand health coverage to children whose families' incomes are too high for the children to be eligible for Medicaid (Title XIX of the Social Security Act), but too low for the families to afford private coverage for their children. Together with Medicaid, SCHIP provides a safety-net for health insurance for low-income children and has significantly reduced the number of low-income uninsured children.

Florida's program implementing the national State Children's Health Insurance Program is KidCare. The Florida KidCare program provides health care coverage to over 1.4 million children in Florida. KidCare is an "umbrella" program, the components of which include Medicaid for children, the Florida Healthy Kids (SCHIP) program, Medikids, and the Children's Medical Services Network (CMSN). Family income and a child's age and having a serious health condition are the eligibility criteria that determine which KidCare component serves a particular child.

As of February 2007, 204,021 children in KidCare are eligible for SCHIP, 1,163,813 are Medicaid eligible, and 26,249 children are not eligible for SCHIP or Medicaid but are supported by other local and state funds.

Congress must reauthorize SCHIP in 2007 for federal financing to continue.

Health care experts agree on the importance of providing health coverage for children. Lack of health insurance is a substantial barrier to health care. Uninsured children have much higher health risks than do covered children. They are more likely to go without health services, may avoid, or delay care when it is needed, and are less likely to receive the proper medical care for childhood illnesses such as sore throats, earaches, and asthma. Children who have health insurance are more likely to have a usual place of care and receive preventive and medical services.

Similar to Medicaid, SCHIP provides each state the flexibility to design its program within broad federal guidelines and to modify aspects such as eligibility standards, benefit designs, and limited cost sharing requirements (premiums, deductibles, and co-insurance). However, unlike Medicaid, SCHIP is not an entitlement program and there are limits to the amount of money the federal government has allocated to each state through federal matching funds, known as the annual federal allotment. The federal match rate for SCHIP is higher than Medicaid.

C. SECTION DIRECTORY:

Not applicable.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

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:

None.

D. STATEMENT OF THE SPONSOR

The State Children's Health Insurance Program (SCHIP) provides important health insurance coverage for our low-income children in Florida. Funding from the Federal Government covers 70% of the cost of the program. It is imperative for the health of these children that the US Congress reauthorize this important program.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

House Memorial

A memorial to the Congress of the United States, urging Congress to reauthorize the State Children's Health Insurance Program to continue to provide federal funding for the Florida Kidcare program.

WHEREAS, the Legislature of the State of Florida regards the health of children to be of paramount importance to families in the state, and

WHEREAS, the Legislature of the State of Florida regards poor child health as a threat to the educational achievement and social and psychological well-being of the children of the State of Florida, and

WHEREAS, the Legislature of the State of Florida considers protecting the health of children to be essential to the well-being of Florida's youngest citizens and the quality of life in the state, and

WHEREAS, the Legislature of the State of Florida considers the Florida Kidcare program, which was created in 1998 and currently has 202,214 children enrolled in the program, to be an integral part of the arrangements for health benefits for the children of the State of Florida, and

WHEREAS, the Legislature of the State of Florida recognizes the value of the Florida Kidcare program in preserving child wellness, preventing and treating childhood disease, improving health outcomes, and reducing overall health costs, and

WHEREAS, the Legislature of the State of Florida considers the federal funding available for the Florida Kidcare program to be indispensable to providing health benefits for children of modest means, NOW, THEREFORE,

Be It Resolved by the Legislature of the State of Florida:

That the Legislature urges the members of the Florida delegation to the United States Congress to ensure that the Congress reauthorizes the State Children's Health Insurance Program (SCHIP) to continue to provide federal funding for the Florida Kidcare program.

BE IT FURTHER RESOLVED that the Legislature urges the Governor to work with the Florida delegation to ensure that SCHIP is reauthorized in a timely manner.

BE IT FURTHER RESOLVED that the Legislature urges the Governor to provide the assistance necessary to identify and enroll children who qualify for Medicaid or the Florida Kidcare program.

BE IT FURTHER RESOLVED that the Legislature proclaims that all components of state government should work together with educators, health care providers, social workers, and parents to ensure that all available public and private assistance for providing health benefits to uninsured children in this state be used to the maximum extent possible.

BE IT FURTHER RESOLVED that copies of this memorial be dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1(for drafter's use only)

Bill No. **0889**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	______	

Council/Committee hearing bill: Healthcare Council

Representative(s) Harrell offered the following:

Amendment

Remove line(s) 20 and insert:

currently has 1,388,520 children enrolled in the program, to be an

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 977 Primary Care Access Network
SPONSOR(S): Gardiner
TIED BILLS: **IDEN./SIM. BILLS:** SB 1732

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Innovation	7 Y, 0 N	Ciccone	Calamas
2) Healthcare Council		Ciccone JC	Gormley CG
3) Policy & Budget Council			
4)			
5)			

SUMMARY ANALYSIS

House Bill 977 provides legislative findings and statutory revisions relating to improving access to health care for the uninsured by expanding health care services through the Primary Care Access Network (PCAN).

The bill requires the Agency for Health Care Administration (agency) to establish a two-year pilot program to offer health care services during the weekend and after regular business hours during the week at PCAN clinics in Orlando and Pasco counties. The bill directs the agency to develop procedures for operating the pilot program.

The bill provides $2.3 million to fund the pilot program.

The bill provides an effective date of July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited government - The bill requires the Agency for Health Care Administration (agency) to establish a two-year pilot program to offer health care services during the weekend and after regular business hours during the week. The bill directs the agency to develop procedures for operating the pilot program.

Empower families - The bill provides greater access to health care services at Primary Care Access Network (PCAN) clinics in Orlando and Pasco counties by offering services during the weekday after regular business hours and on the weekend.

B. EFFECT OF PROPOSED CHANGES:

House Bill 977 establishes a two-year pilot program to offer health care services during the weekend and after regular business hours during the week at existing Primary Care Access Networks (PCAN) in Orlando and Pasco counties. The effect of extending clinic hours of operation should provide uninsured individuals and families with greater access to health care services and delivery of care.

Present Situation

Primary Care Access Networks (PCAN) are currently established in Orlando and Pasco counties and provide access to health care services to persons who are not eligible for Medicaid coverage and who do not have other health care insurance. These networks represent a collaborative approach to health care delivery that includes county health departments, primary health care centers, community agencies, hospitals and state and local social services. The overall mission of PCANs is to improve the access, quality and coordination of health care services to the under insured and uninsured populations.

One of the primary missions of PCANs is to establish a "Medical Home" for individuals and families. Having a "Medical Home" means an individual or family has a doctor, or belongs to a health center. According to the Orange County PCAN informational website, "Medical Homes" help individuals and families avoid emergency room use by more regularly seeing their doctor when they are sick, even if they do not have health insurance. PCAN offers guidance regarding a health care center services, including immunizations and dental care for children, health care center locations, hours of operation and important emergency telephone numbers.[1]

C. SECTION DIRECTORY:

Section 1. Creates an unnumbered section of Florida Statutes; provides legislative intent regarding Primary Care Access Networks; creates a pilot program; provides reporting requirements.

Section 2. Provides an appropriation.

Section 3. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

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[1] www.PCANOrangeCounty.com

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

	FY 2007/08	FY 2008/09
Recurring		
1 FTE		
Salaries/Benefits	$55,838	$55,838
Expense	11,200	11,200
Human Resources Services	401	401
Provider Care Access Networks	2,229,441	2,232,441
Subtotal Recurring	2,297,000	2,300,000
Nonrecurring		
Expense	3,000	
Subtotal Nonrecurring	3,000	
Total Expenditures	2,300,000	2,300,000
General Revenue Fund		

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

According to the Agency for Health Care Administration, the bill would require additional staff to develop procedures for the pilot, to establish the data and reporting system, and to prepare the annual report.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

No statement provided.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 20, 2007, the Health Innovation Committee adopted one amendment.

The amendment:

- Revised the effective date to include specific fiscal appropriations.

The bill was reported favorably with one amendment.

A bill to be entitled

An act relating to the Primary Care Access Network; creating a pilot program to provide extended operating hours for the purpose of offering health care services at overcrowded clinics in the Primary Care Access Network in Orange and Pasco Counties; directing the Agency for Health Care Administration to establish the pilot program in Orange and Pasco Counties; requiring the agency to develop procedures for operating the pilot program; requiring the agency to submit a report with recommendations to the Governor and the Legislature by a specified date; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. (1) The Legislature finds that the Primary Care Access Network (PCAN) was founded to address the needs of the uninsured and those who are medically needy by providing a system of service delivery that builds upon the strengths of its current health provider partners. There has been an average 32-percent decrease in nonurgent emergency room services used by the uninsured in areas where one of the clinics is in operation. In accordance with these findings, the Agency for Health Care Administration shall establish a 2-year pilot program in Orange and Pasco Counties to offer health care services during the weekend and after regular business hours during the week.

(2) To the extent that funding is available, the pilot program shall provide funds to operate the PCAN clinics during

the extended hours that the clinics are open and to pay the employees of those clinics accordingly.

(3) The agency shall develop procedures for operating the pilot program.

(4) Each January 1, for the duration of the pilot program, the agency shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives an annual report on the success and outcomes achieved by the pilot program, which must include a recommendation as to whether the pilot program should be continued, terminated, or expanded.

Section 2. The sum of $2.3 million is appropriated from the General Revenue Fund to the Agency for Health Care Administration for the purpose of implementing this act during the 2007-2008 fiscal year.

Section 3. This act shall take effect July 1, 2007.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. __2___ (for drafter's use only)

Bill No. **HB 977**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	______

Council/Committee hearing bill: Healthcare Council

Representative(s) Galvano offered the following:

Amendment (with directory and title amendments)

Remove line(s) 39-42 and insert:

Section 2. The sum of $3.5 million is appropriated from the General Revenue Fund to the Agency for Health Care Administration for the purpose of implementing this act during the 2007-2008 fiscal year. Of the funds provided, the sum of $2.3 million shall be used for programs in Orange and Pasco counties, and $1.2 million shall be used for programs in Manatee, Sarasota and DeSoto counties.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. __3___ (for drafter's use only)

Bill No. **HB 977**

COUNCIL/COMMITTEE ACTION

ADOPTED __ (Y/N)

ADOPTED AS AMENDED __ (Y/N)

ADOPTED W/O OBJECTION __ (Y/N)

FAILED TO ADOPT __ (Y/N)

WITHDRAWN __ (Y/N)

OTHER ______

Council/Committee hearing bill: Healthcare Council

Representative(s) Galvano offered the following:

Amendment (with directory and title amendments)

Remove line(s) 25 and insert:

and Pasco Counties, and a 1 year pilot program in Manatee, Sarasota, and DeSoto counties to offer health care services during the

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Amendment No. __4__ (for drafter's use only)

Bill No. **HB 977**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

Council/Committee hearing bill: Healthcare Council

Representative(s) Galvano offered the following:

Amendment (with directory and title amendments)

Remove line(s) 43 and insert:

Section 3. This act shall take effect July 1, 2007, only if a specific appropriation to the Agency for Health Care Administration is made in the General Appropriations Act for fiscal year 2007-2008.

================ T I T L E A M E N D M E N T =============

Remove line(s) 12 and insert:

providing an appropriation; providing a contingent effective date.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. __1___ (for drafter's use only)

Bill No. **HB 977**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	______	

Council/Committee hearing bill: Healthcare Council

The Committee on Health Innovation offered the following:

Amendment (with title amendments)

Remove line(s) 43 and insert:

Section 3. This act shall take effect July 1, 2007, only if a specific appropriation to the Agency for Health Care Administration to fund the pilot program is made in the General Appropriations Act for fiscal year 2007-2008.

================ T I T L E A M E N D M E N T =============

Remove line(s) 12 and insert:

providing an appropriation; providing a contingent effective date.

This amendment was adopted in HI on 03/20/07 and is traveling with the bill and requires no further action.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1065 Stem Cell Research
SPONSOR(S): Flores and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2496

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Healthcare Council		Lowell	Gormley
2) Policy & Budget Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

The bill creates the Stem Cell Research Advisory Council ("stem cell council") within the Department of Health ("department"), composed of seven members. The duties of the stem cell council include developing a "donated funds program" to encourage development of private-sector funds for human adult stem cell research; identifying specific ways to improve and promote for-profit and not-for-profit human adult stem cell and related research; and developing a biomedical research grant program to provide grants to eligible state institutions for human adult stem cell research. The stem cell council must consult with the Biomedical Ethics Advisory Council in providing recommendations to the Secretary of Health regarding the award of research grants.

The bill additionally creates the Biomedical Ethics Advisory Council ("ethics council") within the department, composed of seven members. The ethics council is required to review all stem cell research funded through the Biomedical Research Trust Fund to ensure that research complies with ethical and safety guidelines set forth by the United States Department of Health and Human Services.

The bill restricts the use of funds to research using human adult and amniotic stem cells and prohibits the use of funds for embryonic stem cell research from stem cells obtained through the donor embryo's death or destruction. The bill also prohibits "human cloning," providing a second-degree felony for a violation.

The bill annually appropriates, beginning in Fiscal Year 2007-2008, $20 million in recurring general revenue funds, with a 15 percent allowance for administrative costs, over a 10-year period to the Biomedical Research Trust Fund to carry out the purposes of the act.

The effective date of the bill is July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government—The bill appropriates $20 million annually over a 10-year period to fund stem cell research.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Stem Cell Research
According to the National Institutes of Health, stem cells have two unique characteristics that distinguish them from other types of cells:[1] (1) stem cells are unspecialized, renewing over long periods of time through cell division and (2) under certain conditions, stem cells may be induced to become cells with special functions, known as differentiation, such as beating cells of the heart muscle or the insulin-producing cells of the pancreas.

Embryonic and adult stem cells are the two primary types of stem cells that are used for scientific research. Embryonic stem cells are generally generated from embryos that develop from eggs fertilized *in vitro*. The inner cell mass of the embryo is added to a "nutrient broth" within a laboratory culture dish, allowing the inner cell mass to proliferate; the embryo is then discarded. Embryonic stem cells that proliferate in cell culture for six months or more without differentiating are known as "pluripotent," which means the stem cells are potentially able to differentiate into many cell types. This desirable attribute is known as "plasticity."

Embryos for embryonic stem cell research may be obtained from other, more controversial sources, including aborted fetuses and embryos created through somatic cell nuclear transfer (SCNT), otherwise known as "therapeutic cloning." Therapeutic cloning involves removing the nucleus of an unfertilized egg cell, replacing it with the material from the nucleus of a "somatic cell" (such as a skin, heart, or nerve cell), and stimulating the cell to begin dividing. Once the cell begins dividing, stem cells can be extracted 5-6 days later and used for research.[2] The embryo is then discarded.

Embryonic stem cells may, in the future, have significant value in scientific research, including the generation of cells and tissues for cell-based therapies, i.e., replacing ailing or destroyed tissue. These therapies may include treatment of:
- Chronic heart disease through the implantation of heart muscle cells;
- Diabetes through the implantation of insulin-producing cells; and
- Parkinson's Disease through the implantation of dopamine-producing neurons.

Adult stem cells are undifferentiated cells found among differentiated cells in a tissue or organ. An adult stem cell may renew itself and differentiate to produce the major specialized cell types of the tissue or organ. There are a number of types of adult stem cells, including amniotic, bone marrow, liver, neuronal, and umbilical cord blood. Adult stem cells generally generate the cell types of the tissue in which they reside. However, recent research has identified pluripotent stem cells within amniotic fluid, bone marrow, and umbilical cord blood.[3]

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[1] Except where otherwise noted, this section is substantially derived from *Stem Cell Information, The official National Institutes of Health resource for stem cell research* (viewed April 5, 2007) http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf.
[2] Somatic Cell Nuclear Transfer (Therapeutic Cloning) (viewed April 6, 2007) http://www.aamc.org/advocacy/library/research/res0003.htm.
[3] *See, e.g.,* Christian Catalano, *Stem cells take growth of heart tissue a step closer* (viewed April 5, 2007) http://www.theage.com.au/news/world/stem-cells-take-growth-of-heart-tissue-a-step-closer/2007/04/02/1175366160708.html;

While treatments using embryonic stem cells have resulted in limited success in animals,[4] treatments on humans using adult stem cells have resulted in meaningful improvement for conditions such as Parkinson's disease,[5] multiple sclerosis,[6] and lupus,[7] among others.

Stem Cell Research at the Federal Level

On August 9, 2001, President George W. Bush announced his decision to narrow the federal funding of research using embryonic stem cell lines to specific lines. A "stem cell line" is a population of cells that reproduce themselves over a long period of time *in vitro*. Specifically, stem cell research is allowed on existing stem cell lines that were derived:

- With the informed consent of the donors;
- From excess embryos created solely for reproductive purposes; and
- Without any financial inducement to the donors.[8]

At the time of the President's decision, approximately 60 stem cell lines qualified under the criteria noted above. Recent studies have suggested that these lines have become contaminated with non-human molecules.[9]

In 2006, an attempt by Congress to authorize embryonic stem cell research outside existing lines was vetoed by the President.[10]

Stem Cell Research in Florida

In Florida, biomedical research dollars are awarded through at least nine different programs.[11] Of these programs, significant funding is providing for the James and Esther King Biomedical Research Program

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(discussing British scientists who used bone marrow stem cells to grow the same cells present in heart valves); Paolo De Coppi et al., *Isolation of amniotic stem cell lines with potential for therapy,* 25 Nature Biotechnology 100 (2007) (concluding that amniotic stem cells are pluripotent and hold potential for a variety of therapeutic applications); and Ryan Carlin et al., *Expression of early transcription factors Oct-4, Sox-2 and Nanog by porcine umbilical cord (PUC) matrix cells*, 4 Reproductive Biology and Endicronology 8 (2006) (concluding that stem cells obtained from umbilical cord blood contain the three transcription factors expressed at high levels in embryonic stem cells; thus, umbilical cord blood stem cells have properties of primitive pluripotent stem cells).

[4] *See, e.g.,* UCI researchers use human embryonic stem cells to create new nerve insulation tissue that can aid spinal cord repair (viewed April 6, 2007) http://today.uci.edu/news/release_detail.asp?key=1242 ("researchers have used human embryonic stem cells to create new insulating tissue for nerve fibers in a live animal model – a finding that has potentially important implications for treatment of spinal cord injury and multiple sclerosis"). *But see, e.g.,* Adult human neural stem cell therapy successful in treating spinal cord injury (viewed April 6, 2007) http://today.uci.edu/news/release_detail.asp?key=1383 (detailing research at UC Irvine that used adult neural stem cells to successfully regenerate damaged spinal cord tissue and improve mobility in mice).

[5] *See, e.g.,* http://commerce.senate.gov/hearings/witnesslist.cfm?id=1268 (viewed April 6, 2007) (containing a webcast of a 2004 meeting of the U.S. Senate Committee on Commerce, Science, & Transportation regarding adult stem cell research, including testimony of Dr. Dennis Turner, whose Parkinson's Disease was successfully treated using adult neural stem cells).

[6] *See, e.g.,* Saccardi R et al., *Autologous HSCT for severe progressive multiple sclerosis in a multicenter trial: impact on disease activity and quality of life*, 105 Blood 2601 (2005) (concluding that bone marrow stem cell treatment is able to induce a prolonged clinical stabilization in severe progressive MS patients, resulting in both sustained treatment-free periods and quality of life improvement).

[7] *See, e.g.,* Burt RK et al., *Nonmyeloablative hematopoietic stem cell transplantation for systemic lupus erythematosus*, 295 Journal of the American Medical Association 527 (2006) (concluding that an infusion of bone marrow stem cells resulted in amelioration of disease activity, improvement in serologic markers, and either stabilization or reversal of organ dysfunction).

[8] Fact Sheet: Embryonic Stem Cell Research (viewed April 5, 2007) http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html.

[9] *See, e.g., Current human embryonic stem cell lines contaminated UCSD/Salk team finds* (viewed April 5, 2007) http://www.eurekalert.org/pub_releases/2005-01/uoc--che011805.php.

[10] Message to the House of Representatives (viewed April 5, 2007) http://www.whitehouse.gov/news/releases/2006/07/20060719-5.html.

[11] ss. 215.5601 (Lawton Chiles Endowment Fund); 215.5602 (James and Esther King Biomedical Research Program); 381.853 (Florida Center for Brain Tumor Research); 381.855 (Florida Center for Universal Research to Eradicate Disease); 381.92 (Florida Cancer Council); 381.922 (William G. "Bill" Bankhead, Jr., and David Coley Cancer research Program); 430.501 (Alzheimer's Disease Advisory Council); 1004.445 (Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute); and 1004.435, F.S. (Cancer Control and Research Advisory Council).

($9.5 million); the William G. "Bill" Bankhead, Jr., and David Coley Cancer research Program ($9 million); and the Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute ($15 million). In addition to these biomedical research grant programs, another 16 advisory groups and councils are given statutory responsibilities for programs involving medical research.[12]

In particular, the Florida Center for Universal Research to Eradicate Disease is tasked with coordinating, improving, expanding, and monitoring all biomedical research programs within the state, facilitating funding opportunities, and fostering improved technology transfer of research findings into clinical trials and widespread public use.[13]

Of the biomedical research grant programs in Florida, none, by law, specifically designate grants for stem cell research, whether embryonic or adult.

Stem Cell Research in Other States
A number of states have recently funded stem cell research, varying by the amount funded and the restrictions placed on the use of the funds.[14] These states include the following:

California. On November 2, 2004, the voters of California approved Proposition 71,[15] which authorized an average of $295 million per year in bonds over a 10-year period to fund stem cell research. Priority is given to stem cell research that "has the greatest potential for therapies and cures, specifically focused on pluripotent stem cell and progenitor cell research" that are unlikely to receive sufficient federal funding.[16] The bond proceeds may not be used for funding for human reproductive cloning.

Connecticut. In June 2005, Governor Jodi Rell signed Senate Bill 934, creating the Stem Cell Research Fund to provide grants for embryonic and human adult stem cell research.[17] The bill appropriated $100 million through June 30, 2015.[18] According to the Connecticut Department of Public Health, on November 21, 2006, $19.78 million was awarded for 21 stem cell research proposals.[19] In addition, the bill prohibits (1) engaging or assisting, directly or indirectly in the cloning of a human being; (2) implanting human embryos created by nuclear transfer into a uterus or a device similar to a uterus; or (3) facilitating human reproduction through clinical or other use of human embryos created by nuclear transfer. "Cloning of a human being" is defined to mean "inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences."[20]

Illinois. In July 2005, Governor Rod Blagojevich issued Executive Order 2005-6, directing the Illinois Department of Public Health to develop an Illinois Regenerative Medicine Institute program within the department to award grants to medical research facilities to develop treatments and cures from stem

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[12] ss. 385.210 (Arthritis Prevention Education); 385.203 (Diabetes Advisory Council); 385.202 (Statewide Cancer Registry Program); 385.103 (Chronic Disease Community Intervention Program); 381.981 (Health Awareness Campaigns); 381.93 (Mary Brogan Breast and Cervical Cancer Early Detection Program); 381.912 (Cervical Cancer Elimination Task Force); 381.911 (Prostate Cancer Awareness Program); 381.91 (Jessie Trice Cancer Prevention Program); 381.87 (Osteoporosis Prevention and Education Program); 381.04015 (Women's Health Strategy); 381.0032 (Epidemiological Research); 381.0271 (Florida Patient Safety Corporation); 381.0046 (Statewide HIV and AIDS Prevention Program); 430.502 (Alzheimer's Disease Memory Disorder Clinics); and 381.00325, F.S. (Hepatitis Awareness Program).

[13] s. 381.855, F.S.

[14] *See also* http://www.ncsl.org/programs/health/genetics/embfet.htm (viewed April 5, 2007) (containing an in-depth discussion of state embryonic and fetal research laws).

[15] http://vote2004.ss.ca.gov/voterguide/english.pdf (viewed April 4, 2007) (presenting the text of the proposition as well as the arguments in favor of, and in opposition to, the proposition).

[16] *Id.* at 147.

[17] *See* http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=934&which_year=2005&SUBMIT1.x=13&SUBMIT1.y=12&SUBMIT1=Normal (viewed April 5, 2007).

[18] *Id.*

[19] http://www.dph.state.ct.us/StemCell/index.htm (viewed April 5, 2007).

[20] *Id.*

cell research.[21] Stem cell research includes "adult stem cells, cord blood stem cells, pluripotent stem cells, totipotent stem cells, progenitor cells, the product of somatic cell nuclear transfer or any combination of those cells."[22] Among other restrictions, the executive order prohibited the use of grant funds for research involving reproductive cloning of a human being, fetuses from induced abortions, and the creation of embryos through the combination of gametes solely for the purpose of research.[23] "Cloning of a human being" is defined as "asexual human reproduction by implanting or attempting to implant the product of nuclear transplantation into a woman's uterus to initiate a human pregnancy."[24] In 2006, $10 million in grants were awarded to ten organizations, comprising hospitals and universities.[25]

Maryland. In April 2006, Governor Robert Ehrlich signed Senate Bill 144, which created the Maryland Stem Cell Research Fund to promote state-funded stem cell research and cures through grants and loans.[26] "Stem cell" is defined as a human cell that has the ability to (1) divide indefinitely; (2) give rise to many other types of specialized cells; and (3) give rise to new stem cells with identical potential.[27] Up to $15 million was available for the first round of grants and loans. The bill also revised the then-existing human cloning ban, specifically prohibiting a person conducting state-funded research from engaging in any research that intentionally and directly leads to human cloning.[28] "Human cloning" is defined as the "replication of a human being through the production of a precise genetic copy of nuclear human DNA or any other human molecule, cell, or tissue, in order to create a new human being or to allow development beyond an embryo."[29]

New Jersey. In December 2005, New Jersey awarded $5 million in grants to 17 organizations to conduct stem cell research, including embryonic research prohibited from receiving federal funding.[30] In 2007, New Jersey will award an additional $10 million in grants.[31] In addition, in December 2006, Governor Jon Corzine signed Senate Bill 1471, which authorized the New Jersey Economic Development Authority to issue $270 million in bonds for facilities for stem cell research, biomedical research, blood collection, and cancer research. [32]

Human Cloning

As previously described, somatic cell nuclear transfer (SCNT) may be used to produce embryos to obtain stem cells for scientific research, otherwise known as "therapeutic" cloning. However, SCNT may also be used for reproductive cloning. The most well-known example is that of "Dolly the sheep." In that example, the embryo that was created from the SCNT process, like therapeutic cloning, carried all of the chromosomes of the donor cell and none of the chromosomes of the host egg cell. The embryo was implanted in a surrogate "mother" and Dolly was subsequently born as an exact genetic copy of her donor mother. However, in early 2003, Dolly died from lung disease most common in older sheep.[33] The necropsy also revealed that Dolly had developed arthritis prematurely.[34]

As of mid-2006, approximately 15 states have banned reproductive cloning, and some additionally ban therapeutic cloning.[35] The federal government does not currently prohibit the practice of human

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[21] http://www.illinois.gov/Gov/pdfdocs/execorder2005-6.pdf (viewed April 4, 2007).
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=1&RecNum=4799 (viewed April 4, 2007).
[26] http://mlis.state.md.us/2006rs/billfile/sb0144.htm (viewed April 5, 2007).
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] Stem Cell Research in New Jersey (viewed April 4, 2007) http://www.state.nj.us/scitech/stemcell/.
[31] *Id.*
[32] http://www.njleg.state.nj.us/2006/Bills/AL06/102_.PDF (viewed April 4, 2007).
[33] Dolly the sheep dies young (viewed April 6, 2007) http://www.newscientist.com/article.ns?id=dn3393.
[34] *Id.*
[35] State Human Cloning Laws (viewed April 6, 2007) http://www.ncsl.org/programs/health/genetics/rt-shcl.htm.

cloning. However, the federal Food and Drug Administration (FDA) has explicitly stated that clinical research using cloning technology to create a human is subject to FDA regulation.[36]

Ethical Considerations

Embryonic stem cell research raises a number of ethical issues. On the one hand, the destruction of the embryo is understood by some as the equivalent of the destruction of a human life. On the other hand, some may argue that treatments employing embryonic stem cells may relieve countless individuals from suffering the effects of a number of medical conditions or genetic disorders.

Likewise, reproductive human cloning also raises a number of ethical concerns. These concerns include:

- Early clinical failures may lead to an increase in abortions, birth defects, or early deaths.
- A cloned individual may be prevented from having a unique identity and may experience discrimination.
- Society may, over time, lose respect for the uniqueness of human life through the engineering of individuals without undesirable traits or genetic disorders.
- Cloning may eventually lead to human/animal hybrids.

Effect of Proposed Changes

The bill creates the Stem Cell Research Advisory Council ("stem cell council") within the department. The council is composed of the following seven members:

- Secretary of Health, or a designee.
- Two members appointed by the Governor, one of whom must be an academic researcher in the field of stem cell research and one of whom must have a background in bioethics.
- One member appointed by the President of the Senate, who must have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.
- One member appointed by the Speaker of the House of Representatives, who must have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.
- One member appointed by the President of the Senate, who must have a background and experience in either public-sector or private-sector stem cell research and development.
- One member appointed by the Speaker of the House of Representatives, who must be an executive of a biotech company.

Stem cell council members serve two-year terms, with the initial terms staggered. The Secretary of Health acts as chair of the council.

The duties of the stem cell council include:

- Developing a "donated funds program" to encourage development of private-sector funds for human adult stem cell research.
- Identifying specific ways to improve and promote for-profit and not-for-profit human adult stem cell and related research.
- Developing a biomedical research grant program to provide grants to eligible state institutions for human adult stem cell research.

The stem cell council is required to submit an annual progress report on the status of biomedical research to the Florida Center for Universal Research to Eradicate Disease. The report must include, among other items, the amount of grants awarded; the names of the recipients of the grants; the status and progress of stem cell research in the state; and the total amount of biomedical research funding currently flowing into the state. The stem cell council must consult with the Biomedical Ethics Advisory

[36] 10/26/98 Dear Colleague Letter about Human Cloning (viewed April 6, 2007) http://www.fda.gov/oc/ohrt/irbs/irbletr.html.

Council in providing recommendations to the Secretary of Health regarding the award of research grants.

The bill additionally creates the Biomedical Ethics Advisory Council ("ethics council") within the department. The ethics council is composed of the following seven members:

- The Secretary of Health.
- Two members appointed by the Governor.
- One member appointed by the President of the Senate.
- One member appointed by the Speaker of the House of Representatives.
- One member appointed by the Minority Leader of the Senate.
- One member appointed by the Minority Leader of the House of Representatives.

According to the bill, each member of the ethics council must "demonstrate knowledge and understanding of the ethical, medical, and scientific implications of stem cell research" and must demonstrate knowledge in related fields. Members serve a term of four years, except that the initial terms are staggered.

The ethics council is required to review all stem cell research funded through the Biomedical Research Trust Fund to ensure that research complies with ethical and safety guidelines set forth by the United States Department of Health and Human Services.

The bill requires the Secretary of Health to provide grants from the Biomedical Research Trust Fund based on recommendations from the stem cell council.

The bill restricts the use of funds for research to human adult and amniotic stem cells and prohibits the use of funds for embryonic stem cell research from stem cells obtained through the donor embryo's death or destruction.

Last, the bill prohibits "human cloning," providing a second-degree felony for a violation. "Human cloning" is defined as "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte the nuclear material of which has been removed or inactivated so as to produce a living organism at any stage of development that is genetically virtually identical to an existing or previously existing human organism."

C. SECTION DIRECTORY:

Section 1. Creates s. 381.99, F.S., relating to the Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act.

Section 2. Amends s. 20.435, F.S., relating to the Biomedical Research Trust Fund.

Section 3. Amends s. 381.86, F.S., relating to the Institutional Review Board within the Department of Health.

Section 4. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

The bill annually appropriates, beginning in Fiscal Year 2007-2008, $20 million in recurring general revenue funds, with a 15 percent allowance for administrative costs, over a 10-year period to the Biomedical Research Trust Fund to carry out the purposes of the act.

Stem Cell Research Grant Program
(Based on $20 million annual appropriation)

Estimated Expenditures	1st Year	2nd Year
Salaries[a]		
1 Program Administrator @ $55,000	$75,075	$77,327
2 Program Assistants @ $42,000	$114,660	$118,100
1 Administrative Assistant @ $35,000	$47,775	$49,208
0.25 Senior Attorney @ $58,000	$19,793	$20,386
0.25 Legal Secretary@ $35,000	$11,944	$12,302
Subtotal	**$269,246**	**$277,324**
Expense		
1 Professional, w/ maximum travel	$27,728	$20,402
2 Professionals, w/ medium travel	$47,644	$32,992
1 Support Staff, with no travel	$12,504	$6,318
0.25 Professional, w/ limited travel	$14,216	$6,890
0.25 Support Staff, w/ no travel	$12,504	$6,318
3 Stem Cell Research Advisory Council meetings	$21,036	$21,562
2 Stem Cell Research Advisory Council teleconferences	$1,500	$1,538
8 Biomedical Ethics Advisory Council meetings	$56,096	$57,498
Consultation with National Stem Cell Ethics Experts[b]	$50,000	$50,000
Professional development	$15,000	$15,375
Program marketing, information dissemination	$5,000	$5,125
Annual Report	$25,000	$25,625
Honorarium, peer review[c]	$123,000	$71,000
Honorarium, quality assurance site visits[d]	$30,000	$60,000
Technical services contract[e, f]	$1,137,423	$659,725
Subtotal	**$1,578,651**	**$1,040368**
Total Estimated Expenditures	**$1,847,897**	**$1,317,691**

[a] Salaries are computed w/ 30% fringe, 5% administrative fee, and 3% base salary increase for second year.
[b] To develop guidelines and written policies for ethical review of human stem cell research
[c] Based on receiving 150 applications in year one (conducting two funding cycles) and 80 applications in year two.
[d] Honorarium for quality assurance site visits increases with the number of active grants.
[e] Estimates based on James & Esther King and Bankhead-Coley program costs. First year is higher for one time only information systems development cost and conducting two funding cycles in one year.
[f] Estimates based on using current contractor. Costs may increase with a different contractor.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private sector researchers involved in stem cell research will directly benefit from the availability of grant dollars through this act.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take any action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill does not appear to provide sufficient authority to the department, particularly with respect to disbursement of funds for research grants.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Lines 72-87: The council member terms are staggered, but the bill does not specify which members will serve the shorter terms.

Line 109: Eligible institutions are not defined. For the King and Bankhead-Coley Programs, eligible institutions include all universities and research institutions in the state.

Lines 112-113: The department is concerned whether the review of "stem cell research conducted by eligible institutions that receive such grants-in-aid" as recommended by the Stem Cell Research Advisory Council to the Secretary of Health means that the research funded by the program is monitored for progress or if *all* the stem cell research at the institution, whether funded by the program or not, is subject to monitoring.

Lines 114-119: The department recommends a report at the beginning of the calendar year so that the data available to policy makers will not be older than six months by the time the committee meetings held prior to the regular legislative session start.

Lines 146-184: The Biomedical Ethics Advisory Council is created to review research funded through the proposed new program and through the Biomedical Research Trust Fund. The department is concerned that the bill is unclear whether this council is both an institutional review board and an ethics committee. If this council is an institutional review board, the secretary is prohibited from serving as a member.
The National Academy of Sciences recommends that institutions engaged in human embryonic stem cell research establish ethics oversight committees, noting that these committees are not replacements for research compliance bodies such as institutional review boards. Note that the recommended oversight is

for embryonic stem cell research in particular not stem cell research in general. Additionally, the National Academy of Sciences recommends that these oversight committees include legal and ethical experts as well as representatives of the public. The department recommends that the council includes a legal member, an ethicist, and a member of the general population.

Lines 165-168: The council member terms are staggered, but the bill does not specify which members will serve the shorter terms.

Lines 281-291: According to the department, based on new federal guidance, the department's IRB no longer reviews human subject research funded through grants-in-aid programs. This policy extends to the proposed stem cell grant program unless otherwise specified in statute. The department recommends revising s. 381.86, *F.S.* to reflect the change in federal guidance.

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

A bill to be entitled

An act relating to stem cell research; creating s. 381.99, F.S.; providing a short title; providing definitions; creating the Stem Cell Research Advisory Council and Biomedical Ethics Advisory Council within the Department of Health; providing for membership and terms; providing duties and responsibilities; requiring the Secretary of Health to make grants-in-aid from the Biomedical Research Trust Fund for stem cell research; providing requirements relating to applications for and awards of such grants-in-aid; providing specifications for moneys to be made available from the trust fund for stem cell research grants-in-aid; providing restrictions and requirements for uses of funds from such grants-in-aid; providing prohibitions relating to human cloning; providing for penalties; providing an appropriation; amending s. 20.435, F.S.; revising references; amending s. 381.86, F.S.; providing an exception to the Institutional Review Board for the Stem Cell Research Advisory Council and Biomedical Ethics Advisory Council; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.99, Florida Statutes, is created to read:

381.99 Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act.--

(1) SHORT TITLE.--This section may be cited as the

"Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Adult stem cell" means a cell found within differentiated tissue or an organ that can renew itself and give rise to the major cell types of the tissue or organ. This includes cells from the fetal to adult stages of development.

(b) "Amniotic stem cell" means a cell extracted from human amniotic fluid or a placenta.

(c) "Embryonic stem cell" means a cell obtained from the undifferentiated inner mass of an early stage embryo.

(d) "Human cloning" means human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte the nuclear material of which has been removed or inactivated so as to produce a living organism at any stage of development that is genetically virtually identical to an existing or previously existing human organism.

(e) "Stem cell" means a cell that retains the potential to generate some or all other cell types.

(3) STEM CELL RESEARCH ADVISORY COUNCIL.--There is created the Stem Cell Research Advisory Council within the Department of Health.

(a)1. The advisory council shall consist of the Secretary of Health or his or her designee, who shall act as chair, and six additional members, who shall be appointed as follows:

a. Two persons appointed by the Governor, one of whom shall be an academic researcher in the field of stem cell research and one of whom shall have a background in bioethics.

b. One person appointed by the President of the Senate, who shall have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.

c. One person appointed by the Speaker of the House of Representatives, who shall have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.

d. One person appointed by the President of the Senate, who shall have a background and experience in either public-sector or private-sector stem cell research and development.

e. One person appointed by the Speaker of the House of Representatives, who shall be an executive of a biotech company, or his or her designee.

2. Each member shall serve a term of 2 years commencing on October 1, 2007. No member shall serve for more than two consecutive 2-year terms; however, for the purpose of providing staggered terms, of the initial appointments, three members shall be appointed to a 1-year term and three members shall be appointed to a 2-year term. Any vacancy on the advisory council shall be filled in the same manner as the original appointment. All initial appointments shall be made by October 1, 2007. The first meeting shall take place no later than November 1, 2007. All meetings are subject to the call of the chair. Members shall meet at least twice a year or as often as necessary to discharge their duties but shall have no more than four meetings during any 12-month period. Members shall serve without compensation

but may be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The advisory council shall:

1. Develop a donated funds program for recommendation to the Secretary of Health to encourage the development of funds other than state appropriations for human adult stem cell research in the state.

2. Examine and identify specific ways to improve and promote for-profit and not-for-profit human adult stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing human adult stem cell-related businesses, recruiting new human adult stem cell-related businesses to the state, and recruiting scientists and researchers in such fields to the state and state universities.

3. Develop a biomedical research grant program for recommendation to the Secretary of Health that shall provide grants-in-aid to eligible state institutions for the advancement of human adult stem cell research.

4. Develop, no later than December 1, 2007, an application for grants-in-aid under this section for recommendation to the Secretary of Health for the purpose of conducting human adult stem cell research.

5. Review applications from eligible institutions for grants-in-aid on and after December 1, 2007, and provide to the Secretary of Health recommendations for grant awards.

6. Review the stem cell research conducted by eligible

institutions that receive such grants-in-aid.

(c) The advisory council shall submit an annual progress report on the status of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30. The report must include:

1. The amount of grants-in-aid awarded to eligible institutions from the Biomedical Research Trust Fund.

2. The names of the recipients of such grants-in-aid.

3. The current status and progress of stem cell research in the state.

4. A list of research projects supported by grants-in-aid awarded under the program.

5. A list of publications in peer-reviewed journals involving research supported by grants-in-aid awarded under the program.

6. The total amount of biomedical research funding currently flowing into the state.

7. New grants for biomedical research that were funded based on research supported by grants-in-aid awarded under the program.

8. All other materials the advisory council deems advisable to include.

(d) Advisory council members shall disclose any conflict of interest or potential conflict of interest to the Secretary of Health.

(e) The Department of Health shall provide administrative

<u>staff to assist the advisory council in developing the application for the grants-in-aid, reviewing the applications, preparing the written consent form described in paragraph (6)(b), and performing other administrative functions as the advisory council requires.</u>

<u>(4) BIOMEDICAL ETHICS ADVISORY COUNCIL.--There is created within the Department of Health the Biomedical Ethics Advisory Council.</u>

<u>(a)1. The advisory council shall consist of the Secretary of Health or his or her designee, who shall act as chair, and six additional members, who shall be appointed as follows:</u>

<u>a. Two persons appointed by the Governor.</u>

<u>b. One person appointed by the President of the Senate.</u>

<u>c. One person appointed by the Speaker of the House of Representatives.</u>

<u>d. One person appointed by the Minority Leader of the Senate.</u>

<u>e. One person appointed by the Minority Leader of the House of Representatives.</u>

<u>2. All members must demonstrate knowledge and understanding of the ethical, medical, and scientific implications of stem cell research and should also demonstrate knowledge of related fields, including, but not limited to, genetics, cellular biology, and embryology. Each member shall serve a term of 4 years commencing on October 1, 2007; however, for the purpose of providing staggered terms, of the initial appointments, three members shall be appointed to a 2-year term and three members shall be appointed to a 4-year term. No member</u>

shall serve for more than two consecutive terms. Any vacancy on the advisory council shall be filled in the same manner as the original appointment. All initial appointments shall be made by October 1, 2007. The first meeting shall take place no later than November 1, 2007. All meetings are subject to the call of the chair. Members shall meet at least twice a year or as often as necessary to discharge their duties but shall have no more than one meeting per month during any 12-month period. Members shall serve without compensation but may be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The advisory council shall review all stem cell research that is funded or supported in any manner through the Biomedical Research Trust Fund to ensure the adherence to ethical and safety guidelines and procedures as set forth by federal ethical standards established by the United States Department of Health and Human Services.

(5) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--

(a) The Secretary of Health shall make grants-in-aid from the Biomedical Research Trust Fund in accordance with the provisions of this section.

(b) The Department of Health shall require any applicant for a grant-in-aid under this section, for the purpose of conducting stem cell research, to submit a complete description of the applicant's organization, the applicant's plans for stem cell research, the applicant's proposed funding for such research from sources other than the state, and the applicant's proposed arrangements concerning financial benefits to the state as a result of any patent, royalty payment, or similar right resulting from any stem cell research made possible by the awarding of the grant-in-aid. The Stem Cell Research Advisory Council shall provide recommendations to the Secretary of Health with respect to awarding such grants-in-aid after considering the recommendations of the Biomedical Ethics Advisory Council.

(c) Beginning with the 2007-2008 fiscal year, and for 10 consecutive years thereafter, not less than $20 million shall be made available annually from the Biomedical Research Trust Fund within the Department of Health for grants-in-aid to eligible institutions for the purpose of conducting adult stem cell research pursuant to this section. Up to 15 percent of the funds may be used for administrative costs. Any unexpended funds not used for grants-in-aid during the current fiscal year shall be carried forward for the following fiscal year to fund the grants-in-aid.

(6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

(a) Funds provided under this section may only be used for research involving:

1. Human adult stem cells, including, but not limited to, adult stem cells derived from umbilical cord blood and bone marrow. Funding for research may be given for human adult stem cells derived from postmortem tissues, other than from medically induced abortions. Funds may be used for studies of human adult stem cells obtained from either normal or transformed tissues.

2. Amniotic stem cells extracted from human amniotic fluid or placentas that are otherwise discarded after birth.

(b) Amniotic and adult stem cell material may only be donated for research purposes with the informed consent of the donor.

(c) No funds shall be used for research with human embryonic stem cells that are derived by a process entailing the donor embryo's death or destruction.

(7) HUMAN CLONING; PROHIBITION; PENALTIES.--

(a) It is unlawful for any person to knowingly:

1. Perform or attempt to perform human cloning;

2. Participate or assist in an attempt to perform human cloning; or

3. Ship or receive for any purpose an embryo produced by human reproductive cloning or any product derived from such embryo.

(b) A person who violates paragraph (a) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(8) CONTINUING APPROPRIATION.--Beginning in fiscal year 2007-2008, the sum of $20 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for the purpose of carrying out the provisions of this section. The amount of funds appropriated shall not exceed $200 million for the 10-year period beginning in fiscal year 2007-2008 and ending in fiscal year 2016-2017.

Section 2. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

(1) The following trust funds are hereby created, to be administered by the Department of Health:

(h) Biomedical Research Trust Fund.

1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and 381.99 and any other funds appropriated by the Legislature. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program, ~~and~~ the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, and the Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act as specified in ss. 215.5602, 288.955, ~~and~~ 381.922, and 381.99. The trust fund is exempt from the service charges imposed by s. 215.20.

2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.

3. Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant to contract or committed to be expended may be carried forward for up to 3 years following the effective date of the original appropriation.

4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008.

Section 3. Subsection (1) of section 381.86, Florida Statutes, is amended to read:

381.86 Institutional Review Board.--

(1) The Institutional Review Board is created within the Department of Health in order to satisfy federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an institutional review board review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the department, except that a separate Stem Cell Research Advisory Council and Biomedical Ethics Advisory Council shall be appointed under s. 381.99.

Section 4. This act shall take effect July 1, 2007.

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

Council/Committee hearing bill: Healthcare Council

Representative(s) Flores offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 381.99, Florida Statutes, is created to read:

381.99 Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Adult stem cell" means a cell found within differentiated tissue or an organ that can renew itself and give rise to the major cell types of the tissue or organ. This includes cells from the fetal to adult stages of development, including bone marrow.

(b) "Amniotic stem cell" means a stem cell extracted from human amniotic fluid.

(c) "Cord blood stem cell" means a stem cell extracted from the umbilical cord.

(d) "Placental stem cell" means a stem cell extracted from the placenta.

(e) "Embryonic stem cell" means a stem cell obtained from the undifferentiated inner mass of an early stage embryo.

(f) "Stem cell" means a cell that can renew itself and retains the potential to generate some or all other cell types.

(3) STEM CELL RESEARCH AND ETHICS ADVISORY COUNCIL.—There is created the Stem Cell Research and Ethics Advisory Council within the Department of Health.

(a)1. The advisory council shall consist of the Secretary of Health or his or her designee, who shall act as chair, and six additional members, who shall be appointed as follows:

a. Two persons appointed by the Governor, one of whom shall be an academic researcher in the field of stem cell research and one of whom shall have a background in bioethics.

b. One person appointed by the President of the Senate, who shall have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.

c. One person appointed by the Speaker of the House of Representatives, who shall have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.

d. One person appointed by the President of the Senate, who shall have a background and experience in either public-sector or private-sector stem cell research and development.

e. One person appointed by the Speaker of the House of Representatives, who shall be an executive of a biotech company, or his or her designee.

2. All members must demonstrate knowledge and understanding of the ethical, medical, and scientific

implications of stem cell research. Each member shall serve a term of 2 years commencing on July 15, 2007. No member shall serve for more than two consecutive 2-year terms; however, for the purpose of providing staggered terms, of the initial appointments, three members shall be appointed to a 1-year term and three members shall be appointed to a 2-year term. Any vacancy on the advisory council shall be filled in the same manner as the original appointment. All initial appointments shall be made by July 15, 2007. The first meeting shall take place no later than August 15, 2007. All meetings are subject to the call of the chair. Members shall meet at least twice a year or as often as necessary to discharge their duties but shall have no more than four meetings during any 12-month period. Members shall serve without compensation but may be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The advisory council shall:

1. Develop a donated funds program for recommendation to the Secretary of Health to encourage the development of funds other than state appropriations for human adult, amniotic, cord blood and placental stem cell research in the state.

2. Examine and identify specific ways to improve and promote for-profit and not-for-profit human adult, amniotic, cord blood and placental stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing human adult, amniotic, cord blood and placental stem cell-related businesses, recruiting new human adult, amniotic, cord blood and placental stem cell-related businesses to the state, and recruiting scientists and researchers in such fields to the state and state universities.

<u>3. Develop a biomedical research grant program for recommendation to the Secretary of Health that shall provide grants-in-aid to eligible state institutions for the advancement of human adult, amniotic, cord blood and placental stem cell research.</u>

<u>4. Develop, no later than September 15, 2007, an application for grants-in-aid under this section for recommendation to the Secretary of Health for the purpose of conducting human adult, amniotic, cord blood and placental stem cell research.</u>

<u>5. Review applications from eligible institutions for grants-in-aid on and after September 15, 2007, and provide to the Secretary of Health recommendations for grant awards.</u>

<u>6. Review the stem cell research conducted by eligible institutions that receive such grants-in-aid.</u>

<u>7. The advisory council shall review all stem cell research that is funded or supported in any manner through the Biomedical Research Trust Fund to ensure the adherence to ethical and safety guidelines and procedures as set forth by federal ethical standards established by the United States Department of Health and Human Services.</u>

<u>(c) The advisory council shall submit an annual progress report on the status of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30. The report must include:</u>

<u>1. The amount of grants-in-aid awarded to eligible institutions from the Biomedical Research Trust Fund.</u>

<u>2. The names of the recipients of such grants-in-aid.</u>

3. The current status and progress of stem cell research in the state.

4. A list of research projects supported by grants-in-aid awarded under the program.

5. A list of publications in peer-reviewed journals involving research supported by grants-in-aid awarded under the program.

6. The total amount of biomedical research funding currently flowing into the state.

7. New grants for biomedical research that were funded based on research supported by grants-in-aid awarded under the program.

8. All other materials the advisory council deems advisable to include.

(d) Advisory council members shall disclose any conflict of interest or potential conflict of interest to the Secretary of Health.

(e) The Department of Health shall provide administrative staff to assist the advisory council in developing the application for the grants-in-aid, reviewing the applications, preparing the written consent form described in paragraph (5)(b), and performing other administrative functions as the advisory council requires.

(4) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--

(a) The Secretary of Health shall make grants-in-aid from the Biomedical Research Trust Fund in accordance with the provisions of this section.

(b) The Department of Health shall require any applicant for a grant-in-aid under this section, for the purpose of conducting stem cell research, to submit a complete description of the applicant's organization, the applicant's plans for stem cell research, the applicant's proposed funding for such research from sources other than the state, and the applicant's proposed arrangements concerning financial benefits to the state as a result of any patent, royalty payment, or similar right resulting from any stem cell research made possible by the awarding of the grant-in-aid. The Stem Cell Research and Ethics Advisory Council shall provide recommendations to the Secretary of Health with respect to the awarding such grants-in-aid.

(c) Beginning with the 2007-2008 fiscal year, and for 10 consecutive years thereafter, not less than $20 million shall be made available annually from the Biomedical Research Trust Fund within the Department of Health for grants-in-aid to eligible institutions for the purpose of conducting adult, amniotic, cord blood, and placental stem cell research pursuant to this section. Any unexpended funds not used for grants-in-aid during the current fiscal year shall be carried forward for the following fiscal year to fund the grants-in-aid.

(5) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

(a) Funds provided under this section may only be used for research involving:

1. Human adult stem cells. Funding for research may be given for human adult stem cells derived from postmortem tissues, other than from medically induced abortions. Funds may be used for studies of human adult stem cells obtained from either normal or transformed tissues.

2. Amniotic stem cells extracted from human amniotic fluid that are otherwise discarded after birth.

3. Cord blood stem cells extracted from a human umbilical cord that are otherwise discarded after birth.

4. Placental stem cells extracted from the placenta that are otherwise discarded after birth.

(b) Adult, amniotic, cord blood and placental stem cell material may only be donated for research purposes with the informed consent of the donor.

(c) No funds shall be used for research with human embryonic stem cells that are derived by a process entailing the donor embryo's death or destruction.

(d) Funds provided under this section may only be used for research that is conducted in facilities located in Florida.

(6) CONTINUING APPROPRIATION.--Beginning in fiscal year 2007-2008, the sum of $20 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for the purpose of carrying out the provisions of this section. The amount of funds appropriated shall not exceed $200 million for the 10-year period beginning in fiscal year 2007-2008 and ending in fiscal year 2016-2017.

Section 2. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

(1) The following trust funds are hereby created, to be administered by the Department of Health:

(h) Biomedical Research Trust Fund.

1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and 381.99 and any other funds appropriated by the Legislature. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program, ~~and~~ the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, and the Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act as specified in ss. 215.5602, 288.955, ~~and~~ 381.922, and

381.99. The trust fund is exempt from the service charges imposed by s. 215.20.

2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.

3. Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant to contract or committed to be expended may be carried forward for up to 3 years following the effective date of the original appropriation.

4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008.

Section 3. Subsection (1) of section 381.86, Florida Statutes, is amended to read:

381.86 Institutional Review Board.—

(1) The Institutional Review Board is created within the Department of Health in order to satisfy federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an institutional review board review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the department, except that a separate Stem Cell Research and Ethics Advisory Council shall be appointed under s. 381.99.

Section 4. (1) The Department of Health shall prepare an educational publication that includes objective information regarding:

(a) The medical processes involved in the collection of umbilical cord blood;

(b) The medical risks to the mother and her newborn child of umbilical cord blood collection;

(c) 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:

1. Discarding the stem cells;

2. Donating the stem cells to a public umbilical cord blood bank;

3. Storing the stem cells in a family or private umbilical cord blood bank for use by family members; or

4. Storing the stem cells for family use through a family or sibling donor banking program that provides free collection, processing, and storage where there is a medical need;

(d) The current and potential future medical uses, risks, and benefits of umbilical cord blood collection to a mother, her newborn child, and her biological family;

(e) The current and potential future medical uses, risks, and benefits of umbilical cord blood collection to persons who are not biologically related to a mother or her newborn child;

(f) Any costs that may be incurred by a pregnant woman who chooses to make an umbilical cord blood donation;

(g) Options for ownership and future use of the donated material; and

(h) The average cost of public and private umbilical cord blood banking.

(2) The department shall update the publication as

necessary.

(3) The department shall distribute the pamphlet free of charge to physicians and health care institutions on request and shall make the pamphlet available on its web site in printable format.

(4) The department shall encourage health and maternal care professionals providing health care services to a pregnant woman, when those health care services are directly related to her pregnancy, to provide the pregnant woman with the publication by the end of her second trimester.

Section 5. This act shall take effect July 1, 2007.

================= T I T L E A M E N D M E N T =================

Remove the entire title and insert:

A bill to be entitled

An act relating to stem cell research; creating s. 381.99, F.S.; providing a short title; providing definitions; creating the Stem Cell Research and Ethics Advisory Council within the Department of Health; providing for membership and terms; providing duties and responsibilities; requiring the Secretary of Health to make grants-in-aid from the Biomedical Research Trust Fund for stem cell research; providing requirements relating to applications for and awards of such grants-in-aid; providing specifications for moneys to be made available from the trust fund for stem cell research grants-in-aid; providing restrictions and requirements for uses of funds from such grants-in-aid; providing an appropriation; amending s. 20.435, F.S.; revising references; amended s. 381.86, F.S.; providing an exception to the Institutional Review Board for Stem Cell Research and Ethics Advisory Council; requiring the Department of Health to prepare and distribute a publication regarding the process, otions, medical uses, risks, and benefits of umbilical cord blood collection; providing an effective date.

Bill No. **1065**

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

Council/Committee hearing bill: Healthcare Council

Representative(s) Sands offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

(1) The following trust funds are hereby created, to be administered by the Department of Health:

(h) Biomedical Research Trust Fund.

1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and 381.99, and any other funds appropriated by the Legislature. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program, ~~and~~ the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, and the Florida Better Quality of Life and Biomedical Research Act as specified in ss. 215.5602, 288.955, ~~and~~ 381.922, and 381.99. The trust fund is exempt from the service charges imposed by s. 215.20.

2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.

3. Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant to contract or committed to be expended may be carried forward for up to 3 years following the effective date of the original appropriation.

4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008.

Section 2. Subsection (2) of section 381.86, Florida Statutes, is amended to read:

381.86 Institutional Review Board.--

(2) Consistent with federal requirements, the Secretary of Health shall determine and appoint the membership of the board and designate its chair, except that a separate Stem Cell Research Advisory Council shall be appointed pursuant to s. 381.99 for the sole purpose of reviewing research funded under that section.

Section 3. Section 381.99, Florida Statutes, is created to read:

381.99 Florida Better Quality of Life and Biomedical Research Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Better Quality of Life and Biomedical Research Act."

(2) DEFINITIONS.--As used in this section, the term:

(a) "Adult stem cell" means an undifferentiated cell found among differentiated cells in a tissue or an organ that can renew itself and can differentiate to yield the major specialized cell types of the tissue or organ.

(b) "Amniotic stem cell" means a cell extracted from human amniotic fluid or a placenta.

(c) "Embryonic stem cell" means a cell obtained from the undifferentiated inner mass of an early stage embryo.

(d) "Human reproductive cloning" means the practice of creating or attempting to create a human being by transferring the nucleus from a human cell into an egg cell from which the nucleus has been removed for the purpose of implanting the resulting product in a uterus or a substitute for a uterus to initiate a pregnancy.

(e) "In vitro fertilization" means a technique by which oocytes are fertilized by sperm outside of a woman's body resulting in organisms that are not genetically identical to any one existing human.

(f) "Stem cell" means an undifferentiated cell that retains the potential to differentiate into some or all other cell types.

(3) STEM CELL RESEARCH ADVISORY COUNCIL.--There is created the Stem Cell Research Advisory Council.

(a) The advisory council shall consist of the Secretary of Health or his or her designee, who shall act as chair, and six additional members, who shall be appointed as follows:

1. Two persons appointed by the Governor, one of whom shall be an academic researcher in the field of stem cell research and one of whom shall have a background in bioethics.

2. One person appointed by the President of the Senate, who shall have a background in private sector stem cell funding and development and public sector biomedical research and funding.

3. One person appointed by the Speaker of the House of Representatives, who shall have a background in private sector stem cell funding and development and public sector biomedical research and funding.

4. One person appointed by the Minority Leader of the Senate, who shall have a background and experience in either public sector or private sector stem cell research and development.

5. One person appointed by the Minority Leader of the House of Representatives, who shall have a background and experience in business and financial investments.

Each member shall serve a term of 2 years commencing on October 1, 2007. No member shall serve for more than two consecutive 2-year terms; however, for the purpose of providing staggered terms, of the initial appointments, three members shall be appointed to a 1-year term and three members shall be appointed to a 2-year term. No member shall serve for more than two consecutive terms. Any vacancy on the council shall be filled in the same manner as the original appointment. All initial appointments must be made by October 1, 2007. The first meeting shall take place no later than November 1, 2007. All meetings are subject to the call of the chair. Members shall meet at least twice a year or as often as necessary to discharge their duties but shall have no more than four meetings during any 12-month period. Members shall serve without compensation but may be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The advisory council shall:

1. Develop a donated funds program for recommendation to the Secretary of Health to encourage the development of funds other than state appropriations for embryonic, amniotic, and human adult stem cell research in the state.

2. Examine and identify specific ways to improve and promote for-profit and not-for-profit embryonic, amniotic, and human adult stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing embryonic, amniotic, and human adult stem cell related businesses, recruiting new embryonic, amniotic, and human adult stem cell related businesses to the state, and recruiting scientists and researchers in such fields to the state and state universities.

3. Develop a biomedical research grant program for recommendation to the Secretary of Health, which shall provide grants-in-aid to eligible institutions for the advancement of embryonic, amniotic, or human adult stem cell research.

4. Develop, no later than December 1, 2007, an application for grants-in-aid under this section for recommendation to the Secretary of Health for the purpose of conducting embryonic, amniotic, or human adult stem cell research.

5. Review applications from eligible institutions for grants-in-aid on and after December 1, 2007, and provide to the Secretary of Health recommended grant awards.

6. Review the stem cell research conducted by eligible institutions that receive such grants-in-aid.

(c) The advisory council shall submit an annual progress report on the status of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30. The report must include:

1. The amount of grants-in-aid awarded to eligible institutions from the Biomedical Research Trust Fund.

2. The names of the recipients of such grants-in-aid.

3. The current status and progress of stem cell research in the state.

4. A list of research projects supported by grants-in-aid awarded under the program.

5. A list of publications in peer-reviewed journals involving research supported by grants-in-aid awarded under the program.

6. The total amount of biomedical research funding currently flowing into the state.

7. New grants for biomedical research that were funded based on research supported by grants-in-aid awarded under the program.

8. All other materials the council deems advisable to include.

(d) Advisory council members shall disclose any conflict of interest or potential conflict of interest to the Secretary of Health.

(e) The Department of Health shall provide administrative staff to assist the advisory council in developing the application for the grants-in-aid, reviewing the applications, preparing the written consent form described in paragraph (6)(b), and performing other administrative functions as the advisory council requires.

(4) BIOMEDICAL ETHICS ADVISORY COUNCIL.--There is created within the Department of Health the Biomedical Ethics Advisory Council, which shall review the research conducted under s. 381.99.

(a) The advisory council shall consist of the Secretary of Health or his or her designee, who shall act as chair, and six additional members, who shall be appointed as follows:

1. Two persons appointed by the Governor.

2. One person appointed by the President of the Senate.

3. One person appointed by the Speaker of the House of Representatives.

4. One person appointed by the Minority Leader of the Senate.

5. One person appointed by the Minority Leader of the House of Representatives.

All members must demonstrate knowledge and understanding of the ethical, medical, and scientific implications of embryonic, amniotic, and adult stem cell research and should also demonstrate knowledge of related fields, including, but not limited to, genetics, cellular biology, and embryology. Each member shall serve a term of 4 years commencing on October 1, 2007; however, for the purpose of providing staggered terms, of the initial appointments, three members shall be appointed to a 2-year term and three members shall be appointed to a 4-year term. No member shall serve for more than two consecutive terms. Any vacancy on the council shall be filled in the same manner as the original appointment. All initial appointments must be made by October 1, 2007. The first meeting shall take place no later than November 1, 2007. All meetings are subject to the call of the chair. Members shall meet at least twice a year or as often as necessary to discharge their duties but shall have no more than one meeting per month during any 12-month period. Members shall serve without compensation but may be reimbursed for per diem and travel expenses in accordance with s. 112.061.

(b) The council shall review all embryonic, amniotic, or human adult stem cell research that is funded or supported in any manner through the Biomedical Research Trust Fund to ensure the adherence to ethical and safety guidelines and procedures as laid out by federal ethical standards established by the United States Department of Health and Human Services.

(5) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--

(a) The Secretary of Health shall make grants-in-aid from the Biomedical Research Trust Fund in accordance with the provisions of this section.

(b) The Department of Health shall require any applicant for a grant-in-aid under this section, for the purpose of conducting stem cell research, to submit a complete description of the applicant's organization, the applicant's plans for stem cell research, the applicant's proposed funding for such research from sources other than the state, and the applicant's proposed arrangements concerning financial benefits to the state as a result of any patent, royalty payment, or similar right resulting from any stem cell research made possible by the awarding of the grant-in-aid. The Stem Cell Research Advisory Council shall provide recommendations to the Secretary of Health with respect to awarding such grants-in-aid after considering the recommendations of the Biomedical Ethics Advisory Council.

(c) Beginning with the 2007-2008 fiscal year, and for 10 consecutive years thereafter, not less than $20 million shall be made available from the Biomedical Research Trust Fund within the Department of Health for grants-in-aid to eligible institutions for the purpose of conducting embryonic, amniotic, or human adult stem cell research pursuant to this section. Up to 15 percent of the funds may be used for administrative costs. Any unexpended funds not used for grants-in-aid during the current fiscal year shall be carried forward for the following fiscal year to fund the grants-in-aid.

(6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS REGARDING DISPOSITION OF HUMAN EMBRYOS FOLLOWING INFERTILITY TREATMENT.--

(a) Funds provided under this section may only be used for research involving:

1. Human adult stem cells, including, but not limited to, adult stem cells derived from umbilical cord blood and bone marrow.

2. Human embryonic stem cells taken from donated leftover embryos from in vitro fertilization treatments that would otherwise be thrown away or destroyed.

3. Amniotic stem cells extracted from human amniotic fluid or placentas, which are otherwise discarded after birth.

(b) A physician or other health care provider treating a patient for infertility shall provide the patient with timely, relevant, and appropriate information sufficient to allow the person to make an informed and voluntary choice regarding the disposition of any human embryos that remain following infertility treatment. The person to whom the information is provided:

1. Shall be presented with the option of storing any unused embryos remaining after receiving in vitro fertilization,

donating the remaining embryos to another person, donating the remaining embryos for research purposes, or selecting other means of disposition of the remaining embryos.

2. Who elects to donate, for research purposes, any embryos remaining after receiving infertility treatment shall provide written consent for that donation on a consent form provided by the Department of Health and made available to the public on the department's Internet website.

3. May not knowingly, for material or financial gain, purchase, sell, or otherwise transfer or obtain, or promote the sale or transfer of, embryonic fetal tissue for research purposes pursuant to this section. Embryonic, amniotic, and adult stem cell material may only be donated for research purposes with the informed consent of the donor. A person who violates any provision of this subparagraph commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7) HUMAN REPRODUCTIVE CLONING; PROHIBITION; PENALTIES.--

(a) It is unlawful for any person to knowingly:

1. Perform or attempt to perform human reproductive cloning;

2. Participate or assist in an attempt to perform human reproductive cloning; or

3. Ship or receive for any purpose an embryo produced by human reproductive cloning or any product derived from such embryo.

(b) A person who violates any provision of paragraph (a) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(8) CONTINUING APPROPRIATION.--Beginning in fiscal year 2007-2008, the sum of $20 million is appropriated annually from

recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for the purposes of carrying out the provisions of this section. The amount of funds appropriated shall not exceed $200 million for the 10-year period beginning in fiscal year 2007-2008 and ending in fiscal year 2016-2017.

Section 4. This act shall take effect July 1, 2007.

================ T I T L E A M E N D M E N T ================

Remove the entire title and insert:

An act relating to biomedical research; amending s. 20.435, F.S.; revising uses for funds credited to the Biomedical Research Trust Fund; amending s. 381.86, F.S.; providing that the Institutional Review Board within the Department of Health shall not review certain research within the jurisdiction of the Stem Cell Research Advisory Council; creating s. 381.99, F.S.; creating the Florida Better Quality of Life and Biomedical Research Act; providing a short title; providing definitions; creating the Stem Cell Research Advisory Council; providing for appointment, terms, and duties of members; authorizing reimbursement for per diem and travel expenses; requiring a report; requiring the Department of Health to provide administrative support; creating the Biomedical Ethics Advisory Council to regulate research procedures and enforce ethical guidelines; providing for appointment, terms, and duties of members; authorizing reimbursement for per diem and travel expenses; providing duties of the council; providing for a grants-in-aid program for the purpose of conducting embryonic, amniotic, or human adult stem cell research; providing that grants-in-aid shall be provided through funds in the Biomedical Research Trust Fund; restricting the use of such funds for research on certain stem cells; providing requirements with respect to the disposition of human embryos following infertility treatment; requiring the Department of Health to develop and maintain on its Internet website a consent form for the donation of certain embryos; prohibiting purchase or sale of embryonic fetal tissue for research purposes; prohibiting certain acts relating to human reproductive cloning; providing penalties; providing a continuing appropriation; providing an effective date.

WHEREAS, an estimated 130 million Americans suffer from acute, chronic, and degenerative diseases and there is enormous potential for lifesaving treatment and therapy as a result of recent advances in biomedical research, and

WHEREAS, Florida is unique among all states because of the size of the projected net population increase within the next 20 years which raises significant health care concerns as a new generation of retirees moves to Florida, resulting in a corresponding rise in the number of persons suffering from illnesses such as cancer, heart disease, Alzheimer's Disease, Parkinson's Disease, cerebral palsy, juvenile diabetes, atherosclerosis, Amyotrophic Lateral Sclerosis, AIDS, spinal cord injuries, severe burns, osteoporosis, osteoarthritis, cystic fibrosis, muscular dystrophy, multiple sclerosis, macular degeneration, diabetic retinopathy, retinitis pigmentosa, cirrhosis of the liver, motor neuron disease, brain trauma, stroke, sickle cell anemia, and intestinal diseases, and

WHEREAS, in order to maintain a high quality of life for all Floridians, research into stem cell regenerative therapies and treatment should be supported to give hope and relief to the millions of citizens who suffer from degenerative and crippling diseases, and

WHEREAS, to reduce the burden on the health care infrastructure, the state must shift its health care objectives from costly long-term maintenance toward prevention and cures, and

WHEREAS, to bolster and advance Florida's burgeoning biotechnology industry, the state should provide funds and incentives for private research companies to work in the state, and

WHEREAS, the state should advance the goal of scientific and academic discourse in its universities and help bring its public and private universities to the forefront in biomedical research and technology, and

WHEREAS, it will benefit the economy of the state to create a wide array of new projects and high-paying jobs relating to biomedical research, and

WHEREAS, it will benefit the state to foster cooperation between the state's universities and private sector research in terms of jobs, resources, and academic discourse relating to biomedical research, and

WHEREAS, the public funds provided under the Florida Better Quality of Life and Biomedical Research Act are intended to spur innovation and development in Florida's biomedical technology sector, which will be used to treat debilitating chronic diseases, NOW, THEREFORE,

Investing in Florida's Future

Funding Stem Cell Research

Presentation By:
Citizens for Science and Ethics
www.scienceandethics.org
(850) 222-8156
Contact: Brett Doster
brett@flstrategies.com

WHY ARE STEM CELLS IMPORTANT?

Stem Cells are special and differ from all other cells:

- Are capable of dividing and renewing themselves for long periods.
- Are unspecialized or mini-blank slates.
- Can give rise to other specialized cell types.

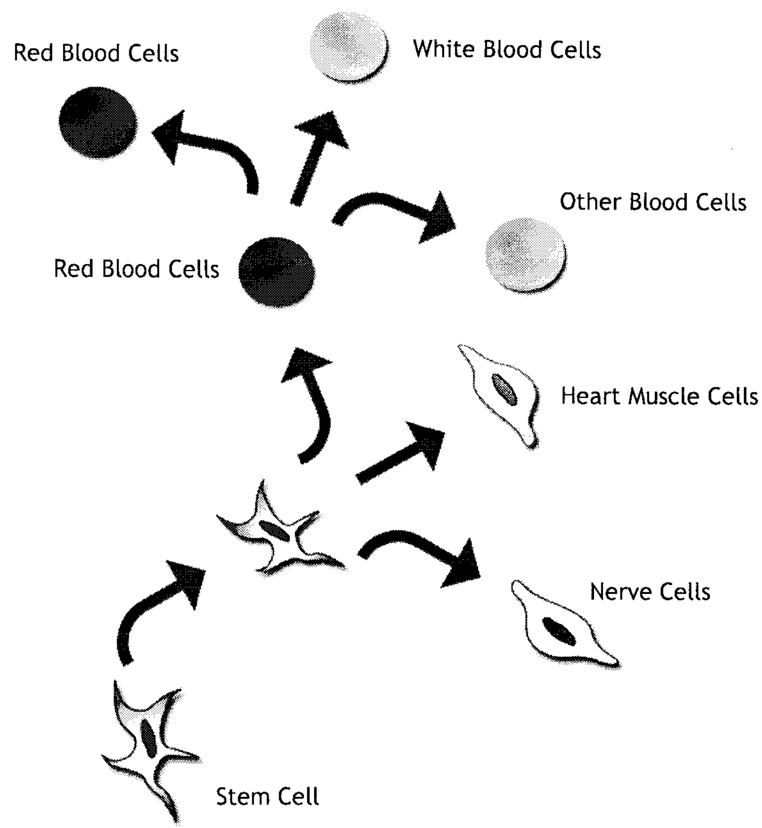
Stem cells are part of the repair system of the body and can be used as a part of regenerative therapies to treat diseases and syndromes such as paralysis, heart disease, Parkinson's Disease, diabetes and more.

Source: National Institutes of Health; http://stemcells.nih.gov/info/basics/basics2.asp

3 TYPES OF STEM CELLS

- **Totipotent**: Found in 1-4 cell embryos, amniotic fluid, and placenta. Total blank slate cells. Give rise to every cell in the body. Impractical to use.
- **Pluripotent**: Found in 3-7 day embryos. Makes all mature tissue. Can give rise to almost every cell in the body. Science has recently shown adult stem cells to be pluripotent as well.
- **Multipotent**: Found in umbilical cords and in the fully developed tissue of children and adults. Recent scientific breakthroughs have shown them to be very plastic and capable of pluripotentcy.

STEM CELL DIFFERENTIATION



THE DEBATE

- Some scientists and researchers want to be able to use embryonic stem cells because they were once thought to be more capable of being engineered into various tissue types. They feel that the potential scientific benefit outweighs the ethical issues regarding the destruction of human embryos to harvest stem cells.

- Other scientists and researchers have proven that the adult stem cells found in sources such as umbilical cord blood, amniotic fluid, and other adult tissues are just as useful as those found in embyros and would rather not deal with the ethical issues associated with creating life to harvest human embryonic stem cells.

Let's examine the facts!

STEM CELL SOURCES

Back-up articles included in clips on left side of packet.

ETHICAL

- Living blood and tissue donors.
- Bone marrow and fat.
- Cadavers.
- Umbilical cords and placentas.
- Amniotic fluid.
- Human hair follicles.
- Embryos and fetuses terminated from natural causes.

UNETHICAL

- Optionally destroyed embryos from IVF clinics.
- Optional abortions.
- Petri-dish created embryos that are destroyed while harvesting their stem cells.

EMBRYONIC STEM CELLS–EFFECTIVE?

Back-up articles included in clips on left side of packet.

- **"Embryonic stem cells have not yet been used for even one therapy, while adult stem cells have already been successfully used in numerous patients…"** Dr. Wolfgang Lillige, "The Case for Adult Stem Cell Research." *21st Century Science and Technology Magazine*, Winter 2001-2002.

- **"…to use embryonic stem cells for diseases in mature tissues, they must be turned into adult stem cells. Another reason that embryonic stem cells cannot be used directly is that they form tumors when transplanted into mature tissues."** Dr. James Sherley, associate professor of biological engineering at the Massachusetts Institute of Technology, "To Clone or Not to Clone." *MercatorNet*, December 2005

- **"The "great promise" of embryonic stem cells is often stated by scientists that either hold key patents or are strongly supported by biotech companies pursuing embryonic cells commercially. The potential of embryonic stem cells to possibly form every cell type in the body is amazing but is of little clinical relevance. As long as a stem/progenitor cell is capable of forming the cell types needed for a particular injury or disease, the capability to form every cell type is a moot point."** Dr. Jean Peduzzi-Nelson, associate professor in the department of anatomy and cell biology at Wayne State University School of Medicine in Detroit, "Adult Stem Cells are Behind Much of Stem Cell Success So Far." *Milwaukee Journal Sentinel*. September 2. 2006.

ADULT STEM CELL THERAPIES

- Cancer
- Child Leukemia
- Crohn's Disease
- Diabetes
- Heart Disease
- Paralysis
- Parkinson's Disease
- …and more.

  One of the great advantages of using adult stem cells is that they can be donated and used by the same patient, thus eliminating risks of rejection.

<u>SUPPORT THE FLORES/HARIDOPLOS PLAN!</u>

There are ethical issues with embryonic stem cell research. No cures or therapies have been developed from ESC, and they are impractical to use because they <u>create tumors</u>, <u>trigger immune rejection</u>, and are <u>genetically unstable</u>.

Support the <u>Flores/Haridopolos Plan</u> and support:

- $20 Million for Adult/Ethical Stem Cell Research
- Prohibition on human cloning and state funding of ESC Research.
- Moving Florida forward by improving our quality of life and saving lives **right now**.

Dr. Daniel Pepin
Introductory Information

Dr. Daniel Pepin is currently a professor of anatomy & physiology and an instructor of human biology. In addition, he is a consultant of bioethics. Dr. Pepin graduated summa cum laude from Lake Superior State University in biological sciences, summa cum laude from the University of Michigan with a doctorate in dental surgery. He has completed post-graduate studies at the University of Detroit Mercy. While in private practice, Dr. Pepin served as a clinical instructor and professor of oral pathology. Since 1993, he has devoted his full time to academic instruction and bioethical research.

Howard J. Leonhardt - Founder, Executive Chairman & Chief Technology Officer [HLeonhardt@aol.com]

Mr. Leonhardt is the Founder of Bioheart and has served as Chairman of the Board and Chief Executive Officer of the Company since it's founding in June of 1999. From December 1998 through June 1999 he held the position of President of World Medical Manufacturing Corporation, a subsidiary of Medtronic, Inc. From 1986 to December 1998 he served as Founder and Chief Executive Officer of World Medical Manufacturing Corporation, a medical technology company that initially produced cardiovascular balloon catheters and later progressed into development of other products including stent grafts for aortic aneurysm repair.

He is also the Founder of World Biotech a private investment fund specializing in biotechnology companies. He graduated from the accelerated International Trade from Anoka - Hennepin Technical College, attended Anoka-Ramsey Community College and the University of Minnesota and has received an honorary Doctorate of Biomedical Engineering degree from the University of Northern California. Mr. Leonhardt serves as Consulting Professor and Board Advisor at Florida International University, Biomedical Engineering Institute.

James P. Kelly

James P. Kelly, who serves as biotech writer for The Seoul Times, is the director of the Cures 1st Foundation, Inc. in the US. As a paralyzed American research advocate, Director Kelly promotes practical research for the sake of treatments and cures. Mr. Kelly has testified on cloning before committees in America's Congress, in debate with actor Christopher Reeve, and most recently on CNN International.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1111 Fiscal Intermediary Services Organizations
SPONSOR(S): Kendrick and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 666

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Innovation	7 Y, 0 N	Ciccone	Calamas
2) Healthcare Council		Ciccone JC	Gormley RG
3)			
4)			
5)			

SUMMARY ANALYSIS

House Bill 1111 revises the definition of fiscal intermediary services organizations (FISOs) by the Office of Insurance Regulation. State regulation of FISOs is designed to protect funds received from a Health Maintenance Organization (HMO) and held by these fiscal intermediary entities, which are obligated to distribute those funds to health care providers who contract with an HMO.

The bill revises the definition of FISOs by deleting the exemption for entities that are owned, operated, or controlled by certain licensed entities. As revised, only the licensed entities themselves would be exempt, including hospitals, authorized insurers, third party administrators, prepaid limited health service organizations, and HMOs. The bill also provides that the current exemption for physician group practices would be limited to group practices providing services under the scope of licenses of the group practice membership.

The bill requires FISOs to comply with certain statutory requirement regarding claims payments and adverse determination of claims. The bill directs OIR to periodically examine FISOs operations and to take remedial action when necessary.

The fiscal impact of the bill appears to be insignificant, which can be absorbed within existing resources..

The bill provides an effective date of October 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government - The bill directs the Office of Insurance Regulation to conduct periodic examinations of fiscal intermediary services organizations and to take remedial action when necessary.

B. EFFECT OF PROPOSED CHANGES:

House Bill 1111 amends s. 641.316, F.S., revising the definition of who must be registered as a FISO by deleting the exemption for entities that are owned, operated, or controlled by certain licensed entities. As revised, only the licensed entities themselves would be exempt, including hospitals, authorized insurers, third party administrators, prepaid limited health service organizations, and HMOs.

The bill also revises the current exemption for physician group practices by limiting the exemption to group practices providing services under the scope of licenses of the group membership.

The bill requires FISOs to be subject to s. 641.27, F.S., which would require OIR to conduct periodic examinations of the operations of the FISO and to take remedial action when necessary.

The bill further requires FISOs to comply with the following statutory requirements (which apply to HMOs):

- Section 641.3155, F.S., which contains the prompt payment requirements;
- Section 641.3156, F.S., which requires HMOs to pay claims for treatment if a provider follows the treatment authorization procedures and receives authorization; and
- Section 641.51(4), F.S., which requires that only a Florida licensed allopathic physician or osteopathic physician may render an adverse determination regarding a service provided by a physician and specifies procedures that must be followed.

The bill requires FISOs to comply with s. 641.21(1)(j), F.S., which requires entities to provide additional reasonable data, financial statements, and other information as requested by the OIR.

Present Situation:

Regulation of Health Maintenance Organizations
The Office of Insurance Regulation regulates health maintenance organization solvency, contracts, rates, and marketing activities under part I of chapter 641, F.S., while the Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of chapter 641, F.S. Any entity that is issued a certificate of authority and is otherwise in compliance with the licensure provisions under part I may enter into contracts in Florida to provide an agreed-upon set of comprehensive health care services to subscribers.

Fiscal Intermediary Services Organizations (FISOs)
The 1997 Legislature amended the HMO laws to provide for the regulation of FISOs under s. 641.316, F.S.[1] At that time, some health care professionals were contracting with unregulated entities to collect payments from HMOs on the providers' behalf and to distribute those funds to the contracting health care providers. There were reported cases of misappropriation of funds by such entities, with no apparent recourse to regulatory agencies. Essentially, the law is designed to protect funds received from an HMO and held by entities, which have an obligation to distribute those funds to medical professionals who contract with the HMO.

[1] Ch. 97-159, L.O.F.; s. 641.316, F.S.

A fiscal intermediary services organization is defined as:

> . . . a person or entity which performs fiduciary or fiscal intermediary services to health care professionals who contract with health maintenance organizations, other than a fiscal intermediary services organization owned, operated, or controlled by a hospital licensed under chapter 395, an insurer licensed under chapter 624, a third party administrator licensed under chapter 626, a prepaid limited health service organization licensed under chapter 636, a health maintenance organization licensed under chapter 641, or physician group practices as defined in s. 456.053(3)(h).[2]

The term, fiduciary or fiscal intermediary services means:

> . . . reimbursements received or collected on behalf of health care professionals for services rendered, patient and provider accounting, financial reporting and auditing, receipts and collections management, compensation and reimbursement disbursement services, or other related fiduciary services pursuant to health care professional contracts with health maintenance organizations. . . [3]

The FISO definition exempts physician group practices, however, it is not clear that this exemption is limited to providing fiscal intermediary services only to members of that group practice, though that may be the intent. This appears to be a broader exemption than a similar exemption for physician group practices from licensure as an administrator in s. 626.88(1)(o), F.S. (See, Regulations of Administrators, to follow.) That statute limits the exemption for physician group practices to providing services under the scope of the license of the members of the group practice. The definition of a FISO also exempts organizations owned, operated, or controlled by various licensed entities, such as hospitals, insurers, third party administrators, HMOs, etc. In contrast, the exemption from licensure as an administrator includes licensed insurers, HMOs, and certain other entities, but does not exempt subsidiaries or other independent organizations that are owned, operated, or controlled by such licensed entities.

The express legislative intent of the statute is to ensure the financial soundness of FISOs. A FISO that is operated for the purpose of acquiring and administering provider contracts with managed care plans must secure and maintain a fidelity bond and a surety bond. As currently required, a fidelity bond must be maintained in the minimum amount of 10 percent of the funds handled by the FISO during the prior year or $1 million, whichever is less, but not less than $50,000. This bond protects the FISO from loss due to dishonesty of its employees. A surety bond must also be maintained in the minimum amount of 5 percent of the funds handled by the FISO during the prior year or $250,000, whichever is less, but not less than $10,000. The surety bond protects against misappropriation of funds within the FISO's control or custody.

A FISO registering with the OIR must meet certain application requirements of chapter 641, F.S., that apply to HMOs. These require that a FISO provide the OIR with a list of the names, addresses and official capacities of the persons who are responsible for the operations of the company, including officers, directors, and owners of more than 5 percent of the common stock of the company. The listed persons must fully disclose all contracts or arrangements between them and the company, including any conflicts of interest, and must submit autobiographical statements, fingerprints, and an independently performed background report. In general, receiving authority to operate as a FISO is conditioned on the OIR being satisfied that the ownership, control and management of the entity is competent and trustworthy, and possesses managerial experience that would make the proposed operation beneficial to its constituents.

[2] Section 641.316(2)(b), F.S.

[3] Section 641.316(2)(a), F.S.

There are currently 16 active FISOs registered with the OIR. Interviews with representatives of the OIR indicate that after a FISO is registered, there is generally no regulatory activity other than periodic review of the surety bond and fidelity bonds to determine if the amounts are adequate relative to the amount of funds handled annually by the FISO, as required by statute. There are no documented investigations or regulatory actions that have been taken against a FISO.

Regulation of ("Third Party") Administrators

A person who acts as an administrator, more commonly referred to as a third party administrator or TPA, must be licensed by the OIR. Section 626.88, F.S., defines an administrator as:

> . . . any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self insurance funds or with insured or self-insured programs which provide life or health insurance coverage. . .or any person who, through a health care risk contract as defined in s. 641.234, with an insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers. . .[4]

The two definitions for a FISO and an administrator overlap to some extent, by encompassing persons or entities that provide billing and collection services to HMOs on behalf of health care providers. However, the definition for an administrator includes authority to engage in claims adjudication or collection of premiums for a health insurer or HMO, which activities are not authorized by the FISO statute. Administrators that are licensed by the OIR are exempt from the requirement of being a registered FISO.

The requirements for administrators under ss. 626.88 - 626.894, F.S., are more extensive than the regulation of FISOs. For example, an administrator must make its books and records available to the OIR for examination, audit, and inspection and must maintain its business records and file annual financial statements with the OIR. However, the fidelity bond requirement may be less for an administrator as compared to a FISO, depending on the amount of funds handled, and a separate surety bond is not required for an administrator as it is for a FISO.

Administrators must have a written agreement with an insurer containing specified provisions. The insurance company, rather than the administrator, must be responsible for determining the benefits, rates underwriting criteria, and claims payment procedures.[5] A payment to the administrator of any premiums on behalf of the insured are deemed to have been received by the insurer and all premiums collected by an administrator on behalf of an insurer must be held by the administrator in a fiduciary capacity. If an administrator is collecting premiums for more than one insurer, the administrator must keep records clearly recording each insurer's accounts.

The administrator law requires that a person who provides billing and collection services to HMOs on behalf of health care providers must comply with s. 641.3155, F.S., the prompt payment statute, and s. 641.51(4), F.S., which requires that only a Florida-licensed allopathic physician or osteopathic physician may render an adverse determination regarding a service provided by a physician and specifies procedures that must be followed.[6]

Payment Documentation by FISOs and Administrators

In 1999, the Legislature amended the FISO and administrator laws to require that payment by a fiscal intermediary to a health care provider include specified information.[7] This was in response

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[4] Section 626.88(1), F.S.
[5] Section 626.8817 and 626.882, F.S.
[6] Section 626.88, F.S.
[7] Ch. 99-273, L.O.F.; ss.626.883(6) and 641.316(2)(a), F.S.

to complaints by health care providers that claims payments by FISOs did not delineate sufficient information for the providers to reconcile their records as to which claims were being paid. The law now requires that for a capitated health care provider, the statement must include the number of patients covered by the contract, the rate per patient, total amount of payment, and the identification of the plan on which behalf the payment is made. For a noncapitated health care provider, the statement must include an explanation of services being reimbursed, including the patient name, date of service, procedure code, amount of reimbursement, and plan identification.

Prompt Payment Requirements

The law requires HMOs to reimburse claims by providers within 35 days of receipt, subject to a 10 percent interest penalty for late payment.[8] Commonly referred to as the prompt payment law, the law also includes a definition of a clean claim, other specific time frames for actions relative to claims payments, and required procedures for HMOs filing claims against providers for overpayments. The law also prohibits HMOs from systematic downcoding with the intent to deny reimbursement otherwise due. The law does not define downcoding, but the term is generally understood to mean an HMO substituting a procedure code that is a lower level of service with a lower reimbursement rate than the procedure billed by the provider.

HMO Responsibility for Violations of Prompt Pay Law (etc.) if Payment Obligations are Transferred

A law enacted in 2002 holds HMOs ultimately responsible for compliance with certain statutory requirements related to prompt payment, treatment authorization, and adverse determinations, if the HMO transfers its payment obligations to a licensed administrator.[9] However, the law apparently does not hold an HMO responsible for compliance with such requirements if it transfers its payment obligations to an entity other than a licensed administrator.

Specifically, this law provides that if an HMO, through a health care risk contract, transfers to any entity the obligations to pay a provider for any claim arising from services provided to a subscriber, the HMO remains responsible for any violations of three specified statutes:

- Section 641.3155, F.S., which are the prompt payment requirements;
- Section 641.3156, F.S., which requires HMOs to pay claims for treatment if a provider follows the treatment authorization procedures and receives authorization; and
- Section 641.51(4), F.S., which requires that only a Florida licensed allopathic physician or osteopathic physician may render an adverse determination regarding a service provided by a physician and specifies procedures that must be followed.

The law also provides the following definitions, which apply to administrative, provider, and management contracts:

- Health care risk contract means: a contract under which an entity receives compensation in exchange for providing to the health maintenance organization a provider network or other services which may include administrative services.
- Entity means: . . . a person licensed as an administrator under s. 626.88, F.S., and does not include any provider or group practice under s. 456.053, F.S., providing services under the scope of the license of the provider or the members of the group practice. The term does not include a hospital providing billing, claims, and collection services solely on its own and its physicians' behalf and providing services under the scope of its license.

The enactment of the prompt payment requirements and persistent efforts by health care provider groups to document complaints and seek enforcement actions by the OIR have resulted in market conduct examinations and regulatory sanctions against HMOs violating these provisions. An

[8] Section 641.3155, F.S.

[9] Ch. 2002-389, L.O.F.; s. 641.234,F.S.

interim project by the Senate Banking and Insurance Committee in 2005 (cited below) reviewed 22 market conduct examinations by the OIR of HMOs that found violations of the prompt payment statute, which resulted in consent orders and corrective action by the targeted HMO, including payment of required interest to providers and, in 14 of theses cases, fines against the HMO ranging from $10,000 to $85,500.

Some of these examinations included situations where HMOs contracted with entities referred to as "management service organizations" and "independent practice associations" which made payments to providers on behalf of the HMO and which did not appear to have been licensed administrators. Interviews with the OIR personnel indicated that the OIR attempted to hold an HMO responsible for violations of prompt payment requirements regardless of whom the HMO may have contracted with to perform payment services. In the market conduct examinations of this type reviewed, a Consent Order was issued by the OIR with the agreement of the HMO, where the HMO consented to pay a fine and to take corrective actions, but did not agree with the findings of the Consent Order.

Banking and Insurance Committee Interim Project (2005-109)
The Present Situation, above, summarizes the background and findings in the 2005 Senate Banking and Insurance Committee staff interim project, "Determining the Sufficiency of Regulation of Third Party Administrators and Fiscal Intermediary Services Organizations" (2005-109). The interim project made the following recommendations:

- Expand the requirements of s. 641.234(4), F.S., to hold an HMO responsible for statutory requirements related to payment to health care providers if the HMO transfers to any entity the obligations to pay providers. The current law may limit this liability to HMO contracts with licensed administrators and limit this responsibility to violations of only certain statutes.
- Narrow the exemption from registration as a FISO for a physician group practice in s. 641.316, F.S., to physician group practices providing fiscal intermediary services to members of the group practice.
- Narrow the exemption from registration as a FISO for licensed insurers, HMOs, administrators, hospitals, and prepaid limited health service organizations to those entities themselves, rather than any entity owned operated, or controlled by such licensed entities.
- Consider repealing the FISO statute and require entities to be licensed as third party administrators if they provide fiscal intermediary services to providers under contract with HMO.[10]

C. SECTION DIRECTORY:

Section 1. Amends s. 641.316, F.S.; relating to fiscal intermediary services.

Section 2. Provides an effective date of October 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The number of entities that would be required to register with the OIR and be subject to examination by the OIR is indeterminate at this time.

[10] Senate Staff Analysis, March 2007, on file with the Committee.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Increased FISO regulation would increase fiscal protection for medical providers and health maintenance organizations transacting services with a fiscal intermediary services organization.

An indeterminate number of entities that are no longer exempt from registration with the OIR as a fiscal intermediary services organization would be subject to expenses associated with registering with the OIR, including, but not limited to a surety bond and a fidelity bond, and fingerprint processing fees. In addition, the FISO would be responsible to pay the costs associated with a market conduct examination conducted by the OIR. Pursuant to s. 641.27, F.S., such expenses may not exceed a maximum of $50,000 for any 1-year period.

D. FISCAL COMMENTS:

To absorb the expanded regulatory responsibilities required, the OIR requests authorization for two positions and an appropriation of $126,723 to implement this proposal. These positions include one Financial Examiner to conduct examinations and one Management Review Specialist as follows:

Financial Examiner/Analyst II

	Recurring	Non-Recurring
Salaries and Benefits	$50,258	
Expense	$6,498	$3,426
OCO		$1,300
Human Resources	$401	

Management Review Specialist

	Recurring	Non-Recurring
Salaries and Benefits	$53,232	
Expense	$6,489	
OCO		$3,426
Human Resources	$401	$1,300

The Management Review Specialist position will be used for the purposes of examination oversight, review of workpapers, and preparation of compliance reports related to the application of prompt pay, treatment authorization requirements, and second opinion notification requirements specified by this legislation.

1. COMMENTS

B. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

   None.

C. RULE-MAKING AUTHORITY:

   None.

D. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

E. STATEMENT OF THE SPONSOR

   No statement provided.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

A bill to be entitled

An act relating to fiscal intermediary services organizations; amending s. 641.316, F.S.; redefining the term "fiscal intermediary services organization" for purposes of provisions governing organizations that manage the business affairs of health care professionals; revising compliance requirements for registration as a fiscal intermediary services organization; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (b) of subsection (2) and subsection (6) of section 641.316, Florida Statutes, are amended to read:

641.316 Fiscal intermediary services.--

(2)

(b) The term "fiscal intermediary services organization" means a person or entity that ~~which~~ performs fiduciary or fiscal intermediary services to health care professionals who contract with health maintenance organizations other than ~~a fiscal intermediary services organization owned, operated, or controlled by~~ a hospital licensed under chapter 395, an insurer licensed under chapter 624, a third-party administrator licensed under chapter 626, a prepaid limited health service organization licensed under chapter 636, a health maintenance organization licensed under this chapter, or a physician group practice ~~practices~~ as defined in s. 456.053(3)(h) which provides services under the scope of licenses of the members of the group practice.

(6) Any fiscal intermediary services organization, other than ~~a fiscal intermediary services organization owned, operated, or controlled by~~ a hospital licensed under chapter 395, an insurer licensed under chapter 624, a third-party administrator licensed under chapter 626, a prepaid limited health service organization licensed under chapter 636, a health maintenance organization licensed under this chapter, or a physician group practice ~~practices~~ as defined in s. 456.053(3)(h) which provides services under the scope of licenses of the members of the group practice, must register with the office and meet the requirements of this section. In order to register as a fiscal intermediary services organization, the organization must comply with ss. 641.21(1)(c), ~~and~~ (d), and (j), ~~and~~ 641.22(6), and 641.27. The fiscal intermediary services organization must also comply with the provisions of ss. 641.3155, 641.3156, and 641.51(4). Should the office determine that the fiscal intermediary services organization does not meet the requirements of this section, the registration shall be denied. If ~~In the event that~~ the registrant fails to maintain compliance with ~~the provisions of~~ this section, the office may revoke or suspend the registration. In lieu of revocation or suspension of the registration, the office may levy an administrative penalty in accordance with s. 641.25.

Section 2. This act shall take effect October 1, 2007.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. ___1__ (for drafter's use only)

Bill No. **HB 1111**

COUNCIL/COMMITTEE ACTION

ADOPTED __ (Y/N)

ADOPTED AS AMENDED __ (Y/N)

ADOPTED W/O OBJECTION __ (Y/N)

FAILED TO ADOPT __ (Y/N)

WITHDRAWN __ (Y/N)

OTHER ______

Council/Committee hearing bill: Healthcare Council

Representative(s) Kendrick offered the following:

Amendment (with directory and title amendments)

Remove line(s) 35 and insert:

health service organization licensed under chapter 636, <u>a not-for-profit corporation which provides health care services directly to patients through employed, salaried physicians and that is affiliated with an accredited hospital licensed in this state,</u> a health

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. ___2__ (for drafter's use only)

Bill No. **HB 1111**

COUNCIL/COMMITTEE ACTION

ADOPTED __ (Y/N)

ADOPTED AS AMENDED __ (Y/N)

ADOPTED W/O OBJECTION __ (Y/N)

FAILED TO ADOPT __ (Y/N)

WITHDRAWN __ (Y/N)

OTHER ______

Council/Committee hearing bill: Healthcare Council

Representative(s) Galvano offered the following:

Amendment (with directory and title amendments)

Between line(s) 29-30 insert:

(4) A fiscal intermediary services organization, as described in subsection (3), shall secure and maintain a surety bond on file with the office, naming the intermediary as principal. The bond must be obtained from a company authorized to write surety insurance in the state, and the office shall be obligee on behalf of itself and third parties. The penal sum of the bond may not be less than 5 percent of the funds handled by the intermediary in connection with its fiscal and fiduciary services during the prior year or $250,000, whichever is less. The minimum bond amount must be $10,000. The condition of the bond must be that the intermediary shall register with the office and shall not misappropriate funds within its control or custody as a fiscal intermediary or fiduciary. The aggregate liability of the surety for any and all breaches of the conditions of the bond may not exceed the penal sum of the bond.

The bond must be continuous in form, must be renewed annually by a continuation certificate, and may be terminated by the surety upon its giving 30 days' written notice of termination to the office. <u>This subsection does not apply to a fiscal intermediary services organization that is owned, operated, or controlled by a third-party administrator holding a certificate of authority under part VII of chapter 626.</u>

=========== D I R E C T O R Y A M E N D M E N T ==========

Remove line(s) 13-14 and insert:

Section 1. Paragraph (b) of subsection (2), subsection (4), and subsection (6) of section 641.316, Florida Statutes, are amended to read:

================ T I T L E A M E N D M E N T =============

Remove line(s) 6 and insert:

the business affairs of health care professionals; providing an exception from the requirement to obtain a bond;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1115 Health Care Clinic Act
SPONSOR(S): Kreegel and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2354

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Innovation	7 Y, 0 N	Ciccone	Calamas
2) Healthcare Council		Ciccone JC	Gormley CG
3)			
4)			
5)			

SUMMARY ANALYSIS

House Bill 1115 provides a licensure exemption for clinical facilities that are wholly owned, directly or indirectly, by a publicly traded corporation. The bill provides a definition of a publicly traded corporation to mean a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

The bill appears to have no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government - The bill reduces the number of facilities that are subject to clinical licensure. Clinics that meet the definition of an exempted facility as defined in the bill would not be subject to state licensure requirements and associated fees.

B. EFFECT OF PROPOSED CHANGES:

House Bill 1115 amends s. 400.9905, F.S., to add an exemption to the list of clinics that are defined in law for the purposes of licensure. The bill would exempt any clinical facility that is wholly owned, directly or indirectly, by a publicly traded corporation defined as a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange. The practical effect of this exemption would apply to clinics that fall within the revised definition of a publicly traded corporation and as such would be subject to the federal oversight contained within the Sarbanes-Oxley Law.

Federal Sarbanes-Oxley Act of 2002
The Sarbanes-Oxley Act of 2002,[1] sponsored by US Senator Paul Sarbanes and US Representative Michael Oxley, represented one of the biggest changes to federal securities laws in recent history. The enactment of this law came as a result of the large corporate financial scandals involving Enron, WorldCom, Global Crossing and Arthur Anderson. The law essentially established that effective in 2006, all publicly-traded companies would be required to submit an annual report of the effectiveness of their internal accounting controls to the Security and Exchange Commission.

Provisions of the Sarbanes-Oxley Act detail criminal and civil penalties for noncompliance, certification of internal auditing and increased financial disclosure. All public U.S. companies and non-U.S. companies with a U.S. presence must comply with this law, the essence of which relates to corporate governance and financial disclosure. Federal oversight is primarily under the jurisdiction of the Public Company Accounting Oversight Board (PCAOB) under the Security and Exchange Commission (SEC), which can impose specified civil and criminal penalties for noncompliance. In addition to lawsuits, a corporate officer who does not comply with this law or submits an inaccurate certification is subject to a fine up to $1million and ten years in prison, even if done mistakenly. If an incorrect certification was submitted purposely, the fine can be up to $5 million and twenty years in prison.

State Health Care Clinic Licensure
Part XIII of ch. 400, F.S., contains the Health Care Clinic Act (act) (ss. 400.990-400.995, F.S.). The act was passed in 2003 to reduce fraud and abuse occurring in the Personal Injury Protection (PIP) insurance system. Under the act, the Agency for Health Care Administration (agency) licenses health care clinics, ensures that such clinics meet basic standards, and provides administrative oversight. Any entity that meets the definition of a "clinic" (an entity at which health care services are provided to individuals and charges for reimbursement for such services) must be licensed as a clinic.[2]

Every entity that meets the definition of a "clinic" must maintain a valid license with the AHCA at all times, and each clinic location must be licensed separately. A clinic license lasts for a 2-year period. The fees payable by each clinic to the AHCA for licensure cannot exceed $2,000, adjusted for changes in the Consumer Price Index for the previous 12 months. Each clinic must file in its application for licensure information regarding the identity of the owners, medical

[1] See www.Sarbanes-Oxleycompliance
[2] S. 400.9905(4), F.S.

providers employed, and the medical director and proof that the clinic is in compliance with applicable rules. The clinic must also present proof of financial ability to operate a clinic. A level 2 background screening pursuant to ch. 435, F.S., is required of each applicant for clinic licensure. A license may not be granted to a clinic if the applicant has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to any offense prohibited under the level 2 standards for screening or a violation of insurance fraud under s. 817.234, F.S., within the past 5 years.

Each clinic must have a medical director or clinic director who agrees in writing to accept legal responsibility pursuant to s. 400.9935, F.S., for the following activities on behalf of the clinic:

- A sign identifying the medical director that is readily visible to all patients;
- Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license;
- Reviewing patient referral contracts or agreements made by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of ch. 456, F.S., the respective practice acts, and rules adopted under the Health Care Clinic Act; and
- Conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. If an unlawful charge is discovered, immediate corrective action must be taken.

Licensed clinics are subject to unannounced inspections of the clinic by AHCA personnel to determine compliance with the Health Care Clinic Act and applicable rules. The clinic must allow full and complete access to the premises and to billing records. The agency may deny, revoke, or suspend a health care clinic license and impose administrative fines of up to $5,000 per violation pursuant to s. 400.995, F.S.

<u>State Health Care Clinic Licensure Exemption</u>
Although all clinics must be licensed with the AHCA, s. 400.9905(4), F.S., contains a lengthy list of entities that are not considered a "clinic" for the purposes of clinic licensure. An entity that is licensed in Florida pursuant to various chapters specified in s. 400.9905(4)(a) - (4)(d), F.S., may be exempt from clinic licensure if it meets one of the following provisions:

- The entity is licensed or registered by the state under one or more of the specified practice acts and only provides services within the scope of its license;
- It is an entity that owns, directly or indirectly, an entity licensed or registered by the state under one or more of the specified practice acts that only provides services within the scope of its license;
- It is an entity that is owned, directly or indirectly, by an entity licensed or registered by the state under one or more of the specified practice acts and only provides services within the scope of its license;
- If the clinic performs only the technical component of a magnetic resonance imaging (MRI), static radiograph, computed tomography (CT scan), or positron emission scan (PET scan), and provides the professional interpretation of such services in a fixed facility accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Association for Ambulatory Health Care (AAA) and the American College of Radiology (ACR), and the percentage of scans in the preceding quarter that were billed to a PIP insurance carrier is under 15 percent, the chief financial officer of the clinic may assume the responsibility for the conduct of systematic reviews of clinic billings to ensure they are not fraudulent or unlawful. See s. 400.9935(1)(g), F.S.; or
- An entity is under common ownership, directly or indirectly, with an entity licensed or registered by the state under one or more of the specified practice acts and only provides services within the scope of its license.

Exemptions from clinic licensure are also available for the following:

- An entity that is exempt from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- A community college or university clinic;
- An entity owned by the federal or state government, including agencies, subdivisions and municipalities;
- Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Entities that provide only oncology or radiation therapy services by physicians licensed under chs. 458 or 459, F.S.; and
- Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

Health care providers and practitioners may voluntarily apply to the AHCA for a certificate of exemption under the act, but are not required to do so. Such providers find it useful to obtain a certificate of exemption to present to an insurance company, particularly a PIP insurer, to prove that the provider is not required to be licensed as a health care clinic.

Health Care and Personal Injury Protection Insurance Fraud; Interim Project Report

Staff of the Senate Banking and Insurance Committee produced an interim project report, *Florida's Motor Vehicle No-Fault Law*, (2006-102). The report outlined several recommendations based on the amount of health care and Personal Injury Protection (PIP) fraud that was found.[3] The fraud statistics indicated the severity of the challenge in enforcing personal injury protection fraud violations as the number of fraud referrals escalates. According to the Director of the DIF, PIP fraud referrals have increased over 400 percent from 2002-2003 (615 referrals) to 2004-2005 (2,628).

Florida's no-fault laws are exploited by sophisticated criminal organizations in schemes that involve heath care clinic fraud, staging (faking) car crashes,[4] manufacturing false crash reports, adding occupants to existing crash reports, filing PIP claims using contrived injuries, colluding with dishonest medical treatment providers to fraudulently bill insurance companies for medically unnecessary or non-existent treatments, and patient-brokering (referring patients to medic al providers for a bounty), according to representatives with the division.

According to DIF officials, the magnitude of the PIP fraud problem is illustrated by the large number of health care clinics established in Florida under the Health Care Clinic Act (Act). Current figures indicate that over 65 percent[5] of the more than 2,435 medical clinics licensed by the AHCA statewide are located in Dade, Broward, and Palm Beach counties. Moreover, 4,590 clinics have received exemption certificates and are therefore subject to no state regulation. (This figure does not count the clinics that have decided not to file for an exemption certificate with the AHCA.) Division intelligence indicates that "hundreds" of these clinics have been established primarily in the South Florida area for the sole purpose of perpetrating PIP fraud according to DIF officials.[6]

C. SECTION DIRECTORY:

Section 1. Creates s. 400.9905(1), F.S., relating to definitions of clinical facilities.

Section 2. Provides an effective date.

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[3] Florida's Chief Financial Officer found that insurance fraud costs the average Florida family $1500 per year in increased premiums and higher costs for goods and services.

[4] Health care clinic fraud and staged accidents are the most common types of PIP fraud.

[5] National Insurance Crime Bureau, White Paper: Addressing Personal Injury Protection Fraud through the Florida Medical Fraud Task Force (August 2005).

[6] Division of Fraud Budget Request, FY 2005-2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See fiscal comments.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Facilities that are currently subject to licensure requirements and fees would no longer be subject to such requirements and fees.

D. FISCAL COMMENTS:

The Agency for Health Care Administration found that because the bill exempts certain clinics that are currently subject to licensure, there could be a reduction in the number of licensees/revenues; however, since the licensure program is growing, the net increase in other licensed clinics would offset the reduction.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

No statement provided.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Health Care Clinic Act; amending s. 400.9905, F.S.; providing that pt. X of ch. 400, F.S., does not apply to certain clinical facilities owned by publicly traded corporations; providing a definition; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (l) is added to subsection (4) of section 400.9905, Florida Statutes, to read:

400.9905 Definitions.--

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(l) Clinical facilities that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a "publicly traded corporation" is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

Section 2. This act shall take effect July 1, 2007.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **1115**

<u>COUNCIL/COMMITTEE ACTION</u>

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	______

Council/Committee hearing bill: Healthcare Council

Representative(s) Kreegel offered the following:

Amendment (with directory and title amendments)

Between lines 18 and 19, insert:

(a) Entities licensed or registered by the state under chapter 395; or entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services <u>or other health care services</u> by licensed practitioners solely within a hospital licensed under chapter 395.

====== D I R E C T O R Y A M E N D M E N T =====

Remove line(s) 10 and 11 and insert:

Amendment No. 1 (for drafter's use only)

Section 1. Paragraph (a) of subsection (4) of section 400.9905, Florida Statutes, is amended, and paragraph (l) is added to that subsection, to read:

======= T I T L E A M E N D M E N T =======

Remove line(s) 3 and insert:

400.9905, F.S.; revising the definition of the term "clinic" to exclude an entity that provides certain neonatal or pediatric health care services from licensure requirements; providing that pt. X of ch. 400, F.S.,

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1361 Emergency Services
SPONSOR(S): Garcia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Innovation	6 Y, 1 N	Ciccone	Calamas
2) Healthcare Council		Ciccone SC	Gormley CG
3) Policy & Budget Council			
4)			
5)			

SUMMARY ANALYSIS

House Bill 1361 provides for the application and operation of “off-premises” hospital emergency departments providing certain conditions are met.

The bill specifies the following criteria establishing that an off-premises emergency department:

- provides emergency services and care for any emergency medical condition that is within the service capability of the main hospital;
- is not located within described distances of a class 1 hospital in both large and small counties;
- can transport inpatient care from the off-premises emergency department to the main hospital if inpatient admission is determined by a physician;
- can ensure that the same medical specialists are available for consult as are available at the main hospital;
- has a written agreement with emergency medical services providers regarding transferring patients,
  - o the Department of Health (DOH) is to develop and implement protocols to be followed by emergency medical services providers when transporting patients, and
  - o protocols to ensure that emergency medical services providers transport persons experiencing ST segment elevation myocardial infarctions to the nearest appropriate hospital;
- has a written agreement with an acute care hospital located within one hour’s travel time and that the hospital agrees to accept the transfer of patients requiring emergency medical care not within the off-premises emergency department or its main hospital’s service capability,
  - o such agreement must specify the particular medical service to be provided; the criteria to be met by the physician who is responsible for the supervision of the off-premises emergency department; that all patients must be accepted for treatment of emergency medical conditions;
- must meet all rules governing emergency care;
- must be accredited; and
- must meet the physical plant criteria in the construction of the off-premises emergency department.

The bill provides that the distance requirements shall not be applied to off-premises emergency departments licensed prior to July 1, 2007.

The bill appears to have no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

1. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – This bill would require the Agency for Health Care Administration to establish criteria regarding off-premises emergency departments. The bill would require the Department of Health to develop and implement protocols for emergency medical services providers regarding transporting patients to off-premises emergency departments and any subsequent patient transfers from the site.

I. EFFECT OF PROPOSED CHANGES

House Bill 1361 provides criteria for hospitals to establish off-premises emergency departments. There are two state entities that are affected by this proposal: the Department of Health (DOH) and the Agency for Health Care Administration (AHCA). According to the Department of Health the new requirements in the proposal will effect minimal change—the department is required to develop and implement protocols for emergency medical services (EMS) providers to follow when transporting patients to an off-premises emergency department and when transporting patients from an off-premises emergency department to the most appropriate hospital.

The AHCA and the entities the AHCA regulates are affected in several significant ways. The AHCA establishes criteria for the location of the off-premises emergency department, to not be within a 15 mile radius of a licensed class 1 general hospital, if the location is within a county of a population of 200,000 or more; or within a 25 mile radius of a licensed class I general hospital, if the location is within a county of a population of less than 200,000. This would have an effect on the potential number of off-premises emergency departments which could be established. For example, in counties such as Pinellas, Pasco, Orange, and Miami-Dade, the distance requirements would make it unlikely that off-premises emergency departments would be established in rural counties where there are no hospitals or no hospitals within a 25 mile radius of an existing class 1 general hospital, it is also unlikely because of the distance requirements that off-premises emergency departments could exist. While the location criteria is not applicable to off-premises emergency departments licensed prior to July 1, 2007; it is unclear if it is the intent of the bill to require compliance of the remaining new criteria to these same, already licensed and operational, off-premises emergency departments.

Assuming the location of a proposed off-premises department were met, this bill adds criteria that exceed those of existing licensed on or off-premises emergency departments; setting different standards for emergency departments depending upon location. These standards include:

- The requirement to have a written agreement with emergency medical services providers to transfer patients needing emergency care,
- The requirement for the DOH to develop and implement protocols for emergency medical services providers to follow when transporting patients to or from an off-premises department,
- The requirement that the DOH develop and implement protocols for emergency medical services providers to ensure that patients experiencing ST segment elevation myocardial infarctions are transported to the nearest appropriate hospital,
- The requirement to have a written agreement with an acute care hospital located within one hour's drive time agreeing to accept transferring patients in need of emergency medical services not within the service capability of the main hospital or the off-premises emergency department,
- The requirement to be accredited by the Joint Commission on Accreditation of Healthcare Organizations, and
- The construction criteria for off-premises emergency departments, although it does not address architectural requirements or whether these architectural requirements must be met.

The bill provides clear authority for the inclusion of competitive economic considerations in the licensure process. Such considerations are usually the purview of the certificate of need process, and are rarely, if ever, found in the context of licensure. Licensure is usually concerned with quality of care. Such authority could provide a foundation for a competitor to participate in – and litigate the outcome of – the licensing process.[1]

Present Situation

By law, Florida hospitals are not required to have emergency departments but they must provide emergency care and services for the medical services within their service capability. Hospital emergency departments must meet requirements for operation and construction as identified in statute and rule.

There are currently two hospitals with off-premises emergency departments within their licensed services and locations: Munroe Regional Medical Center (MRMC) and Ft. Walton Beach Medical Center (FWB). MRMC's off-premises emergency department, Emergency Center at Timber Ridge, is located approximately 12 miles to the southwest of the MRMC main hospital in Ocala. The building was newly constructed to meet hospital standards and was added to the license of MRMC in April of 2002. The FWB off-premises emergency department is housed in a building which was previously licensed as a hospital and is located in Destin, some 12 miles from the FWB main hospital. It was licensed in October of 2003.

In 2004, Section 23, Chapter 2004-350, Laws of Florida (CS/SB 2448) directed the Agency for Health Care Administration (AHCA) to submit a report recommending whether or not hospital off-premises emergency departments were in the best interests of the public; and if so, to recommend licensure criteria, including criteria related to quality of care and the service capability of off-premises emergency departments. That report[2] found that:

- It is in the public interest to allow hospitals in certain unique communities to develop freestanding emergency departments and to have them listed separately on their license. Such communities are likely to be high growth areas within a reasonable travel time to the main hospital to enable patient transport for surgery and inpatient services. This allows growing communities to gain quicker access to emergency care but avoids the premature development of a hospital in a community that cannot yet support it.

- It is reasonable to assume that interest in freestanding emergency departments will remain limited. Factors such as liability concerns and staffing problems will prevent many hospitals from pursuing this option.

- There is currently no indication of any quality of care concerns at either of the state's two freestanding emergency departments. The two existing freestanding emergency departments have served as pilot projects to allow the AHCA to gain information about any quality problems that might be associated with freestanding facilities. Since April 2002, there have been no reports of any problem in either facility.

While there are no separate standards for off-premises emergency departments, the AHCA currently applies all the regulatory standards applicable to on premises emergency departments to off-premises emergency departments. The following regulatory standards currently apply to offsite emergency departments:

[1] See, Fla. Soc. of Ophthalmology v. St. Bd. of Optometry, 532 So.2d 1279 (Fla. 1st Dist. Ct. App. 1988); Shared Svcs., Inc., v. St. of Fla. Dept. of Health and Rehabilitative Svcs., 426 So.2d 56 (Fla. 1st Dist. Ct. App. 1983).
[2] http://ahca.myflorida.com/freestanding/docs/report.pdf

- The offsite emergency department must be inspected and meet the requirements of Rule 59A-3.255, Florida Administrative Code.

- If the hospital is accredited, the offsite location must also be accredited.

- The same services provided at the main emergency department must be provided at the freestanding emergency department, 24 hours per day, seven days per week.

- Since a freestanding emergency department is a department of the hospital, it must be able to provide emergency services and care for any emergency medical condition that is within the service capability of the hospital. Patients may be transported from one area of the hospital (offsite) to another (main) as long as emergency services and care are provided within the service capability of the hospital. Transportation from one area of the hospital (offsite) to another (main) must be provided by the hospital or through a contract with the local community EMS system. All services provided by on-call physicians must be available to patients at the offsite facility as well as the main hospital.

- A hospital's freestanding emergency department is subject to the same signage requirements (Chapter 59A-3.255, F.A.C.) as the main emergency department. Signs posted in the freestanding emergency department must be identical to signs posted in the onsite emergency department, as they must identify the service capability of the hospital.

- A list of services provided at the main campus and at the freestanding location must be provided.

- Medical screening and stabilization are required for all patients seeking emergency services at both the main emergency department and the freestanding location.

- An emergency medicine physician member of the organized medical staff must be in charge of each emergency department location.

- Supervision of care by a registered nurse qualified by relevant training and experience in emergency care for all emergency department nursing staff must be provided at each location.

- A control register identifying all persons seeking emergency care must be maintained at each location.

- Both onsite and freestanding emergency departments must have procedures in place and a listing of on-call physicians.

- Onsite and freestanding emergency departments are subject to the federal Emergency Medical Treatment and Labor Act (EMTALA) regulations as well as Florida's emergency access statute.

- The AHCA Office of Plans and Construction must review and approve construction plans for freestanding emergency departments.

- Freestanding emergency departments must meet all of the physical plant requirements, including electrical and mechanical, of an onsite emergency department as described in Section 419.4.11 of the Florida Building Code. These facilities must also meet the requirements of section 7.D.9, Definitive Emergency Care, as described in the *Guidelines for the Design and Construction of Hospitals and Health Care Facilities, 2001*, edition incorporated by referenced in Section 419.2.1.2 of the Florida Building Code.

- Freestanding emergency departments must meet the occupancy and construction requirements of the Life Safety Code and Florida Building Code relevant to the actual use of the facility.

The 2004 statute placed a moratorium on any additional off-premises emergency departments until July 1, 2005. The following year the moratorium was extended until July 1, 2006. Subsequently, the moratorium expired, and hospitals have contacted the Agency about the development of additional off-premises departments. These hospitals have been directed that the same standards for operation and construction must be met as those for any hospital emergency department. Two hospitals have submitted construction plans to the Agency which have completed Stage 1 or Stage 2 review.

There are currently no limitations on where an off-premises emergency department can be located; however an off-premises emergency department can only be established by an existing licensed hospital as a department of that same hospital. The off-premises emergency department must be accredited by the same entity as the main hospital if that hospital is accredited (but hospitals and emergency departments are not required to be accredited), and must provide the same emergency services as are provided by the main hospital. Medical specialists must be on call and available to provide services 24/7. All emergency departments (on and off-premises) are subject to the federal Emergency Medical Treatment and Labor Act (EMTALA) and Florida emergency access statutes. Off-premises emergency departments must meet the same requirements as on site emergency departments. Policies and procedures must include direction of the emergency department by a designated physician who is a member of the organized medical staff. All hospitals and their emergency departments, whether on or off-premises, must treat all patients regardless of ability to pay. Hospitals are not required to have written transfer agreements with emergency medical services providers.

2. SECTION DIRECTORY:

Section 1. Amends s. 395.1041(6), F.S., relating to access to emergency services.

Section 2. Provides an effective date of July 1, 2007.

3. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

4. Revenues:

   None.

5. 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 require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

6. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

No statement provided.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 20, 2007, the Health Innovation Committee adopted one strike-all amendment to the bill. This amendment:

- Provided licensure criteria for hospital off-premises emergency departments.
- Directed the Agency for Health Care Administration to review hospital licensure applications for off-premises emergency departments based on certain criteria.

The bill was reported favorably with one strike-all amendment.

A bill to be entitled

An act relating to emergency services; amending s. 395.1041, F.S.; providing for hospitals to apply for a license to operate off-premises emergency departments; providing licensure criteria; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (8) is added to section 395.1041, Florida Statutes, to read:

395.1041 Access to emergency services and care.--

<u>(8) OFF-PREMISES EMERGENCY DEPARTMENTS.--A hospital may apply for a license to operate an emergency department at a location off the hospital's premises provided that the application complies with all of the requirements of this subsection. An off-premises emergency department must provide emergency services and care for any emergency medical condition that is within the service capability of the hospital seeking a license for an off-premises emergency department. Criteria for licensure of off-premises emergency departments are as follows:</u>

<u>(a) In a county with a population of 200,000 or more, an off-premises emergency department may not be located within a 15-mile radius of the nearest licensed class 1 general hospital. In a county with a population of less than 200,000, an off-premises emergency department may not be located within a 25-mile radius of the nearest licensed class 1 general hospital. The distance requirements of this paragraph shall be determined as of the date of initial licensure of the off-premises</u>

emergency department and shall not be applicable to any off-premises emergency department licensed prior to July 1, 2007.

(b) Patients may be transported from an off-premises emergency department to the premises of the hospital that holds the off-premises emergency department license for inpatient care only after a physician determines that the patient requires inpatient admission. The off-premises emergency department must ensure that the same types of medical specialists as are available on the premises of the hospital are available to consult with patients at the off-premises emergency department.

(c) An off-premises emergency department must have a written agreement with emergency medical services providers for the transfer of patients in need of emergency care. The Department of Health shall develop and implement protocols for emergency medical services providers to follow when transporting patients to an off-premises emergency department and from an off-premises emergency department to the most appropriate hospital, without regard to whether that hospital holds the off-premises emergency department license. The Department of Health shall develop and implement protocols to ensure that emergency medical services providers transport persons experiencing ST segment elevation myocardial infarctions to the nearest appropriate hospital, without regard to whether that hospital holds the off-premises emergency department license.

(d) An off-premises emergency department must have a written agreement with an acute care hospital located within 1 hour's drive time that has agreed to accept the transfer of patients in need of emergency medical services that are not within the service capability of the off-premises emergency department or its licensed acute care hospital. The transfer agreement must specify the medical services to which the transfer agreement applies and contain a transfer protocol executed by the off-premises emergency department and the receiving hospital.

(e) An off-premises emergency department must be supervised at all times by a physician who is a member of the hospital's medical staff and who is board certified by the American College of Emergency Physicians.

(f) An off-premises emergency department must treat all patients with emergency medical conditions without regard for their ability to pay.

(g) An off-premises emergency department must comply with rules adopted that govern emergency care.

(h) An off-premises emergency department must be accredited by the Joint Commission on the Accreditation of Healthcare Organizations or an equivalent credentialing body.

(i) An off-premises emergency department must meet all physical plant requirements, including electrical and mechanical requirements, of an onsite emergency department as specified in the Florida Building Code, as amended. These facilities must also meet the requirements for Definitive Emergency Care, as described in the Guidelines for the Design and Construction of Hospitals and Health Care Facilities, 2001, incorporated by reference in section 419.2.1.2 of the Florida Building Code, as amended.

Section 2. This act shall take effect July 1, 2007.

Amendment No. _____ (for drafter's use only)

Bill No. **HB 1361**

COUNCIL/COMMITTEE ACTION

ADOPTED __ (Y/N)

ADOPTED AS AMENDED __ (Y/N)

ADOPTED W/O OBJECTION __ (Y/N)

FAILED TO ADOPT __ (Y/N)

WITHDRAWN __ (Y/N)

OTHER ______

Council/Committee hearing bill: Healthcare Council

Representative(s) Galvano offered the following:

Substitute Amendment for Amendment (1) by the Committee on Health Innovation (with directory and title amendments)

Remove everything after the enacting clause and insert:

Section 1. Subsection (1) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; issuance, renewal, denial, modification, suspension, and revocation.--

(1)(a) A person may not establish, conduct, or maintain a hospital, ambulatory surgical center, or mobile surgical facility in this state without first obtaining a license under this part.

(b)1. It is unlawful for a person to use or advertise to the public, in any way or by any medium whatsoever, any facility as a "hospital," "ambulatory surgical center," or "mobile surgical facility" unless such facility has first secured a license under the provisions of this part.

2. This part does not apply to veterinary hospitals or to commercial business establishments using the word "hospital,"

"ambulatory surgical center," or "mobile surgical facility" as a part of a trade name if no treatment of human beings is performed on the premises of such establishments.

~~3. Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be authorized by the agency.~~

(c) A hospital may apply for a license to operate an emergency department at a location off the hospital's premises and the agency shall approve such license if the hospital complies with all of the following criteria:

1. The off-premises emergency department must provide emergency services and care for any emergency medical condition that is within the service capability of the hospital seeking the license.

2. The off-premises emergency department must ensure that the same types of medical specialties that are available to the hospital seeking the license are available for consultations to patients of the off-premises emergency department.

3. The licenseholder must provide for the transport of patients between the off-premises emergency department and its licensed hospital consistent with chapter 401. The department shall determine whether statewide transport and transfer protocols should be developed with respect to off-premises emergency departments and shall report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 31, 2008.

4. The off-premises emergency department must be directed by a designated physician who is a member of the organized medical staff.

5. The off-premises emergency department must treat all patients who have an emergency medical condition without regard to ability to pay.

6. The off-premises emergency departments must comply with all adopted rules governing emergency care.

7. If the main hospital is accredited, the off-premises emergency department must be accredited by the same accrediting organization.

8. The off-premises emergency department must meet all physical plant requirements, including electrical, architectural, and mechanical of an onsite emergency department as specified in the Florida Building Code. The facility must also meet the requirements for Definitive Emergency Care, as described in the Guidelines for the Design and Construction of Health Care Facilities, 2006 edition, incorporated by reference in Section 419.2.1.2 of the Florida Building Code.

Section 2. An off-premises emergency department of a hospital operating as of July 1, 2007, may continue to operate in accordance with the licensure criteria under which it was originally approved by the agency. A hospital that has received a letter of nonreviewability from the agency for an off-premises emergency department and has had Stage 2 architectural plans approved by July 1, 2007, is subject to the licensure criteria in existence before July 1, 2007.

Section 3. This act shall take effect July 1, 2007.

================ T I T L E A M E N D M E N T =============

Remove the entire title and insert:

A bill to be entitled

An act relating to hospitals; amending s. 395.003, F.S.; authorizing hospitals to operate an off-premises emergency department; requiring a license; providing criteria; providing that all off-premises emergency departments operating as of a certain date may continue to operate in accordance with the criteria in effect at the time of approval and that an off-premises emergency department that has had architectural plans approved by a certain date is subject to the license criteria in effect at the time of submission; providing an effective date.

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	______

Council/Committee hearing bill: Healthcare Council

The Committee on Health Innovation offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (8) is added to section 395.1041, Florida Statutes, to read:

395.1041 Access to emergency services and care.--

(8) Off-premises emergency departments.--Hospitals may apply for a license to operate an emergency department at a location off the hospital's premises and the agency shall approve such license provided that the application complies with all of the requirements of this section. Off-premises emergency departments must provide emergency services and care for any emergency medical condition that is within the service capability of the hospital seeking a license for an off-premises emergency department. Criteria for licensure of off-premises emergency departments are as follows:

(a) In counties of more than 200,000 persons, an off-premises emergency department may not be located within a 10 mile radius of the nearest licensed Class 1 general hospital. In counties of less than 200,000 persons, an off-premises emergency department may not be located within a 20 mile radius of the nearest licensed Class 1 general hospital. The distance requirements of this sub-paragraph shall be determined as of the date of initial licensure of the off-premises emergency department and shall not be applicable to any off-premises emergency department licensed prior to the effective date of this act.

(b) The off-premises emergency department must ensure that the same types of medical specialties as are available on the premises of the hospital are available to consult with patients of the off-premises emergency department.

(c) The license holder must provide for the transport of patients between the off-premises emergency department and its licensed hospital. The Department of Health shall determine whether statewide transport protocols should be developed with respect to off-premises emergency departments and shall report its findings to the Speaker of the House, President of the Senate, and the Governor no later than January 31, 2008.

(d) Off-premises emergency departments must be directed by a designated physician who is a member of the organized medical staff.

(e) Off-premises emergency departments shall treat all patients with an emergency medical condition without regard to ability to pay.

(f) Off-premises emergency departments must comply with all adopted rule standards governing emergency care.

(g) If the main hospital is accredited, the off-premises emergency departments must be accredited by the same accrediting organization.

(h) Off-premises emergency departments must meet all physical plant requirements, including electrical, architectural and mechanical, of an onsite emergency department as specified in the Florida Building Code. These facilities must also meet the requirements for Definitive Emergency Care, as described in the Guidelines for the Design and Construction of Health Care Facilities, 2006 edition incorporated by reference in Section 419.2.1.2 of the Florida Building Code.

Section 2. This act shall take effect upon becoming a law.

================ T I T L E A M E N D M E N T ================

Remove the entire title and insert:

A bill to be entitled

An act relating to emergency services; amending s. 395.1041, F.S.; providing for hospitals to apply for a license to operate off-premises emergency departments; providing licensure criteria; providing an effective date.

HB 1477

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1477 Forensic Mental Health Services
SPONSOR(S): Ausley and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 542

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Healthy Families	8 Y, 0 N	Mitchell	Mitchell
2) Healthcare Council		Mitchell	Gormley
3) Policy & Budget Council			
4)			
5)			

SUMMARY ANALYSIS

HB 1477 creates the Public Safety Mental Health and Substance Abuse Local Matching Grant Program. It provides matching grant awards to local communities to address the needs of persons with serious mental illness and substance abuse problems who are in or at risk of entering the criminal justice system. It establishes the Criminal Justice Mental Health Policy Council within the Substance Abuse and Mental Health Corporation to oversee the grants and creates the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center to help local communities plan and implement their local efforts.

The House version of the General Appropriations Act appropriates $4,000,000 from the General Revenue Fund to provide grants through the Public Safety, Mental Health and Substance Abuse Matching Grant program and to establish the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center.

The enacting date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government: The bill provides grants for local communities to plan and implement programs to better use local resources to serve people with serious mental illnesses and substance use disorders in Florida's criminal justice system, to reduce the number who must be held in state forensic mental health facilities and prisons.

B. EFFECT OF PROPOSED CHANGES:

This bill addresses the high number of people with serious mental illnesses and substance use disorders in Florida's criminal justice system. The bill provides for grants to communities to bring together key stakeholders to implement programs to serve this population and help reduce the use of state forensic treatment facilities and prisons. The bill requires equal local matching funds.

Currently there is no required planning process that brings together all of the local stakeholders who should be addressing the needs of this population. Local governments, the judiciary, law enforcement, providers of mental health and substance abuse services, advocates, consumers and state agencies should all be working together to address the situation.

The bill amends the composition of the local Public Safety Councils to include mental health and substance abuse experts and consumers, and to require them to make recommendations to the county boards of commissioners regarding local forensic mental health and substance abuse problems.

Based upon these recommendations, counties can apply for local matching grant awards. Grant awards include a 1-year planning grant or a 3-year implementation grant. Both awards require counties to address systemic change for the identification and treatment of mental illnesses and substance abuse disorders, and strategies to divert these individuals from commitment to the department under s. 916.17, F.S.

The Criminal Justice Mental Health Policy Council of the Florida Substance Abuse and Mental Health Corporation will establish award criteria and notify the department of approved applications. The composition of the Council includes the Secretaries of the Departments of Children and Family Services, Corrections, Health Care Administration, Juvenile Justice and the State Courts Administrator who will serve as the grant review committee for the program.

The bill creates the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center at the Louis de la Parte Florida Mental Health Institute at the University of South Florida. The Technical Assistance Center will assist local communities with their planning and implementation. The Technical Assistance Center and the Florida Substance Abuse and Mental Health Corporation will jointly submit annual reports concerning the program to the Governor, President of the Senate and Speaker of the House.

PRESENT SITUATION

According to the Department of Children and Families, as of March 7, 2007, there are 218 persons designated incompetent to proceed to trial or not guilty by reason of insanity, awaiting placement in a state mental health forensic treatment facility. One hundred fifty individuals have been waiting longer than 15 days for admission due to lack of available capacity.

Currently, the Department of Children and Families and the Department of Corrections work to ensure former inmates with severe and persistent mental illnesses receive aftercare follow-up. The department, including its state mental health treatment facilities, works with community mental health providers to identify limited resources to serve forensic individuals in the community who remain under court jurisdiction on conditional release or administrative probation.

Many individuals with mental illnesses and co-occurring substance abuse disorders become involved with the criminal justice system because they lack access to appropriate therapeutic services and medications. Often, they become repeat offenders and eventually serve time in prison. In addition, many individuals with chronic mental illnesses are referred to state mental health treatment facilities due to a lack of local coordination of resources to address their needs. Many of these individuals can receive community-based services that are more appropriate and cost-effective in meeting their needs.

The GAINS Center of the U. S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, estimates approximately 800,000 persons with serious mental illness are admitted to U.S. jails annually and 72 percent of these individuals meet criteria for co-occurring substance abuse. The Bureau of Justice Statistics reports over 16 percent of adults incarcerated in U.S. jails and prisons have mental illnesses. According to the Florida Commission on Mental Health and Substance Abuse, at least 15,870 inmates in Florida's jails and prisons have mental illnesses. Approximately 16 percent of the adult correctional population has a mental illness (Department of Corrections, 2006).

The Department of Corrections 2005 data indicates approximately 64 percent (54,242) of the inmate prison population (84,895) are identified as being in need of substance abuse treatment. Of those, 17 percent have a co-occurring mental illness needing treatment.

In June 2006, the Department of Children and Families, Department of Juvenile Justice and Department of Corrections applied for a grant from the Bureau of Justice Assistance to implement local, community planning grants for addressing the needs of individuals with mental illnesses involved with the criminal justice system. Although a grant award was not received, community planning and implementation grants with major stakeholder involvement can build on these efforts to help address the problems of persons with mental health and substance abuse problems in Florida's forensic system who are most in need of treatment.

C. SECTION DIRECTORY:

Section 1. Creates s. 394.6551, F.S., establishing the Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program and program requirements.

Section 2. Amends s. 951.26, F.S., relating to Public Safety Councils to add membership representing mental health and substance abuse stakeholders and require recommendations to the board of county commissioners on use of grant funds.

Section 3. Creates an unnumbered section of Florida Statutes to establish a Criminal Justice Mental Health Policy Council and its requirements.

Section 4. Provides for the establishment of the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center to assist communities in planning and implementing their local efforts.

Section 5. Provides the effective date of the bill of upon become law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

The House version of the General Appropriations Act (GAA) appropriates $4,000,000 from the General Revenue Fund to provide grants through the Public Safety, Mental Health and Substance Abuse Matching Grant program and to establish the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center. The proviso in the House proposed GAA specifies that $3,850,000 shall be used to provide grants and $150,000 is for the technical assistance center.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

The bill requires local governments to provide equal matching funds in order to receive a grant award.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

Estimated expenditures for the Substance Abuse and Mental Health Corporation and the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center are based on the following cost analysis provided by the department:

- First year non-recurring furniture and computer expenses of $4,328.
- Recurring PG 26 equivalent position with travel and expenses, for the Substance Abuse and Mental Health Corporation of $90,251, in the first year and $113,826 in the second year.
- Travel expenses to 12 meetings and meeting space for the SAMH Corporation Review Committee of $20,000 each year.
- The Florida Mental Health Institute Public Safety, Mental Health, and Substance Abuse Technical Assistance Center indicates it will require at least $500,000 each year to perform the legislatively mandated functions. The Institute will hire a Center director and Staff expert in methods for collecting and analyzing data as required by the bill.
- Printing of annual report is estimated to cost $5,000 each year.

The Florida Mental Health Institute indicates it has the technical ability to perform the functions detailed in this bill but it is difficult to predict the cost of performing the required functions. Staff will be required to analyze the utilization of services and to evaluate the performance of the counties.

The bill requires the Department of Children and Families to be the pass-through agent for the grant awards, providing transfer authority to the counties receiving grant awards. According to the department if funding for 3-year implementation grants provide a significant increase in funding, the department may require additional contract management staff to cover the increased workload.

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 proposed bill requires communities to use the local Public Safety Councils and does not allow for other bodies such as Miami-Dade County Mayor's Task Force that are currently addressing this issue. In discussions with counties, some wish to have flexibility to use existing task forces for this purpose.

D. STATEMENT OF THE SPONSOR

No statement provided.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 20, 2007, the Committee on Healthy Families adopted an amendment by the bill sponsor that is traveling with the bill, and voted the bill favorably.

The amendment provides that the bill takes effect only if a specific appropriation to fund its provisions is made in the General Appropriations Act. The House version of the General Appropriations Act contains an appropriation.

A bill to be entitled

An act relating to forensic mental health services; creating s. 394.6551, F.S.; creating the Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program within the Department of Children and Family Services, contingent upon an appropriation by the Legislature; requiring the Substance Abuse and Mental Health Corporation, in collaboration with the department, to establish criteria to be used by the Criminal Justice Mental Health Policy Council to award grants; providing for planning grants and implementation or expansion grants; providing definitions; requiring public safety councils to make recommendations to county boards of commissioners regarding implementation of the grant program; providing eligibility criteria for grants; providing a limitation on administrative costs; amending s. 951.26, F.S.; revising the membership of public safety coordinating councils; requiring public safety councils to make recommendations to county boards of commissioners regarding implementation of the grant program; creating s. 951.261, F.S.; creating the Criminal Justice Mental Health Policy Council within the Substance Abuse and Mental Health Corporation; providing for membership; providing the purpose of the council; requiring that the council serve as the statewide Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program review committee; requiring the council to submit a list of approved applicants for such grants; requiring the council to work with other specified entities; providing for agency liaisons; establishing the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center within the Louis de la Parte Florida Mental Health Institute at the University of South Florida; providing for certain functions to be performed by the center; requiring the center to submit an annual report to the Governor and Legislature by a specified date; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 394.6551, Florida Statutes, is created to read:

<u>394.6551 Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program.--Contingent upon an annual appropriation by the Legislature, the Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program is established and shall be operated by the Department of Children and Family Services for the purpose of providing funds to counties to plan, implement, or expand initiatives that will increase public safety, avert increased corrections expenditures, and improve the accessibility and effectiveness of mental health and substance abuse treatment services for persons with mental illnesses, substance abuse disorders, or co-occurring mental health and substance abuse disorders and who are in, or at risk of entering, the criminal justice system.</u>

<u>(1) The Substance Abuse and Mental Health Corporation in</u>

collaboration with the Department of Children and Family Services shall establish criteria to be used by the Criminal Justice Mental Health Policy Council created under s. 951.261 to award public safety, mental health, and substance abuse local matching grants in the form of planning grants and implementation or expansion grants.

(a) To receive a 1-year planning grant, a county or consortium of counties must provide information that demonstrates a strategic, collaborative plan to initiate systemic change for the identification and treatment of persons with mental illnesses, substance abuse disorders, or co-occurring mental health and substance abuse disorders who are in, or at risk of entering, the criminal justice system. The 1-year planning grant shall include support from all levels of government and criminal justice, mental health, and substance abuse treatment services, including public-private partnership models. The planning grant shall address strategies to divert individuals from commitment to the department in accordance with s. 916.17.

(b) To receive a 3-year implementation or expansion grant, a county must provide information that demonstrates the completion of a well-established collaboration plan that includes public-private partnership models and demonstrates best use and evidence-based practices. Implementation or expansion grants may support programs and initiatives such as mental health courts and diversion and alternative prosecution and sentencing programs, crisis intervention teams, treatment accountability services, specialized training for criminal justice and treatment services professionals, service delivery for collateral services such as housing and corrections, transitional housing, and supported employment and reentry services to create or expand mental health and substance abuse support services. Each application must include the following information:

1. An analysis of the current jail population in the county, which includes:

a. The screening and assessment process that the county uses to identify a person with mental illness, a substance abuse problem, or a co-occurring disorder.

b. The percentage of persons admitted to the jail with mental illness, a substance abuse problem, or a co-occurring disorder, respectively.

c. An analysis of observed contributing factors that affect county jail population trends.

2. The strategies the county intends to use to serve one or more clearly defined subsets of the jail population with mental illness or those at risk of arrest and incarceration. The proposed strategies may include the identification of the population designated to receive the new interventions, a description of the services and supervision strategies to be applied to that population, and the goals and measurable objectives of the new interventions. The interventions a county may use may include, but are not limited to:

a. Specialized responses by law enforcement agencies.

b. Centralized receiving facilities for an individual evidencing behavioral difficulties.

c. Postbooking alternatives to incarceration.

d. New court programs, including pretrial services and specialized dockets.

e. Specialized diversion programs.

f. Intensified transition services that are directed to designated populations while an individual is incarcerated and services to facilitate transition back into the community.

g. Specialized probation processes.

h. Day-reporting centers.

i. Specific linkages to community-based, evidence-based treatment programs for persons with mental illnesses who are in, or at risk of entering, the criminal justice system.

j. Community services and programs designed to prevent high-risk populations from becoming involved in the criminal justice system.

3. The projected impact of the proposed initiative on the jail population and the jail's budget, including:

a. How the county's proposed initiative will reduce the expenditures associated with the incarceration of persons with mental illnesses.

b. The methodology that the county will use to measure the defined outcomes and the corresponding fiscal savings or averted costs.

c. How the fiscal savings or averted costs will facilitate the sustainability or expansion of mental health or substance abuse services in the community.

d. How the county's proposed initiative will reduce the number of individuals committed to state mental health treatment

<u>facilities.</u>

<u>4. The proposed strategies that the county will use to preserve and enhance its community mental health and substance abuse system that serves as the local behavioral health safety net and receives federal, state, and local funding to serve low-income and uninsured individuals, and the proposed strategies for long-term sustainability of the implemented or expanded programs and initiatives that resulted from this grant funding.</u>

<u>(2)(a) A 1-year planning grant may not be awarded unless the applicant county or consortium of counties contributes available resources in an amount equal to the total amount of the grant.</u>

<u>(b) A 3-year implementation or expansion grant may not be awarded unless the applicant county or consortium of counties contributes available resources equal to the total amount of the grant. This contribution must be used for expansion of services and not to supplant existing funds dedicated to providing those services. An implementation or expansion grant must be used for the implementation of new services or the expansion of existing services and not to supplant existing funds for services.</u>

<u>As used in this subsection, the term "available resources" includes in-kind contributions from participating counties.</u>

<u>(3) Public safety coordinating councils, in coordination with county offices of planning and budget, shall make a formal recommendation to the board of county commissioners regarding how the Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program may best be implemented within the</u>

community. Other established criminal justice, mental health, and substance abuse planning committees or task forces are not prohibited from making recommendations to the board of county commissioners regarding the grant program. The board of county commissioners may assign any entity to prepare the application on behalf of the county administration for submission to the corporation for review.

(4)(a) Upon majority approval by the board of county commissioners of a county, a county administration may apply for a 1-year planning grant or a 3-year implementation or expansion grant for investment in treatment services for persons with mental illnesses, substance use disorders, or co-occurring mental health and substance use disorders who are in, or at risk of entering, the criminal justice system.

(b) To be eligible to receive a 1-year planning grant or a 3-year implementation or expansion grant, the applying county must have an established planning committee to assist in implementing the grant proposal.

(5) The administrative costs for each county or consortium of counties shall not exceed 10 percent of the dollars received for planning grants or for implementation and expansion grants.

Section 2. Subsections (1) and (2) of section 951.26, Florida Statutes, are amended to read:

951.26 Public safety coordinating councils.--

(1) Each board of county commissioners shall establish a county public safety coordinating council for the county or shall join with a consortium of one or more other counties to

establish a public safety coordinating council for the geographic area represented by the member counties.

(a)1. The public safety coordinating council for a county shall consist of:

a. The state attorney, or an assistant state attorney designated by the state attorney.

b. The public defender, or an assistant public defender designated by the public defender.

c. The chief circuit judge, or another circuit judge designated by the chief circuit judge.

d. The chief county judge, or another county judge designated by the chief county judge.

e. The chief correctional officer or the chief of police of the largest municipality within the county, or a member designated by the chief of police.

f. The sheriff, or a member designated by the sheriff, if the sheriff is not the chief correctional officer.

g. The state probation circuit administrator, or a member designated by the state probation circuit administrator, to be appointed to a 4-year term.

h. The court administrator or designee.

i.~~h.~~ The chairperson of the board of county commissioners, or another county commissioner as designee, or, in the case of a consortium of counties, a county commissioner or designee from each member county.

j.~~i.~~ If the county has such program available, the director of any county probation or pretrial intervention program, to be appointed to a 4-year term.

k.~~j.~~ The director of a local substance abuse treatment program, or a member designated by the director, to be appointed to a 4-year term.

l. The director of a community mental health agency operating in the county, or a member designated by the director.

m. A representative of the Mental Health and Substance Abuse Program Offices of the Department of Children and Family Services selected by the district administrator of the service district having jurisdiction over the county.

n. The director of a juvenile justice detention facility in the county, or a member designated by the director.

o.~~k.~~ Representatives from county and state jobs programs and other community groups who work with offenders and victims, appointed by the chairperson of the board of county commissioners to 4-year terms.

p. Three representatives recommended by members of the mental health or substance abuse community appointed by the board of county commissioners from the following list:

(I) A primary consumer of mental health services, recommended by the district administrator of the district having jurisdiction over the county.

(II) A primary consumer of substance abuse treatment services, recommended by the district administrator of the district having jurisdiction over the county.

(III) A primary family member of a consumer of community-based mental health or substance abuse treatment services, recommended by the district administrator of the district having jurisdiction over the county.

(IV) A physician who practices in the area of alcohol and substance abuse.

(V) A physician who practices in the area of psychiatry.

(VI) A psychiatrist familiar with community-based care.

(VII) A representative from an area homeless program or supportive housing coalition.

2. The chairperson of the board of county commissioners, or another county commissioner as designee, shall serve as the chairperson of the council until the council elects a chairperson from the membership of the council.

(b)1. The public safety coordinating council for a consortium of two or more counties shall consist of the following members, appointed with the approval of each board of county commissioners within the consortium:

a. A chief circuit judge, or a circuit judge designated by a chief circuit judge.

b. A chief county judge, or a county judge designated by a chief county judge.

c. A state attorney, or an assistant state attorney designated by a state attorney.

d. A public defender, or an assistant public defender designated by a public defender.

e. A state probation circuit administrator, or a member designated by a state probation circuit administrator, to be appointed to a 4-year term.

f. A physician who practices in the area of alcohol and substance abuse, to be appointed to a 4-year term.

g. A mental health professional who practices in the area of alcohol and substance abuse, to be appointed to a 4-year term.

h. A sheriff or a jail administrator for a county within the consortium.

i. A chief of police for a municipality within the geographic area of the consortium.

j. A county commissioner from each member county of the consortium.

k. An elected member of the governing body of the most populous municipality within the geographic area of the consortium.

l. An elected member of a school board within the geographic area of the consortium.

2. The members of the public safety coordinating council shall elect a chairperson from among its members.

(2) The council shall meet at the call of the chairperson for the purpose of assessing the population status of all detention or correctional facilities owned or contracted by the county, or the county consortium, and formulating recommendations to ensure that the capacities of such facilities are not exceeded. Such recommendations shall include an assessment of the availability of pretrial intervention or probation programs, work-release programs, substance abuse programs, gain-time schedules, applicable bail bond schedules, and the confinement status of the inmates housed within each facility owned or contracted by the county, or the county consortium. <u>The council shall also provide a formal</u>

recommendation to the board of county commissioners in coordination with the county's or counties' offices of planning and budget on how the Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program may be best implemented within their community.

Section 3. Section 951.261, Florida Statutes, is created to read:

951.261 Criminal Justice Mental Health Policy Council.--

(1) The Substance Abuse and Mental Health Corporation shall establish a Criminal Justice Mental Health Policy Council, which shall consist of the following members:

(a) The chairperson of the corporation.

(b) The Secretary of Children and Family Services.

(c) The Secretary of Corrections.

(d) The Secretary of Health Care Administration.

(e) The Secretary of Juvenile Justice.

(f) The State Courts Administrator.

(2) The purpose of the council is to align policy initiatives in the criminal justice and mental health systems to ensure the most effective use of resources and to coordinate the development of legislative proposals and budget requests relating to the shared needs of persons with mental illnesses, substance abuse problems, and co-occurring mental health and substance abuse problems who are in, or at risk of entering, the criminal justice system. The council shall also serve as the statewide grant review committee for the Public Safety, Mental Health, and Substance Abuse Local Matching Grant Program.

(3) The council shall provide the department with a list

of the applications that are approved to receive planning grants and implementation or expansion grants. The department is authorized to transfer funds to the county or counties that are awarded grants.

(4) The council shall work with local grantees to develop statewide strategies. The council shall coordinate its efforts with the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center.

(5) Each member agency of the council shall designate an agency liaison.

Section 4. Establishment of Public Safety, Mental Health, and Substance Abuse Technical Assistance Center.--The Legislature shall establish the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center at the Louis de la Parte Florida Mental Health Institute at the University of South Florida.

(1) Recipients of public safety, mental health, and substance abuse local matching grants awarded under s. 394.6551, Florida Statutes, shall receive technical assistance from the center for preparation, development, and evaluation of planning grants and implementation or expansion grants. The center shall:

(a) Provide technical assistance to counties that are applying for a grant.

(b) Assess the impact of the proposed intervention on the population of the county detention facility.

(c) Provide technical assistance to counties that are awarded a grant.

(d) Monitor the impact of grant awards on the criminal justice system in the counties that receive the grants.

(e) Disseminate and share evidenced-based practices and best practices among grantees.

(f) Act as a clearinghouse for information and resources related to criminal justice, mental health, and substance abuse services.

(2) The Florida Substance Abuse and Mental Health Corporation and the Public Safety, Mental Health, and Substance Abuse Technical Assistance Center shall jointly submit an annual report concerning the grant program to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1 of each year, beginning on January 1, 2009. The report must include:

(a) A detailed description of the progress made by each grantee to meet the goals described in the application.

(b) The impact of grant-funded initiatives on meeting the needs of persons with mental illnesses, substance use disorders, or co-occurring mental health and substance use disorders who are in, or at risk of entering, the criminal justice system, thereby reducing the number of forensic commitments to state mental health treatment facilities.

(c) A summary of the impact of the grant program on jail and prison growth and expenditures.

(d) A summary of the impact of the grant program on the availability and accessibility of effective community-based mental health and substance abuse treatment services for people with mental illnesses, substance use disorders, or co-occurring mental health and substance use disorders who are in, or at risk

<u>of entering, the criminal justice system, thereby expanding community diversion alternatives to incarceration and placement in a state mental health treatment facility.</u>

<u>(e) A summary of the local match provided by the county or consortium and the effect of the funding on furthering the goals of the grant program.</u>

Section 5. This act shall take effect upon becoming law.

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	______	

Council/Committee hearing bill: Healthcare Council

Representative(s) Ausley offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Criminal Justice, Mental Health, and Substance Abuse Reinvestment Grant Program.--

(1) There is created within the Department of Children and Family Services the Criminal Justice, Mental Health, and Substance Abuse Reinvestment Grant Program. The purpose of the program is to provide funding to counties with which they can plan, implement, or expand initiatives that increase public safety, avert increased spending on criminal justice, and improve the accessibility and effectiveness of treatment services for adults and juveniles who have a mental illness, substance use disorder, or co-occurring mental health and substance use disorder and who are in, or at risk of entering, the criminal or juvenile justice system.

(2) The Florida Substance Abuse and Mental Health Corporation created in s. 394.655, shall create a statewide grant review subcommittee. The subcommittee shall include:

(a) Five current members or appointees of the corporation;

(b) One representative of the Department of Children and Family Services;

(c) One representative of the Department of Corrections;

(d) One representative of the Department of Juvenile Justice;

(e) One representative of the Department of Elderly Affairs; and

(f) One representative of the State Courts Administrator.

To the extent possible, the members of the subcommittee shall have expertise in grant writing, grant reviewing, and grant application scoring.

(3)(a) A county may apply for a 1-year planning grant or a 3-year implementation or expansion grant. The purpose of the grants are to demonstrate that investment in treatment efforts related to mental illness, substance abuse disorders, or co-occurring mental health and substance abuse disorders results in reduced demand on the resources of the judicial, corrections, juvenile detention, or health and social services systems.

(b) To be eligible to receive a 1-year planning grant or a 3-year implementation or expansion grant, a county applicant must have a county planning committee that is in compliance with the membership requirements set forth in this section.

(4) The grant review subcommittee shall notify the Department of Children and Family Services in writing of the applicants who have been selected by the subcommittee to receive a grant. Contingent upon the availability of funds and upon notification by the review committee of those applicants approved to receive planning, implementation, or expansion grants, the Department of Children and Family Services may

transfer funds appropriated for the grant program to any county awarded a grant.

Section 2. County planning councils or committees.--

(1) Each board of county commissioners shall use its public safety coordinating council established in s. 951.26, another criminal or juvenile justice mental health and substance abuse council or committee designated or established by the board of county commissioners as the planning council. The public safety coordinating council or other designated criminal or juvenile justice mental health and substance abuse council or committee, in coordination with the county offices of planning and budget, shall make a formal recommendation to the board of county commissioners regarding how the Criminal Justice, Mental Health, and Substance Abuse Reinvestment Grant Program may best be implemented within a community. The board of county commissioners may assign any entity to prepare the application on behalf of the county administration for submission to the corporation for review. A county may join with one or more counties to form a consortium and use a regional public safety coordinating council or another county-designated regional criminal or juvenile justice mental health and substance abuse planning council or committee for the geographic area represented by the member counties.

(2)(a) For the purposes of this section, the membership of a designated planning council or committee must include:

1. The state attorney, or an assistant state attorney designated by the state attorney.

2. The public defender, or an assistant public defender designated by the public defender.

3. A circuit judge designated by the chief judge of the circuit.

<u>4. A county court judge designated by the chief judge of the circuit.</u>

<u>5. The chief correctional officer.</u>

<u>6. The sheriff, or a person designated by the sheriff if the sheriff is not the chief correctional officer.</u>

<u>7. A police chief or a person designated by the local police chief's association.</u>

<u>8. The state probation circuit administrator, or a person designated by the state probation circuit administrator.</u>

<u>9. The local court administrator or the court administrator's designee.</u>

<u>10. The chairperson of the board of county commissioners, or another county commissioner designated by the chairperson, or if the planning council is a consortium of counties, a county commissioner or designee from each member county.</u>

<u>11. The director of any county probation or pretrial intervention program, if the county has such a program.</u>

<u>12. The director of a local substance abuse treatment program, or a person designated by the director.</u>

<u>13. The director of a community mental health agency, or a person designated by the director.</u>

<u>14. A representative of the substance abuse and mental health program office of the Department of Children and Family Services, selected by the substance abuse and mental health program supervisor of the district in which the county is located.</u>

<u>15. A primary consumer of mental health services, selected by the substance abuse and mental health program supervisor of the district in which the primary consumer resides. If multiple counties apply together, a primary consumer may be selected to represent each county.</u>

16. A primary consumer of substance abuse services, selected by the substance abuse and mental health program supervisor of the district in which the county is located. If the planning council is a consortium of counties, a primary consumer may be selected to represent each county.

17. A family member of a primary consumer of community-based treatment services, selected by the abuse and mental health program supervisor of the district in which the family member resides.

18. A representative from an area homeless program or a supportive housing program.

19. The director or designee of the detention facility of the Department of Juvenile Justice.

20. The chief probation officer of the Department of Juvenile Justice, or an employee designated by the chief probation officer.

(b) The chairperson of the board of county commissioners or another county commissioner, if designated, shall serve as the chairperson of the council or committee until a chairperson is elected from the membership.

(c) All meetings of the planning council or committee, as well as its records, books, documents, and papers, shall be open and available to the public in accordance with ss. 119.07 and 286.011.

(3)(a) If a public safety coordinating council established in s. 951.26, is used as the planning council, its membership must include all persons listed in subparagraphs (2)(a)1-20.

(b) A public safety coordinating council that is acting as the planning council must include an assessment of the availability of mental health programs in addition to the assessments required in s. 951.26(2).

Section 3. Criminal Justice, Mental Health, and Substance Abuse Reinvestment Grant Program requirements.--

(1) The Substance Abuse and Mental Health Corporation Statewide Grant Review Committee, in collaboration with the Department of Children and Family Services, the Department of Corrections, the Department of Juvenile Justice, the Department of Elderly Affairs, and the State Courts Administrator's office, shall establish criteria to be used by the corporation to review submitted applications and to select the county that will be awarded a 1-year planning grant or a 3-year implementation or expansion grant. A planning, or implementation or expansion, grant may not be awarded unless the application of the county meets the established criteria.

(a) The application criteria for a 1-year planning grant must include a requirement that the applicant county or counties have a strategic plan to initiate systemic change to identify and treat individuals who have mental illnesses, substance abuse disorders, or co-occurring mental health and substance abuse disorders who are in, or at risk of entering, the justice system. The 1-year planning grant must be used to develop effective collaboration efforts among participants in affected governmental agencies, including the criminal, juvenile, and civil justice systems, mental health and substance abuse treatment service providers, transportation programs, and housing assistance programs. The collaboration efforts shall be the basis for developing a problem-solving model and strategic plan for treating adults and juveniles who are in or at risk of entering the criminal or juvenile justice system and doing so at the earliest point of contact, taking into consideration public safety. The planning grant shall include strategies to divert individuals from judicial commitment to community-based service programs offered by the Department of Children and Family Services, in accordance with ss. 916.13 and 916.17.

(b) The application criteria for a 3-year implementation or expansion grant shall require information from a county that demonstrates its completion of a well-established collaboration plan that includes public-private partnership models and the application of evidence-based practices. The implementation or expansion grants may support programs and diversion initiatives that include, but need not be limited to:

1. Mental health courts;

2. Diversion programs;

3. Alternative prosecution and sentencing programs;

4. Crisis-intervention teams;

5. Treatment accountability services;

6. Specialized training for criminal justice, juvenile justice, and treatment services professionals;

7. Service delivery of collateral services such as housing, transitional housing, and supported employment; and

8. Reentry services to create or expand mental health and substance abuse and support services for affected persons.

(c) Each county application must include the following information:

1. An analysis of the current population of the jail and juvenile detention center in the county, which includes:

a. The screening and assessment process that the county uses to identify an adult or juvenile who has a mental illness, substance abuse problem, or co-occurring disorder;

b. The percentage of each category of persons admitted to the jail and juvenile detention center which represents people who have a mental illness, substance abuse problem, or co-occurring disorder; and

c. An analysis of observed contributing factors that affect population trends in the county jail and juvenile detention center.

2. A description of the strategies the county intends to use to serve one or more clearly defined subsets of the population of the jail and juvenile detention center who have a mental illness or to serve those at risk of arrest and incarceration. The proposed strategies may include identifying the population designated to receive the new interventions, a description of the services and supervision methods to be applied to that population, and the goals and measurable objectives of the new interventions. The interventions a county may use with the target population may include, but are not limited to:

a. Specialized responses by law enforcement agencies;

b. Centralized receiving facilities for individuals evidencing behavioral difficulties;

c. Post-booking alternatives to incarceration;

d. New court programs, including pretrial services and specialized dockets;

e. Specialized diversion programs;

f. Intensified transition services that are directed to the designated populations while they are in jail or juvenile detention to facilitate the person's transition to the community;

g. Specialized probation processes;

h. Day-reporting centers;

i. Linkages to community-based, evidence-based treatment programs for adults and juveniles who have mental illness or substance abuse problems; and

j. Community services and programs designed to prevent criminal justice or juvenile justice involvement of high-risk populations.

3. The projected effect the proposed initiatives will have on the population of the jail and juvenile detention center and the budget of the jail and juvenile detention center. The information must include:

a. The county's estimate of how the initiative will reduce the expenditures associated with the incarceration of adults and the detention of juveniles who have a mental illness;

b. The methodology that the county intends to use to measure the defined outcomes, and the corresponding savings or averted costs;

c. The county's estimate of how the cost savings or averted costs will sustain or expand the mental health and substance abuse treatment services and supports needed in the community; and

d. How the county's proposed initiative will reduce the number of individuals judicially committed to a state mental health treatment facility.

4. The proposed strategies that the county intends to use to preserve and enhance its community mental health and substance abuse system, which serves as the local behavioral health safety net for low-income and uninsured individuals.

5. The proposed strategies that the county intends to use to continue the implemented or expanded programs and initiatives that have resulted from the grant funding.

(2)(a) As used in this subsection, the term "available resources" includes in-kind contributions from participating counties.

(b) A 1-year planning grant may not be awarded unless the applicant county makes available resources in an amount equal to the total amount of the grant. A planning grant may not be used to supplant funding for existing programs. For fiscally constrained counties, the available resources may be at 50 percent of the total amount of the grant.

(c) A 3-year implementation or expansion grant may not be awarded unless the applicant county or consortium of counties makes available resources equal to the total amount of the grant. For fiscally constrained counties, the available resources may be at 50 percent of the total amount of the grant. This match shall be used for expansion of services and may not supplant existing funds for services. An implementation or expansion grant must support the implementation of new services or the expansion of services and may not be used to supplant existing services.

(3) Using the criteria adopted by rule, the county designated or established criminal justice, juvenile justice, mental health, and substance abuse planning council or committee shall prepare the county or counties' application for the 1-year planning or 3-year implementation or expansion grant. The county shall submit the completed application to the corporation statewide grant review committee.

Section 4. Criminal Justice, Mental Health, and Substance Abuse Technical Assistance Center.--

(1) There is created a Criminal Justice, Mental Health, and Substance Abuse Technical Assistance Center at the Louis de la Parte Florida Mental Health Institute at the University of South Florida which shall:

(a) Provide technical assistance to counties in preparing a grant application.

(b) Assist an applicant county in projecting the effect of the proposed intervention on the population of the county detention facility.

(c) Assist an applicant county in monitoring the effect of the effect of a grant award on the criminal justice system in the county.

(d) Disseminate and share evidence-based practices and best practices among grantees.

(e) Act as a clearinghouse for information and resources related to criminal justice, juvenile justice, mental health, and substance abuse.

(f) Coordinate and organize the process of the state interagency justice, mental health, and substance abuse work group with the outcomes of the local grant projects for state and local policy and budget developments and system planning.

(2) The Substance Abuse and Mental Health Corporation and the Criminal Justice, Mental Health, and Substance Abuse Technical Assistance Center shall submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1 of each year, beginning on January 1, 2009. The report must include:

(a) A detailed description of the progress made by each grantee in meeting the goals described in the application;

(b) A description of the effect the grant-funded initiatives have had on meeting the needs of adults and juveniles who have mental illness, substance use disorders, or co-occurring mental health and substance use disorders, therefore reducing the number of forensic commitments to state mental health treatment facilities;

(c) A summary of the effect of the grant program on the growth and expenditures of the jail, juvenile detention center, and prison;

(d) A summary of the initiative's effect on the availability and accessibility of effective community-based mental health and substance abuse treatment services for adults and juveniles who have mental illnesses, substance use disorders, or co-occurring mental health and substance use disorders. The summary must describe how the expanded community diversion alternatives have reduced incarceration and commitments to state mental health treatment facilities; and

(e) A summary of how the local matching funds provided by the county or consortium leveraged additional funding to further the goals of the grant program.

Section 5. Administrative costs and number of grants awarded.--

(1) The administrative costs for each applicant county or consortium of counties may not exceed 10 percent of the total funding received for any grant.

(2) The number of grants awarded shall be based on funding appropriated for that purpose.

Section 6. Subsection (12) is added to section 394.655, Florida Statutes, to read:

394.655 The Substance Abuse and Mental Health Corporation; powers and duties; composition; evaluation and reporting requirements.--

(12)(a) There is established a Criminal Justice, Mental Health, and Substance Abuse Policy Council within the Florida Substance Abuse and Mental Health Corporation. The members of the council are:

1. The chairperson of the corporation;

2. The Secretary of Children and Family Services;

3. The Secretary of Corrections;

4. The Secretary of Health Care Administration;

5. The Secretary of Juvenile Justice;

6. The Secretary of Elderly Affairs; and

7. The State Courts Administrator.

(b) The purpose of the council shall be to align policy initiatives in the criminal justice, juvenile justice, and mental health systems to ensure the most effective use of resources and to coordinate the development of legislative proposals and budget requests relating to the shared needs of adults and juveniles who have mental illnesses, substance abuse disorders, and co-occurring disorders who are in, or at risk of entering, the criminal justice system.

(c) The council shall work in conjunction with the local grantees to ensure that effective strategies identified by local grantees are disseminated statewide and to create a feedback loop for purposes of policy and budget development and system change and improvement. The council shall coordinate its efforts with the Criminal Justice, Mental Health, and Substance Abuse Technical Assistance Center.

(d) Each member agency of the council shall designate an agency liaison to assist in the work of the policy council.

Section 7. This act shall take effect July 1, 2007, only if a specific appropriation to fund the provisions of the act is made in the General Appropriations Act for fiscal year 2007-2008.

================= T I T L E A M E N D M E N T =================

Remove the entire title and insert:

An act relating to forensic mental health; creating the Criminal Justice, Mental Health, and Substance Abuse Reinvestment Grant Program within the Department of Children and Family Services; providing for the purpose of the grant program; requiring the Substance Abuse and Mental Health Corporation to establish a statewide justice and mental health reinvestment grant review committee; providing for membership on the review committee; authorizing counties to apply for a planning grant or an implementation or expansion grant; requiring each county applying for a grant to have a planning council committee; providing for membership on the planning council or committee; requiring that all records and meetings be open to the public; requiring the corporation, in collaboration with others, to develop criteria to be used in reviewing submitted applications and selecting counties to be awarded a planning, or implementation or expansion, grant; requiring counties to include certain specified information when submitting the grant application; prohibiting a county from using grant funds to supplant existing funding; creating the Criminal Justice, Mental Health, and Substance Abuse Technical Assistance Center; providing for certain functions to be performed by the technical assistance center; requiring the technical assistance center to submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by a specified date; specifying the information to be included in the annual report; limiting the administrative costs a county may charge to the grant funds; amending s. 394.655, F.S.; creating the Criminal Justice, Mental Health, and Substance Abuse Policy Council in the Florida Substance Abuse and Mental Health Corporation; providing for membership; providing for the purpose of the council; providing an effective date, subject to appropriation.

Amendment No. 1

Bill No. 1477

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	______	

Council/Committee hearing bill: Healthcare Council
Committee on Healthy Families offered the following:

Amendment (with title amendment)

Remove line 397 and insert:

Section 5. This act shall take effect July 1, 2007, only if a specific appropriation to fund the provisions of the act is made in the General Appropriations Act for fiscal year 2007-2008.

================ T I T L E A M E N D M E N T =============

Remove line 37 and insert:

effective date, subject to an appropriation.

This amendment was adopted in HF on 03/20/07 and is traveling with the bill and requires no further action. However, the new strike all will supercede the traveling amendment which is encompassed in the strike all.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1007 Physician Assistants
SPONSOR(S): Baxley
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Quality	8 Y, 0 N	Guy	Lowell
2) Healthcare Council		Guy	Gormley
3)			
4)			
5)			

SUMMARY ANALYSIS

House Bill 1007 authorizes a physician assistant to dispense medicinal drugs if the physician assistant is supervised by a physician registered to dispense medical drugs.

The bill appears to have an insignificant fiscal impact on the state or local governments.

The effective date of this bill is July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – this bill will authorize physician assistants to dispense medicinal drugs directly to patients, rather than through a pharmacy.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Assistants

Sections 458.347(7), and 459.022(7), F.S., govern the licensure of physician assistants ("PA") in Florida. Physician assistants are licensed by the Department of Health ("department") and are regulated by the Council on Physician Assistants and either the Florida Board of Medicine or the Florida Board of Osteopathic Medicine. Among other requirements, an applicant for licensure as a physician assistant must demonstrate passage of the National Commission on Certification of Physician Assistants examination and submit certification of completion of a physician assistant training program. Fees for licensure and renewal are set in statute and renewal occurs biennially.[1] Applicants for renewal must complete 100 hours of continuing medical education every two years or hold a current certification issued by the National Commission on Certification of Physician Assistants.

A supervising physician may only delegate tasks and procedures to the physician assistant that are within the supervising physician's scope of practice. The supervising physician is responsible and liable for any and all acts of the PA and may only supervise up to four PAs at any time.

Sections 458.347(4) and 459.022(4), F.S. authorize a supervisory physician to delegate to a PA the authority to prescribe any medication used in the supervisory physician's practice. The department must be notified by the supervising physician of the intent to delegate prescribing authority to the PA and the PA must be licensed to prescribe by the department. Licensure for a PA to prescribe is predicated upon completion of a three hour medical education course in prescriptive practice and at least three months of clinical experience in the specialty area of the supervising physician. Further, prescriptions written by PAs must be written in a form that complies with Chapter 499, F.S., and, with the exception of a drug sample, may only be filled in a pharmacy permitted under Chapter 465, F.S. Section 458.347(4)(F)(1) directs the Council on Physician Assistants to establish a formulary of medications that a PA may not prescribe. Medications that are prohibited in the formulary include controlled substances as defined in Chapter 893, F.S., antipsychotics, spinal or epidural anesthetics, radiographic contrast materials, and any parenteral preparation except insulin and epinephrine.

There are currently 3,675 active, licensed physician assistants practicing in the state of Florida.[2]

Dispensing of Medications

Section 465.0276, F.S., provides that practitioners who are authorized by law to prescribe drugs may dispense medicinal drugs, if they register with their applicable licensing boards. Approved practitioners are subject to all of the same laws and regulations as licensed pharmacists and pharmacies, including premises inspection by the department. A practitioner who only dispenses manufacturer drug samples is not required to register under this section. Currently, allopathic and osteopathic physicians and advanced register nurse practitioners may register as dispensing practitioners.

Effect of Proposed Changes

[1] ss. 458.347(7) and 459.022(7), F.S.

[2] Florida Department of Health, Division of Medical Quality Assurance Annual Report 2005-2006.

The bill authorizes a physician assistant to dispense medicinal drugs if the physician assistant is supervised by a physician registered to dispense medical drugs.

C. SECTION DIRECTORY:

Section 1. Amends s. 458.347, F.S., relating to physician assistants.

Section 2. Provides for an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to department staff, the fiscal impact is insignificant as there is minimal cost to the department for enforcement and compliance functions associated with this bill.

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:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Physician assistants are supervised by both allopathic and osteopathic physicians. However, the bill only authorizes physician assistants practicing under allopathic physicians to dispense medicinal drugs. Further, the bill only inserts dispensing authority in one subsection of the statute, while multiple subsections apply to the prescribing of medicinal drugs by a physician assistant.

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 13, 2007, the Health Quality Committee adopted one strike-all amendment to the bill. The strike-all amendment corrects a number of drafting errors and clarifies that a PA may dispense medicinal drugs only if his or her supervising physician is registered to dispense medicinal drugs.

The bill was reported favorably with recommended Council Substitute.

Bill No. **1007**

COUNCIL/COMMITTEE ACTION

ADOPTED ___ (Y/N)
ADOPTED AS AMENDED ___ (Y/N)
ADOPTED W/O OBJECTION ___ (Y/N)
FAILED TO ADOPT ___ (Y/N)
WITHDRAWN ___ (Y/N)
OTHER ______

Council/Committee hearing bill: Healthcare Council
Representative(s) Baxley offered the following:

Substitute Amendment for Amendment (1) by Committee on Health Quality (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Effective July 1, 2007, Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.--

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant.

3. The physician assistant must file with the department, before commencing to prescribe, evidence that he or she has completed a continuing medical education course of at least 3 classroom hours in prescriptive practice, conducted by an accredited program approved by the boards, which course covers the limitations, responsibilities, and privileges involved in prescribing medicinal drugs, or evidence that he or she has received education comparable to the continuing education course as part of an accredited physician assistant training program.

4. The physician assistant must file with the department, before commencing to prescribe, evidence that the physician assistant has a minimum of 3 months of clinical experience in the specialty area of the supervising physician.

5. The physician assistant must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

6. The department shall issue a license and a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements.

7. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. <u>A physician assistant</u>

may dispense drugs provided that the supervising physician is a dispensing physician. However, unless it is a drug ~~sample~~ dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

8. The physician assistant must note the prescription in the appropriate medical record, and the supervisory physician must review and sign each notation. For dispensing purposes only, the failure of the supervisory physician to comply with these requirements does not affect the validity of the prescription.

9. This paragraph does not prohibit a supervisory physician from delegating to a physician assistant the authority to order medication for a hospitalized patient of the supervisory physician.

This paragraph does not apply to facilities licensed pursuant to chapter 395.

Section 2. Section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.--

(1) A ~~No~~ person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to ~~nonlicensed~~ pharmacy technicians registered pursuant to this section those duties, tasks, and functions which do not fall within the purview of s. 465.003(13). All such delegated acts shall be performed under the direct supervision of a licensed

pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A ~~No~~ licensed pharmacist may not ~~shall~~ supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise up to four registered ~~more than one but not more than three~~ pharmacy technicians, at least one of whom shall be certified through the Pharmacy Technician Certification Board or any other nationally accredited certifying body approved by the board.

(2) Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed $50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed $50; and is at least 16 years of age.

(3) A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to be registered as a pharmacy technician.

(4) Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student may be placed in a pharmacy for the purpose of obtaining practical training required by the body accrediting the pharmacy technician training program. A pharmacy technician student shall

wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5) Notwithstanding the requirements of this section or any other provision of law, a person licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6) As a condition of registration renewal, a pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmaceutical Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7) The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department and such other rules as necessary to administer the provisions of this section.

(8) If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

(9) The board shall adopt rules requiring and specifying the manner in which a pharmacy shall notify the board when a registered technician is employed or ceases employment with the pharmacy.

(10) The board shall maintain a current directory of registered pharmacy technicians indicating their place of employment and which must be published on the Internet.

Section 3. Paragraph (d) is added to subsection (3) of section 465.015, Florida Statutes, to read:

465.015 Violations and penalties.--

(3)

(d) It is unlawful for a person who is not registered as a pharmacy technician under this chapter, or who is not otherwise exempt from the requirement to register as a pharmacy technician, to perform the functions of a registered pharmacy technician or hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in this state.

Section 4. Subsection (5) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.--

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise utilizes registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a pharmacy technician is allowed to perform.

Section 5. Section 465.0196, Florida Statutes, is amended to read:

465.0196 Special pharmacy permits.--Any person desiring a permit to operate a special pharmacy shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for such duties. Every permittee that employs or otherwise utilizes pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a <u>registered</u> pharmacy technician is allowed to perform.

Section 6. Subsection (1) of section 465.0197, Florida Statutes, is amended to read:

465.0197 Internet pharmacy permits.--

(1) Any person desiring a permit to operate an Internet pharmacy shall apply to the department for an Internet pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in this state. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in

the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in this state occurs. The permittee shall notify the department within 30 days of any change of the licensed pharmacist responsible for such duties. Every permittee that employs or otherwise utilizes <u>registered</u> pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a <u>registered</u> pharmacy technician is allowed to perform.

Section 7. Except as otherwise provided herein, this act shall take effect January 1, 2009.

================ T I T L E A M E N D M E N T ================

Remove the entire title and insert:

An act relating to pharmaceuticals; amending s. 458.347, F.S.; requiring that a prescription be filled in a pharmacy unless it is a drug dispensed by a physician assistant; amending s. 465.014, F.S.; providing for the registration of pharmacy technicians; requiring the Board of Pharmacy to set fees and rules to register pharmacy technicians; providing qualification requirements; providing a limitation; exempting pharmacy technician students and licensed pharmacy interns from certain registration requirements; providing continuing education requirements for registration renewal; requiring the board to adopt rules; providing grounds for denial, suspension, or revocation of registration or other disciplinary action; authorizing the board to impose certain penalties; requiring the board to adopt rules requiring a pharmacy to notify the board when employing technicians; requiring the board to maintain a directory of technicians and publish the directory on the Internet; amending s. 465.015, F.S.; prohibiting a person who is not registered as a pharmacy technician from performing certain functions or holding himself or herself out to others as a pharmacy technician; amending ss. 465.019, 465.0196, and 465.0197, F.S.; conforming references; providing effective dates.

Bill No. **HB 1007**

COUNCIL/COMMITTEE ACTION

ADOPTED ___ (Y/N)
ADOPTED AS AMENDED ___ (Y/N)
ADOPTED W/O OBJECTION ___ (Y/N)
FAILED TO ADOPT ___ (Y/N)
WITHDRAWN ___ (Y/N)
OTHER ______

Council/Committee hearing bill: Healthcare Council
Committee on Health Quality offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.--

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe <u>or dispense</u> any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe <u>or dispense</u> such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed <u>or dispensed</u> by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must file with the department, before commencing to prescribe or dispense, evidence that he or she has completed a continuing medical education course of at least 3 classroom hours in prescriptive practice, conducted by an accredited program approved by the boards, which course covers the limitations, responsibilities, and privileges involved in prescribing medicinal drugs, or evidence that he or she has received education comparable to the continuing education course as part of an accredited physician assistant training program.

4. The physician assistant must file with the department, before commencing to prescribe or dispense, evidence that the physician assistant has a minimum of 3 months of clinical experience in the specialty area of the supervising physician.

5. The physician assistant must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

6. The department shall issue a license and a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician

<u>assistant shall not be required to independently register pursuant to s. 465.0276.</u>

7. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a <u>drug or</u> drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

8. The physician assistant must note the prescription <u>or dispensing of medication</u> in the appropriate medical record, and the supervisory physician must review and sign each notation. For dispensing purposes only, the failure of the supervisory physician to comply with these requirements does not affect the validity of the prescription.

9. This paragraph does not prohibit a supervisory physician from delegating to a physician assistant the authority to order medication for a hospitalized patient of the supervisory physician.

This paragraph does not apply to facilities licensed pursuant to chapter 395.

Section 2. Paragraph (e) of subsection (4) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.--

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.--

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must file with the department, before commencing to prescribe or dispense, evidence that she or he has completed a continuing medical education course of at least 3 classroom hours in prescriptive practice, conducted by an accredited program approved by the boards, which course covers the limitations, responsibilities, and privileges involved in prescribing medicinal drugs, or evidence that she or he has received education comparable to the continuing education course as part of an accredited physician assistant training program.

4. The physician assistant must file with the department, before commencing to prescribe or dispense, evidence that the physician assistant has a minimum of 3 months of clinical experience in the specialty area of the supervising physician.

5. The physician assistant must file with the department a signed affidavit that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

6. The department shall issue a license and a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

7. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

8. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record, and the supervisory physician must review and sign each notation. For dispensing purposes only, the failure of the supervisory

physician to comply with these requirements does not affect the validity of the prescription.

9. This paragraph does not prohibit a supervisory physician from delegating to a physician assistant the authority to order medication for a hospitalized patient of the supervisory physician.

This paragraph does not apply to facilities licensed pursuant to chapter 395.

Section 3. This act shall take effect July 1, 2007.

================= T I T L E A M E N D M E N T =================

Remove the entire title and insert:

A bill to be entitled

An act relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; requiring that a prescription be filled in a pharmacy unless it is a drug dispensed by a physician assistant; providing that authority to dispense may be delegated only by supervisory physicians registered as dispensing practitioners; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCC 07-16 cardiac care
SPONSOR(S): Committee on Health Innovation
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Committee on Health Innovation		Ciccone JC	Calamas CEC
1)			
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

PCB HC 07-16 revises the term *cardiology services* to reflect *cardiovascular services.* The term *adult interventional cardiology services* is revised as *adult cardiovascular services,* which is a general term that includes surgical services, as in Level II adult cardiovascular services.

The bill extends the "grandfathered in" provision applied to hospital-based adult cardiovascular services for 3 years or until July 1, 2008, whichever is longer. The bill requires the Agency for Health Care Administration to develop rules that would require licensed hospitals that provide Level I and Level II adult cardiovascular services to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic surgeons.

The bill appears to have no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government – the bill standardizes data reporting elements and requires the Agency for Health Care Administration to develop rules requiring licensed hospitals providing Level I and Level II adult cardiovascular services to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

B. EFFECT OF PROPOSED CHANGES:

Background

Certificate-of-Need (CON) Review
The CON is a regulatory review process administered by the Agency for Health Care Administration (AHCA) which requires specified health care providers to obtain prior authorization before offering certain new or expanded services or making major capital expenditures. A "Certificate of Need" is defined as: "...a written statement issued by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice."[1]

Florida's CON program has been in operation since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986.

Currently, chapter 408, part I, F.S., specifies those health providers and services subject to CON review and includes hospitals, long term care facilities, hospices, intermediate care facilities for the developmentally disabled,[2] inpatient diagnostic, curative, or comprehensive medical rehabilitative services[3] and tertiary health services, which due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service. Examples of such service include, but are not limited to pediatric, cardiac catheterization, pediatric open-heart surgery, organ transplantation, and comprehensive rehabilitation.[4]

In 2004, the Legislature amended s. 408.036(3), F.S., to provide for an exemption from CON review for hospitals providing diagnostic cardiac catheterization services without an approved adult open-heart surgery program. Section 408.036(3)(o), F.S., establishes criteria with which a hospital must comply in order to be granted and keep an exemption.

In 2004, the Legislature also amended s. 408.0361, F.S., to require the agency to adopt administrative rules for the licensure of adult inpatient diagnostic cardiac catheterization programs and adult interventional cardiology services and burn units, in Florida hospitals. This licensure would revise the regulation of these services to create licensure of services rather than a service that is authorized through an exemption from CON review.

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[1] See s. 408.032(3), F.S.
[2] See s. 408.032(8), F.S.
[3] See s. 408.032(9), F.S.
[4] See s. 408.032(17), F.S.

With regard to diagnostic cardiac catheterization services, rules must ensure that such programs comply with the guidelines of the American College of Cardiology and the American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. With regard to providers of adult interventional cardiology services[5] agency staff was to develop rules governing providers of adult interventional cardiology services or operators of a burn unit that establish standards governing the provision of such services, and that such rules must consider, at a minimum, staffing, equipment, physical plant, operating protocols, Medicaid services and services to charity care patients, accreditation, licensure period and fees, and minimum standards enforcement

Existing providers and any provider with a notice of intent to grant a certificate of need or agency final order granting a certificate of need for adult interventional services or burn units were to be "grandfathered in" and receive a license for their programs effective July 1, 2004. The grandfathered licensure period was established for at least 3 years or a period specified in rule, whichever was longer, and subject to licensure standards applicable to existing programs for every subsequent licensure period.

Effect of Proposed Changes

The bill revises the term *adult interventional cardiology services*, to *adult cardiovascular services*, which is a more general service term that includes adult interventional cardiology, according to the Agency for Health Care Administration. The bill extends the "grandfathered in" provision applied to adult cardiovascular services until July 1, 2008. The bill specifies the mechanism for hospitals licensed for Level I or Level II adult cardiovascular services to use in clinical outcome reporting--requiring such hospitals to use reporting systems operated by the American College of Cardiology and the Society of Thoracic Surgeons. This reporting system requirement is already used by many hospitals[6] and should have the effect of providing patients, families, employers, payers and other interested parties with increased access to information about the quality of hospital services.

SECTION DIRECTORY:

Section 1. Amends s. 408.0361, F.S., Cardiology services and burn unit licensure.

Section 2. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

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[5] See s. 408.0361, F.S., see also Senate Bill 182, 2004 Legislative Session

[6] Agency for Health Care Administration analysis, April 1007, on file with the committee.

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals that wish to be licensed to provide adult cardiovascular services will be required to participate in outcome measurement systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

None.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

A bill to be entitled

An act relating to cardiac care; amending s. 408.0361, F.S.; revising provisions relating to licensing standards for adult cardiovascular services; revising period of validity for certain grandfathered licenses; revising criteria for adoption of rules by the Agency for Health Care Administration; requiring certain hospitals to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons for purposes of such rule criteria; removing a requirement that the agency include specified data in rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (2), (3), and (4) of section 408.0361, Florida Statutes, are amended to read:

408.0361 Cardiovascular ~~Cardiology~~ services and burn unit licensure.--

(2) Each provider of adult cardiovascular ~~interventional cardiology~~ services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult cardiovascular ~~interventional cardiology~~ services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. The certificate-of-need rules for adult cardiovascular ~~interventional cardiology~~

services and burn units in effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for adult cardiovascular ~~interventional cardiology~~ services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 3 years or until July 1, 2008 ~~a period specified in the rule~~, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

(3) In establishing rules for adult cardiovascular ~~interventional cardiology~~ services, the agency shall include provisions that allow for:

(a) Establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

(e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) Demonstration of a plan to provide services to Medicaid and charity care patients.

(4)<u>(a)</u> The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of interventional cardiac programs. Members of the panel shall include representatives of the Florida Hospital Association, the Florida Society of Thoracic and Cardiovascular Surgeons, the Florida Chapter of the American College of Cardiology, and the Florida Chapter of the American Heart Association and others with experience in statistics and outcome measurement. Based on recommendations from the panel, the agency shall develop and adopt rules for the interventional cardiac programs that include at least the following:

~~(a) A standard data set consisting primarily of data elements reported to the agency in accordance with s. 408.061.~~

1.~~(b)~~ A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state.

2.~~(c)~~ Outcome standards specifying expected levels of performance in Level I and Level II adult cardiovascular ~~interventional cardiology~~ services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery.

3.~~(d)~~ Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

(b) Hospitals licensed for Level I or Level II adult cardiovascular services shall participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

Section 2. This act shall take effect July 1, 2007.

COUNCIL/COMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	______	

Council/Committee hearing bill: Healthcare Council
Representative(s) Garcia offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (9) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; issuance, renewal, denial, modification, suspension, and revocation.--

(9) A hospital may not be licensed or relicensed if:

(a) The diagnosis-related groups for 65 percent or more of the discharges from the hospital, in the most recent year for which data is available to the Agency for Health Care Administration pursuant to s. 408.061, are for diagnosis, care, and treatment of patients who have:

1. Cardiac-related diseases and disorders classified as diagnosis-related groups in major diagnostic category 5 ~~103-145, 478-479, 514-518, or 525-527~~;

2. Orthopedic-related diseases and disorders classified as diagnosis-related groups in major diagnostic category 8 ~~209-256, 471, 491, 496-503, or 519-520~~;

3. Cancer-related diseases and disorders classified as discharges in which the principal diagnosis is neoplasm or carcinoma or is for an admission for radiotherapy or antineoplastic chemotherapy or immunotherapy ~~diagnosis-related groups 64, 82, 172, 173, 199, 200, 203, 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367, 400-414, 473, or 492~~; or

4. Any combination of the above discharges.

(b) The hospital restricts its medical and surgical services to primarily or exclusively cardiac, orthopedic, surgical, or oncology specialties.

Section 2. Subsections (2), (3), and (4) of section 408.0361, Florida Statutes, are amended to read:

408.0361 Cardiovascular ~~Cardiology~~ services and burn unit licensure.--

(2) Each provider of adult cardiovascular ~~interventional cardiology~~ services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult cardiovascular ~~interventional cardiology~~ services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. The certificate-of-need rules for adult cardiovascular ~~interventional cardiology~~ services and burn units in effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of

need for adult cardiovascular ~~interventional cardiology~~ services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 3 years or until July 1, 2008 ~~a period specified in the rule~~, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

(3) In establishing rules for adult cardiovascular ~~interventional cardiology~~ services, the agency shall include provisions that allow for:

(a) Establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

(e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) Demonstration of a plan to provide services to Medicaid and charity care patients.

(4)(a) The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of adult cardiovascular services ~~interventional cardiac programs~~. Members of the panel shall include representatives of the Florida Hospital Association, the Florida Society of Thoracic and Cardiovascular Surgeons, the Florida Chapter of the American College of Cardiology, and the Florida Chapter of the American Heart Association and others with experience in statistics and outcome measurement. Based on recommendations from the panel, the agency shall develop and adopt rules for the adult cardiovascular services ~~interventional cardiac programs~~ that include at least the following:

~~(a) A standard data set consisting primarily of data elements reported to the agency in accordance with s. 408.061.~~

1.~~(b)~~ A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state.

2.~~(c)~~ Outcome standards specifying expected levels of performance in Level I and Level II adult cardiovascular

~~interventional cardiology~~ services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery.

3. ~~(d)~~ Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

(b) Hospitals licensed for Level I or Level II adult cardiovascular services shall participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

Section 3. This act shall take effect July 1, 2007.

================= T I T L E A M E N D M E N T =================

Remove the entire title and insert:

A bill to be entitled

An act relating to hospitals; amending s. 395.003, F.S.; revising provisions designating disease classes; amending s. 408.0361, F.S.; revising provisions relating to licensing standards for adult cardiovascular services; revising period of validity for certain grandfathered licenses; revising criteria for adoption of rules by the Agency for Health Care Administration; requiring certain hospitals to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons for purposes of such rule criteria; removing a requirement that the agency include specified data in rules; providing an effective date.

A bill to be entitled

An act relating to home health care; creating s. 400.519, F.S.; creating the Home Care Consumer and Worker Protection Act; creating s. 400.520, F.S.; providing legislative intent; creating s. 400.521, F.S.; providing definitions; creating s. 400.522, F.S.; providing applicability; creating s. 400.523, F.S.; requiring that an organization provide consumers with certain notice; prescribing information to be included in the notice; requiring the organization to retain the notice for a specified period of time; providing penalties for failure to provide the notice; granting a consumer the right of indemnification against the organization under certain circumstances; creating s. 400.524, F.S.; requiring that an organization provide home care services workers with certain notice; prescribing information to be included in the notice; requiring the organization to retain the notice for a specified period of time; providing penalties for failure to provide the notice; creating s. 400.525, F.S.; authorizing the Agency for Health Care Administration to conduct investigations, receive testimony, administer oaths, and take certain actions when a violation has occurred; authorizing the agency to impose penalties and collect attorney's fees and costs; amending s. 400.497, F.S.; authorizing certain personal care services providers to provide home health aide training; conforming cross-references; amending s. 400.509, F.S.; providing an exemption from licensure for personal care services providers under certain circumstances; requiring personal care services providers to have liability insurance and submit proof of coverage; conforming cross-references; amending ss. 400.141, 400.191, 400.461, 400.462, 400.464, 400.471, 400.474, 400.4785, 400.484, 400.487, 400.495, 400.506, 400.512, 400.515, 400.93, 408.07, 408.802, 408.806, 408.820, 409.905, 429.04, 483.285, and 627.6617, F.S.; conforming cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 400.519, Florida Statutes, is created to read:

<u>400.519 Short title.--Sections 400.519-400.525 may be cited as the "Home Care Consumer and Worker Protection Act."</u>

Section 2. Section 400.520, Florida Statutes, is created to read:

<u>400.520 Legislative intent.--It is the intent of the Legislature to protect home care services consumers and the home care services workers who provide those services by ensuring that both the consumer and the home care services worker have the ability to make informed decisions regarding their status as employers, independent contractors, and employees.</u>

Section 3. Section 400.521, Florida Statutes, is created to read:

<u>400.521 Definitions.--As used in ss. 400.519-400.525:</u>

<u>(1) "Agency" means the Agency for Health Care Administration.</u>

<u>(2) "Consumer" means a person who receives skilled or</u>

CODING: Words ~~stricken~~ are deletions; words <u>underlined</u> are additions.

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<u>nonskilled care in his or her temporary or permanent residence from a home care services worker or a person who pays for and directs the services if that person is not the person receiving services.</u>

<u>(3) "Home care services" means skilled or nonskilled care provided to a person in or at his or her temporary or permanent residence for the purpose of enabling that person to remain safely and comfortably in his or her temporary or permanent residence.</u>

<u>(4) "Home care services worker" means a person who performs home care services of any kind or character for hire.</u>

<u>(5) "Nonskilled care" means services that are provided by a person who is trained or qualified to provide personal care as defined in s. 400.462(21). Nonskilled care includes, but is not limited to, homemaker services, companion services, and personal care services.</u>

Section 4. Section 400.522, Florida Statutes, is created to read:

<u>400.522 Application.--Sections 400.519-400.525 shall apply to an organization that is licensed or registered under s. 400.506 or s. 400.509 and provides skilled or nonskilled care.</u>

Section 5. Section 400.523, Florida Statutes, is created to read:

<u>400.523 Consumer notice.--</u>

<u>(1) An organization shall provide a consumer with a notice that includes, but is not limited to, the following information:</u>

<u>(a) A description of the duties, responsibilities, obligations, and legal liabilities of the organization to the consumer and to the home care services worker. The description</u>

CODING: Words ~~stricken~~ are deletions; words <u>underlined</u> are additions.

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shall clearly set forth the consumer's responsibility for:

1. Daily supervision of the home care services worker.

2. Assigning duties to the home care services worker.

3. Hiring, firing, and disciplining the home care services worker.

4. Providing the home care services worker with the equipment and materials necessary to care for the consumer.

5. Conducting a level 2 background check on the home care services worker.

6. Conducting a reference check on the home care services worker.

7. Ensuring that the home care services worker has the proper credentials and the appropriate licensure or certification.

(b) A statement identifying the organization as an employer, joint employer, leasing employer, or nonemployer of the home care services worker and the organization's responsibility for the payment of the home care services worker's wages, including overtime pay for hours worked in excess of 40 hours in a workweek; federal, state, and local taxes; social security and Medicare taxes; workers' compensation payments; and unemployment compensation payments.

(c) A statement that, regardless of the organization's status, the consumer may be considered an employer under state or federal law and he or she may be held responsible for the payment of the home care services worker's federal, state, and local taxes; social security and Medicare taxes; minimum wages and overtime pay; and unemployment and workers' compensation insurance.

(d) A list of the forms that the consumer may be required by law to complete and submit as an employer.

(e) The penalties that may be assessed against the consumer in the event that he or she is determined to be an employer but has not fulfilled his or her obligations as an employer.

(f) The phone number and address of the organization.

(2) The notice shall be:

(a) Provided to the consumer when a home care services worker is placed in the consumer's home. A separate notice is not required when a home care services worker is a temporary substitute for the consumer's regular home care service worker.

(b) On a form developed by the agency.

(c) Signed by the consumer and retained by the organization at its office for at least 3 years.

(3) An organization that does not provide a notice to the consumer shall be subject to fines and penalties as set forth in s. 400.525.

(4) The failure of an organization to provide a notice to the consumer does not relieve a consumer of any of his or her duties or obligations as an employer. However, in the event that an organization fails to provide a notice and the consumer is found to be liable for payment of wages, taxes, workers' compensation, or unemployment compensation to the home care services worker, the consumer shall have a right of indemnification against the organization, which shall include the actual amounts paid to or on behalf of the home care services worker and the attorney's fees and costs of the consumer.

Section 6. Section 400.524, Florida Statutes, is created to read:

400.524 Worker notice.--

(1) An organization shall provide a home care services worker with a notice that explains the home care services worker's legal relationship with the organization and the consumer. The notice shall include, at a minimum, the following information:

(a) A description of the duties, responsibilities, obligations, and legal liabilities of the organization, the consumer, and the home care services worker in the event that the home care services worker is determined to be an independent contractor. The description shall include the following information:

1. A statement indicating the party that is responsible for the payment of the home care services worker's wages, including overtime pay for hours worked in excess of 40 hours in a workweek; federal, state, and local taxes; social security and Medicare taxes; and unemployment and workers' compensation insurance.

2. A statement identifying the party responsible for hiring, firing, disciplining, supervising, assigning duties to, and providing equipment or materials for use by the home care services worker.

(b) The phone number and address of the organization.

(2) The notice shall be:

(a) Provided to the home care services worker upon his or her placement in the home of a consumer.

(b) On a form developed by the agency.

(c) Signed by the worker and retained by the organization at its office for at least 3 years.

(3) An organization that does not provide a notice to the home care services worker shall be subject to fines and penalties as set forth in s. 400.525.

Section 7. Section 400.525, Florida Statutes, is created to read:

400.525 Investigations; orders; civil penalties.--

(1) The agency may at any time, and shall upon receiving a complaint from any interested person, investigate a possible violation of ss. 400.519-400.525.

(2) The agency may examine the premises of any organization; may compel by subpoena for examination or inspection the attendance and testimony of witnesses and the production of books, payrolls, records, papers, and other evidence in any investigation or hearing; and may administer oaths or affirmations to witnesses.

(3) After appropriate notice and investigation, and if supported by the evidence, the agency may issue and cause to be served on any person an order to cease and desist from violation of ss. 400.519-400.525 and take any further action that is determined to be necessary to eliminate the effect of the violation.

(4) Whenever it appears that any person has violated a valid order of the agency issued under ss. 400.519-400.525, the agency may commence an action and obtain from the court an order directing the person to obey the order of the agency or be subject to punishment for contempt of court.

(5) In addition to any order or action, the agency may petition a court of competent jurisdiction for an order enjoining any violation of ss. 400.519-400.525.

(6) Any organization that violates ss. 400.519-400.525 or rules adopted under ss. 400.519-400.525 shall be subject to a civil penalty of $500 per day per violation. Civil penalties may be assessed by the agency in an administrative action and may, if necessary, be recovered in a civil action brought by the agency through the Attorney General or the state attorney in the county in which the violation occurred. The court may order that the civil penalties assessed for violation of ss. 400.519-400.525, together with any costs or attorney's fees arising out of the action to collect the penalties, be paid to the agency. The fact that the violation has ceased does not excuse a person from liability for civil penalties arising from the violation.

Section 8. Subsection (7) of section 400.141, Florida Statutes, is amended to read:

400.141 Administration and management of nursing home facilities.--Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(7) If the facility has a standard license or is a Gold Seal facility, exceeds the minimum required hours of licensed nursing and certified nursing assistant direct care per resident per day, and is part of a continuing care facility licensed under chapter 651 or a retirement community that offers other services pursuant to ss. 400.461-400.518 ~~part III of this chapter~~ or part I or part III of chapter 429 on a single campus, be allowed to share programming and staff. At the time of inspection and in the semiannual report required pursuant to subsection (15), a continuing care facility or retirement community that uses this option must demonstrate through staffing records that minimum staffing requirements for the facility were met. Licensed nurses

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and certified nursing assistants who work in the nursing home facility may be used to provide services elsewhere on campus if the facility exceeds the minimum number of direct care hours required per resident per day and the total number of residents receiving direct care services from a licensed nurse or a certified nursing assistant does not cause the facility to violate the staffing ratios required under s. 400.23(3)(a). Compliance with the minimum staffing ratios shall be based on total number of residents receiving direct care services, regardless of where they reside on campus. If the facility receives a conditional license, it may not share staff until the conditional license status ends. This subsection does not restrict the agency's authority under federal or state law to require additional staff if a facility is cited for deficiencies in care which are caused by an insufficient number of certified nursing assistants or licensed nurses. The agency may adopt rules for the documentation necessary to determine compliance with this provision.

Facilities that have been awarded a Gold Seal under the program established in s. 400.235 may develop a plan to provide certified nursing assistant training as prescribed by federal regulations and state rules and may apply to the agency for approval of their program.

Section 9. Paragraph (a) of subsection (2) of section 400.191, Florida Statutes, is amended to read:

400.191 Availability, distribution, and posting of reports and records.--

(2) The agency shall publish the Nursing Home Guide annually in consumer-friendly printed form and quarterly in electronic form to assist consumers and their families in comparing and evaluating nursing home facilities.

(a) The agency shall provide an Internet site which shall include at least the following information either directly or indirectly through a link to another established site or sites of the agency's choosing:

1. A section entitled "Have you considered programs that provide alternatives to nursing home care?" which shall be the first section of the Nursing Home Guide and which shall prominently display information about available alternatives to nursing homes and how to obtain additional information regarding these alternatives. The Nursing Home Guide shall explain that this state offers alternative programs that permit qualified elderly persons to stay in their homes instead of being placed in nursing homes and shall encourage interested persons to call the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) Program to inquire if they qualify. The Nursing Home Guide shall list available home and community-based programs which shall clearly state the services that are provided and indicate whether nursing home services are included if needed.

2. A list by name and address of all nursing home facilities in this state, including any prior name by which a facility was known during the previous 24-month period.

3. Whether such nursing home facilities are proprietary or nonproprietary.

4. The current owner of the facility's license and the year that that entity became the owner of the license.

5. The name of the owner or owners of each facility and whether the facility is affiliated with a company or other organization owning or managing more than one nursing facility in this state.

6. The total number of beds in each facility and the most recently available occupancy levels.

7. The number of private and semiprivate rooms in each facility.

8. The religious affiliation, if any, of each facility.

9. The languages spoken by the administrator and staff of each facility.

10. Whether or not each facility accepts Medicare or Medicaid recipients or insurance, health maintenance organization, Veterans Administration, CHAMPUS program, or workers' compensation coverage.

11. Recreational and other programs available at each facility.

12. Special care units or programs offered at each facility.

13. Whether the facility is a part of a retirement community that offers other services pursuant to <u>ss. 400.461-400.518</u> ~~part III of this chapter~~ or part I or part III of chapter 429.

14. Survey and deficiency information, including all federal and state recertification, licensure, revisit, and complaint survey information, for each facility for the past 30 months. For noncertified nursing homes, state survey and deficiency information, including licensure, revisit, and

complaint survey information for the past 30 months shall be provided.

15. A summary of the deficiency data for each facility over the past 30 months. The summary may include a score, rating, or comparison ranking with respect to other facilities based on the number of citations received by the facility on recertification, licensure, revisit, and complaint surveys; the severity and scope of the citations; and the number of recertification surveys the facility has had during the past 30 months. The score, rating, or comparison ranking may be presented in either numeric or symbolic form for the intended consumer audience.

Section 10. Section 400.461, Florida Statutes, is amended to read:

400.461 Short title; purpose.--

(1) Sections ~~This part, consisting of ss.~~ 400.461-400.518~~,~~ may be cited as the "Home Health Services Act."

(2) The purpose of ss. 400.461-400.518 ~~this part~~ is to provide for the licensure of every home health agency and nurse registry and to provide for the development, establishment, and enforcement of basic standards that will ensure the safe and adequate care of persons receiving health services in their own homes.

Section 11. Section 400.462, Florida Statutes, is amended to read:

400.462 Definitions.--As used in ss. 400.461-400.518 ~~this part~~, the term:

(1) "Administrator" means a direct employee, as defined in subsection (9). The administrator must be a licensed physician, physician assistant, or registered nurse licensed to practice in

this state or an individual having at least 1 year of supervisory or administrative experience in home health care or in a facility licensed under chapter 395, under part II of this chapter, or under part I of chapter 429. An administrator may manage a maximum of five licensed home health agencies located within one agency service district or within an immediately contiguous county. If the home health agency is licensed under this chapter and is part of a retirement community that provides multiple levels of care, an employee of the retirement community may administer the home health agency and up to a maximum of four entities licensed under this chapter or chapter 429 that are owned, operated, or managed by the same corporate entity. An administrator shall designate, in writing, for each licensed entity, a qualified alternate administrator to serve during absences.

(2) "Admission" means a decision by the home health agency, during or after an evaluation visit to the patient's home, that there is reasonable expectation that the patient's medical, nursing, and social needs for skilled care can be adequately met by the agency in the patient's place of residence. Admission includes completion of an agreement with the patient or the patient's legal representative to provide home health services as required in s. 400.487(1).

(3) "Advanced registered nurse practitioner" means a person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, as defined in s. 464.003.

(4) "Agency" means the Agency for Health Care Administration.

(5) "Certified nursing assistant" means any person who has been issued a certificate under part II of chapter 464. The licensed home health agency or licensed nurse registry shall ensure that the certified nursing assistant employed by or under contract with the home health agency or licensed nurse registry is adequately trained to perform the tasks of a home health aide in the home setting.

(6) "Client" means an elderly, handicapped, or convalescent individual who receives companion services or homemaker services in the individual's home or place of residence.

(7) "Companion" or "sitter" means a person who spends time with or cares for an elderly, handicapped, or convalescent individual and accompanies such individual on trips and outings and may prepare and serve meals to such individual. A companion may not provide hands-on personal care to a client.

(8) "Department" means the Department of Children and Family Services.

(9) "Direct employee" means an employee for whom one of the following entities pays withholding taxes: a home health agency; a management company that has a contract to manage the home health agency on a day-to-day basis; or an employee leasing company that has a contract with the home health agency to handle the payroll and payroll taxes for the home health agency.

(10) "Director of nursing" means a registered nurse who is a direct employee, as defined in subsection (9), of the agency and who is a graduate of an approved school of nursing and is licensed in this state; who has at least 1 year of supervisory experience as a registered nurse; and who is responsible for overseeing the professional nursing and home health aid delivery

of services of the agency. A director of nursing may be the director of a maximum of five licensed home health agencies operated by a related business entity and located within one agency service district or within an immediately contiguous county. If the home health agency is licensed under this chapter and is part of a retirement community that provides multiple levels of care, an employee of the retirement community may serve as the director of nursing of the home health agency and of up to four entities licensed under this chapter or chapter 429 which are owned, operated, or managed by the same corporate entity.

(11) "Home health agency" means an organization that provides home health services and staffing services.

(12) "Home health agency personnel" means persons who are employed by or under contract with a home health agency and enter the home or place of residence of patients at any time in the course of their employment or contract.

(13) "Home health services" means health and medical services and medical supplies furnished by an organization to an individual in the individual's home or place of residence. The term includes organizations that provide one or more of the following:

(a) Nursing care.

(b) Physical, occupational, respiratory, or speech therapy.

(c) Home health aide services.

(d) Dietetics and nutrition practice and nutrition counseling.

(e) Medical supplies, restricted to drugs and biologicals prescribed by a physician.

(14) "Home health aide" means a person who is trained or qualified, as provided by rule, and who provides hands-on personal care, performs simple procedures as an extension of therapy or nursing services, assists in ambulation or exercises, or assists in administering medications as permitted in rule and for which the person has received training established by the agency under s. 400.497(1). The licensed home health agency or licensed nurse registry shall ensure that the home health aide employed by or under contract with the home health agency or licensed nurse registry is adequately trained to perform the tasks of a home health aide in the home setting.

(15) "Homemaker" means a person who performs household chores that include housekeeping, meal planning and preparation, shopping assistance, and routine household activities for an elderly, handicapped, or convalescent individual. A homemaker may not provide hands-on personal care to a client.

(16) "Home infusion therapy provider" means an organization that employs, contracts with, or refers a licensed professional who has received advanced training and experience in intravenous infusion therapy and who administers infusion therapy to a patient in the patient's home or place of residence.

(17) "Home infusion therapy" means the administration of intravenous pharmacological or nutritional products to a patient in his or her home.

(18) "Nurse registry" means any person that procures, offers, promises, or attempts to secure health-care-related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, companions, or homemakers, who are compensated by fees as independent

contractors, including, but not limited to, contracts for the provision of services to patients and contracts to provide private duty or staffing services to health care facilities licensed under chapter 395, this chapter, or chapter 429 or other business entities.

(19) "Organization" means a corporation, government or governmental subdivision or agency, partnership or association, or any other legal or commercial entity, any of which involve more than one health care professional discipline; a health care professional and a home health aide or certified nursing assistant; more than one home health aide; more than one certified nursing assistant; or a home health aide and a certified nursing assistant. The term does not include an entity that provides services using only volunteers or only individuals related by blood or marriage to the patient or client.

(20) "Patient" means any person who receives home health services in his or her home or place of residence.

(21) "Personal care" means assistance to a patient in the activities of daily living, such as dressing, bathing, eating, or personal hygiene, and assistance in physical transfer, ambulation, and in administering medications as permitted by rule.

(22) "Physician" means a person licensed under chapter 458, chapter 459, chapter 460, or chapter 461.

(23) "Physician assistant" means a person who is a graduate of an approved program or its equivalent, or meets standards approved by the boards, and is licensed to perform medical services delegated by the supervising physician, as defined in s. 458.347 or s. 459.022.

(24) "Skilled care" means nursing services or therapeutic services required by law to be delivered by a health care professional who is licensed under part I of chapter 464; part I, part III, or part V of chapter 468; or chapter 486 and who is employed by or under contract with a licensed home health agency or is referred by a licensed nurse registry.

(25) "Staffing services" means services provided to a health care facility or other business entity on a temporary basis by licensed health care personnel and by certified nursing assistants and home heath aides who are employed by, or work under the auspices of, a licensed home health agency or who are registered with a licensed nurse registry. Staffing services may be provided anywhere within the state.

Section 12. Subsections (3), (4), and (5) of section 400.464, Florida Statutes, are amended to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.--

(3) Any home infusion therapy provider shall be licensed as a home health agency. Any infusion therapy provider currently authorized to receive Medicare reimbursement under a DME - Part B Provider number for the provision of infusion therapy shall be licensed as a noncertified home health agency. Such a provider shall continue to receive that specified Medicare reimbursement without being certified so long as the reimbursement is limited to those items authorized pursuant to the DME - Part B Provider Agreement and the agency is licensed in compliance with the other provisions of ss. 400.461-400.518 ~~this part~~.

(4)(a) An organization may not provide, offer, or advertise home health services to the public unless the organization has a valid license or is specifically exempted under ss. 400.461-400.518 ~~this part~~. An organization that offers or advertises to the public any service for which licensure or registration is required under ss. 400.461-400.518 ~~this part~~ must include in the advertisement the license number or registration number issued to the organization by the agency. The agency shall assess a fine of not less than $100 to any licensee or registrant who fails to include the license or registration number when submitting the advertisement for publication, broadcast, or printing. The fine for a second or subsequent offense is $500. The holder of a license issued under ss. 400.461-400.518 ~~this part~~ may not advertise or indicate to the public that it holds a home health agency or nurse registry license other than the one it has been issued.

(b) The operation or maintenance of an unlicensed home health agency or the performance of any home health services in violation of ss. 400.461-400.518 ~~this part~~ is declared a nuisance, inimical to the public health, welfare, and safety. The agency or any state attorney may, in addition to other remedies provided in ss. 400.461-400.518 ~~this part~~, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the home health agency or the provision of home health services in violation of ss. 400.461-400.518 ~~this part~~, until compliance with ss. 400.461-400.518 ~~this part~~ or the rules adopted under ss. 400.461-400.518 ~~this part~~ has been demonstrated to the satisfaction of the agency.

(c) A person who violates paragraph (a) is subject to an injunctive proceeding under s. 400.515. A violation of paragraph (a) is a deceptive and unfair trade practice and constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501.

(d) A person who violates the provisions of paragraph (a) commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Any person who commits a second or subsequent violation commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation constitutes a separate offense.

(e) Any person who owns, operates, or maintains an unlicensed home health agency and who, within 10 working days after receiving notification from the agency, fails to cease operation and apply for a license under ss. 400.461-400.518 ~~this part~~ commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.

(f) Any home health agency that fails to cease operation after agency notification may be fined $500 for each day of noncompliance.

(5) The following are exempt from the licensure requirements of ss. 400.461-400.518 ~~this part~~:

(a) A home health agency operated by the Federal Government.

(b) Home health services provided by a state agency, either directly or through a contractor with:

1. The Department of Elderly Affairs.

2. The Department of Health, a community health center, or a rural health network that furnishes home visits for the purpose of providing environmental assessments, case management, health

education, personal care services, family planning, or followup treatment, or for the purpose of monitoring and tracking disease.

3. Services provided to persons with developmental disabilities, as defined in s. 393.063.

4. Companion and sitter organizations that were registered under s. 400.509(1) on January 1, 1999, and were authorized to provide personal services under a developmental services provider certificate on January 1, 1999, may continue to provide such services to past, present, and future clients of the organization who need such services, notwithstanding the provisions of this act.

5. The Department of Children and Family Services.

(c) A health care professional, whether or not incorporated, who is licensed under chapter 457; chapter 458; chapter 459; part I of chapter 464; chapter 467; part I, part III, part V, or part X of chapter 468; chapter 480; chapter 486; chapter 490; or chapter 491; and who is acting alone within the scope of his or her professional license to provide care to patients in their homes.

(d) A home health aide or certified nursing assistant who is acting in his or her individual capacity, within the definitions and standards of his or her occupation, and who provides hands-on care to patients in their homes.

(e) An individual who acts alone, in his or her individual capacity, and who is not employed by or affiliated with a licensed home health agency or registered with a licensed nurse registry. This exemption does not entitle an individual to perform home health services without the required professional license.

(f) The delivery of instructional services in home dialysis and home dialysis supplies and equipment.

(g) The delivery of nursing home services for which the nursing home is licensed under part II of this chapter, to serve its residents in its facility.

(h) The delivery of assisted living facility services for which the assisted living facility is licensed under part I of chapter 429, to serve its residents in its facility.

(i) The delivery of hospice services for which the hospice is licensed under part IV of this chapter, to serve hospice patients admitted to its service.

(j) A hospital that provides services for which it is licensed under chapter 395.

(k) The delivery of community residential services for which the community residential home is licensed under chapter 419, to serve the residents in its facility.

(l) A not-for-profit, community-based agency that provides early intervention services to infants and toddlers.

(m) Certified rehabilitation agencies and comprehensive outpatient rehabilitation facilities that are certified under Title 18 of the Social Security Act.

(n) The delivery of adult family-care home services for which the adult family-care home is licensed under part II of chapter 429, to serve the residents in its facility.

Section 13. Subsections (2), (7), (10), and (14) of section 400.471, Florida Statutes, are amended to read:

400.471 Application for license; fee; provisional license; temporary permit.--

(2) The initial applicant must file with the application satisfactory proof that the home health agency is in compliance with ss. 400.461-400.518 ~~this part~~ and applicable rules, including:

(a) A listing of services to be provided, either directly by the applicant or through contractual arrangements with existing providers.

(b) The number and discipline of professional staff to be employed.

(c) Proof of financial ability to operate.

(d) Completion of questions concerning volume data on the renewal application as determined by rule.

(7) Sixty days before the expiration date, an application for renewal must be submitted to the agency under oath on forms furnished by it, and a license must be renewed if the applicant has met the requirements established under ss. 400.461-400.518 ~~this part~~ and applicable rules. The home health agency must file with the application satisfactory proof that it is in compliance with ss. 400.461-400.518 ~~this part~~ and applicable rules. If there is evidence of financial instability, the home health agency must submit satisfactory proof of its financial ability to comply with the requirements of ss. 400.461-400.518 ~~this part~~. The agency shall impose an administrative fine of $50 per day for each day the home health agency fails to file an application within the timeframe specified in this subsection. Each day of continuing violation is a separate violation; however, the aggregate of such fines may not exceed $500.

(10) The license fee and renewal fee required of a home health agency are nonrefundable. The agency shall set the license

fees in an amount that is sufficient to cover its costs in carrying out its responsibilities under ss. 400.461-400.518 ~~this part~~, but not to exceed $2,000. However, state, county, or municipal governments applying for licenses under ss. 400.461-400.518 ~~this part~~ are exempt from the payment of license fees. All fees collected under ss. 400.461-400.518 ~~this part~~ must be deposited in the Health Care Trust Fund for the administration of ss. 400.461-400.518 ~~this part~~.

(14) The agency may not issue a license to a home health agency that has any unpaid fines assessed under ss. 400.461-400.518 ~~this part~~.

Section 14. Paragraph (a) of subsection (2) of section 400.474, Florida Statutes, is amended to read:

400.474 Denial, suspension, revocation of license; injunction; grounds; penalties.--

(2) Any of the following actions by a home health agency or its employee is grounds for disciplinary action by the agency:

(a) Violation of ss. 400.461-400.518 ~~this part~~ or of applicable rules.

Section 15. Subsection (2) of section 400.4785, Florida Statutes, is amended to read:

400.4785 Patients with Alzheimer's disease or other related disorders; staff training requirements; certain disclosures.--

(2) An agency licensed under ss. 400.461-400.518 ~~this part~~ which claims that it provides special care for persons who have Alzheimer's disease or other related disorders must disclose in its advertisements or in a separate document those services that distinguish the care as being especially applicable to, or suitable for, such persons. The agency must give a copy of all

such advertisements or a copy of the document to each person who requests information about the agency and must maintain a copy of all such advertisements and documents in its records. The Agency for Health Care Administration shall examine all such advertisements and documents in the agency's records as part of the license renewal procedure.

Section 16. Subsection (1) of section 400.484, Florida Statutes, is amended to read:

400.484 Right of inspection; deficiencies; fines.--

(1) Any duly authorized officer or employee of the agency may make such inspections and investigations as are necessary in order to determine the state of compliance with ss. 400.461-400.518 ~~this part~~ and with applicable rules. The right of inspection extends to any business that the agency has reason to believe is being operated as a home health agency without a license, but such inspection of any such business may not be made without the permission of the owner or person in charge unless a warrant is first obtained from a circuit court. Any application for a license issued under ss. 400.461-400.518 ~~this part~~ or for license renewal constitutes permission for an appropriate inspection to verify the information submitted on or in connection with the application.

Section 17. Subsection (5) of section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.--

(5) When nursing services are ordered, the home health agency to which a patient has been admitted for care must provide the initial admission visit, all service evaluation visits, and the discharge visit by a direct employee. Services provided by others under contractual arrangements to a home health agency must be monitored and managed by the admitting home health agency. The admitting home health agency is fully responsible for ensuring that all care provided through its employees or contract staff is delivered in accordance with <u>ss. 400.461-400.518</u> ~~this part~~ and applicable rules.

Section 18. Section 400.495, Florida Statutes, is amended to read:

400.495 Notice of toll-free telephone number for central abuse hotline.--On or before the first day home health services are provided to a patient, any home health agency or nurse registry licensed under <u>ss. 400.461-400.518</u> ~~this part~~ must inform the patient and his or her immediate family, if appropriate, of the right to report abusive, neglectful, or exploitative practices. The statewide toll-free telephone number for the central abuse hotline must be provided to patients in a manner that is clearly legible and must include the words: "To report abuse, neglect, or exploitation, please call toll-free (phone number) ." The Agency for Health Care Administration shall adopt rules that provide for 90 days' advance notice of a change in the toll-free telephone number and that outline due process procedures, as provided under chapter 120, for home health agency personnel and nurse registry personnel who are reported to the central abuse hotline. Home health agencies and nurse registries shall establish appropriate policies and procedures for providing such notice to patients.

Section 19. Section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.--The agency shall adopt, publish, and enforce rules to implement <u>ss. 400.461-400.518</u> ~~this part~~, including, as applicable, ss. 400.506 and 400.509, which must provide reasonable and fair minimum standards relating to:

(1) The home health aide competency test and home health aide training. The agency shall create the home health aide competency test and establish the curriculum and instructor qualifications for home health aide training. Licensed home health agencies <u>or organizations licensed or registered under s. 400.509 that provide personal care</u> may provide this training and shall furnish documentation of such training to other licensed home health agencies upon request. Successful passage of the competency test by home health aides <u>or organizations licensed or registered under s. 400.509</u> may be substituted for the training required under this section and any rule adopted pursuant thereto.

(2) Shared staffing. The agency shall allow shared staffing if the home health agency is part of a retirement community that provides multiple levels of care, is located on one campus, is licensed under this chapter or chapter 429, and otherwise meets the requirements of law and rule.

(3) The criteria for the frequency of onsite licensure surveys.

(4) Licensure application and renewal.

(5) The requirements for onsite and electronic accessibility of supervisory personnel of home health agencies.

(6) Information to be included in patients' records.

(7) Geographic service areas.

(8) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.

(a) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the plan and plan updates, with the concurrence of the Department of Health and in consultation with the Department of Community Affairs.

(b) The rules must address the requirements in s. 400.492. In addition, the rules shall provide for the maintenance of patient-specific medication lists that can accompany patients who are transported from their homes.

(c) The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders when necessary. The county health department shall complete its review to ensure that the plan is in accordance with the criteria in the Agency for Health Care Administration rules within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home health agency that its failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(d) For any home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders when necessary. The department shall complete its review within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. The department shall make every effort to avoid imposing differing requirements on a home health agency that operates in more than one county as a result of differing or conflicting comprehensive plan requirements of the counties in which the home health agency operates.

(e) The requirements in this subsection do not apply to:

1. A facility that is certified under chapter 651 and has a licensed home health agency used exclusively by residents of the facility; or

2. A retirement community that consists of residential units for independent living and either a licensed nursing home or an assisted living facility, and has a licensed home health agency used exclusively by the residents of the retirement community, provided the comprehensive emergency management plan for the facility or retirement community provides for continuous care of all residents with special needs during an emergency.

Section 20. Subsection (3) and paragraph (c) of subsection (8) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.--

(3) Application for license must be made to the Agency for Health Care Administration on forms furnished by it and must be accompanied by the appropriate licensure fee, as established by rule and not to exceed the cost of regulation under ss. 400.461-400.518 ~~this part~~. The licensure fee for nurse registries may not exceed $2,000 and must be deposited in the Health Care Trust Fund.

(8)

(c) Any person who owns, operates, or maintains an unlicensed nurse registry and who, within 10 working days after receiving notification from the agency, fails to cease operation and apply for a license under ss. 400.461-400.518 ~~this part~~ commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.

Section 21. Subsections (1) and (6) of section 400.509, Florida Statutes, are amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants; liability insurance.--

(1)(a) Any organization that provides companion services or homemaker services or that provides personal care services through employed certified nursing assistants certified under part II of chapter 464 or through employed home health aides who are trained and have successfully completed the home health aide competency test established by the agency under s. 400.497(1) and does not provide a home health service, other than assisting a patient with bathing, dressing, toileting, grooming, eating, physical transfer, and those normal daily routines the patient

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could perform for himself or herself if he or she was physically capable, ~~to a person~~ is exempt from licensure under ss. 400.461-400.518 ~~this part~~. However, any organization that provides companion services, ~~or~~ homemaker services, or personal care services must register with the agency.

(b) Any organization that provides personal care services must obtain and maintain liability insurance coverage as defined in s. 624.605(1)(b) in an amount of at least $250,000 per claim and must submit proof of liability insurance coverage with an initial application for registration and with each annual application for registration renewal.

(6) On or before the first day on which services are provided to a patient or client, any registrant under ss. 400.461-400.518 ~~this part~~ must inform the patient or client and his or her immediate family, if appropriate, of the right to report abusive, neglectful, or exploitative practices. The statewide toll-free telephone number for the central abuse hotline must be provided to patients or clients in a manner that is clearly legible and must include the words: "To report abuse, neglect, or exploitation, please call toll-free (phone number)." Registrants must establish appropriate policies and procedures for providing such notice to patients or clients.

Section 22. Paragraph (a) of subsection (7) of section 400.512, Florida Statutes, is amended to read:

400.512 Screening of home health agency personnel; nurse registry personnel; and companions and homemakers.--The agency shall require employment or contractor screening as provided in chapter 435, using the level 1 standards for screening set forth in that chapter, for home health agency personnel; persons referred for employment by nurse registries; and persons employed by companion or homemaker services registered under s. 400.509.

(7)(a) It is a misdemeanor of the first degree, punishable under s. 775.082 or s. 775.083, for any person willfully, knowingly, or intentionally to:

1. Fail, by false statement, misrepresentation, impersonation, or other fraudulent means, to disclose in any application for voluntary or paid employment a material fact used in making a determination as to such person's qualifications to be an employee under this section;

2. Operate or attempt to operate an entity licensed or registered under <u>ss. 400.461-400.518</u> ~~this part~~ with persons who do not meet the minimum standards for good moral character as contained in this section; or

3. Use information from the criminal records obtained under this section for any purpose other than screening that person for employment as specified in this section or release such information to any other person for any purpose other than screening for employment under this section.

Section 23. Section 400.515, Florida Statutes, is amended to read:

400.515 Injunction proceedings.--In addition to the other powers provided under this chapter, the agency may institute injunction proceedings in a court of competent jurisdiction to restrain or prevent the establishment or operation of a home health agency or nurse registry that does not have a license or that is in violation of any provision of <u>ss. 400.461-400.518</u> ~~this part~~ or any rule adopted pursuant to <u>ss. 400.461-400.518</u> ~~this part~~. The agency may also institute injunction proceedings in a

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court of competent jurisdiction when violation of ss. 400.461-400.518 ~~this part~~ or of applicable rules constitutes an emergency affecting the immediate health and safety of a patient or client.

Section 24. Paragraph (d) of subsection (5) of section 400.93, Florida Statutes, is amended to read:

400.93 Licensure required; exemptions; unlawful acts; penalties.--

(5) The following are exempt from home medical equipment provider licensure, unless they have a separate company, corporation, or division that is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence pursuant to the provisions of this part:

(d) Home health agencies licensed under ss. 400.461-400.518 ~~part III~~.

Section 25. Subsection (28) of section 408.07, Florida Statutes, is amended to read:

408.07 Definitions.--As used in this chapter, with the exception of ss. 408.031-408.045, the term:

(28) "Home health agency" means an organization licensed under ss. 400.461-400.518 ~~part III of chapter 400~~.

Section 26. Subsections (15), (16), and (17) of section 408.802, Florida Statutes, are amended to read:

408.802 Applicability.--The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 440, 483, and 765:

(15) Home health agencies, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~.

(16) Nurse registries, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~.

(17) Companion services or homemaker services providers, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~.

Section 27. Paragraph (b) of subsection (7) of section 408.806, Florida Statutes, is amended to read:

408.806 License application process.--

(7)

(b) An initial inspection is not required for companion services or homemaker services providers, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~, or for health care services pools, as provided under part IX ~~XII~~ of chapter 400.

Section 28. Subsections (15), (16), and (17) of section 408.820, Florida Statutes, are amended to read:

408.820 Exemptions.--Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

(15) Home health agencies, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~, are exempt from s. 408.810(10).

(16) Nurse registries, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~, are exempt from s. 408.810(6) and (10).

(17) Companion services or homemaker services providers, as provided under ss. 400.461-400.518 ~~part IV of chapter 400~~, are exempt from s. 408.810(6)-(10).

Section 29. Subsection (4) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.--The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(4) HOME HEALTH CARE SERVICES.--The agency shall pay for nursing and home health aide services, supplies, appliances, and durable medical equipment, necessary to assist a recipient living at home. An entity that provides services pursuant to this subsection shall be licensed under <u>ss. 400.461-400.518</u> ~~part III of chapter 400~~. These services, equipment, and supplies, or reimbursement therefor, may be limited as provided in the General Appropriations Act and do not include services, equipment, or supplies provided to a person residing in a hospital or nursing facility.

(a) In providing home health care services, the agency may require prior authorization of care based on diagnosis.

(b) The agency shall implement a comprehensive utilization management program that requires prior authorization of all private duty nursing services, an individualized treatment plan that includes information about medication and treatment orders, treatment goals, methods of care to be used, and plans for care coordination by nurses and other health professionals. The utilization management program shall also include a process for periodically reviewing the ongoing use of private duty nursing services. The assessment of need shall be based on a child's condition, family support and care supplements, a family's ability to provide care, and a family's and child's schedule regarding work, school, sleep, and care for other family dependents. When implemented, the private duty nursing utilization management program shall replace the current authorization program used by the Agency for Health Care Administration and the Children's Medical Services program of the Department of Health. The agency may competitively bid on a contract to select a qualified organization to provide utilization management of private duty nursing services. The agency is authorized to seek federal waivers to implement this initiative.

Section 30. Paragraph (g) of subsection (2) of section 429.04, Florida Statutes, is amended to read:

429.04 Facilities to be licensed; exemptions.--

(2) The following are exempt from licensure under this part:

(g) Any facility certified under chapter 651, or a retirement community, may provide services authorized under this part or <u>ss. 400.461-400.518</u> ~~part III of chapter 400~~ to its residents who live in single-family homes, duplexes, quadruplexes, or apartments located on the campus without obtaining a license to operate an assisted living facility if residential units within such buildings are used by residents who do not require staff supervision for that portion of the day when personal services are not being delivered and the owner obtains a home health license to provide such services. However, any building or distinct part of a building on the campus that is designated for persons who receive personal services and require supervision beyond that which is available while such services are being rendered must be licensed in accordance with this part. If a facility provides personal services to residents who do not otherwise require supervision and the owner is not licensed as a home health agency, the buildings or distinct parts of buildings where such services are rendered must be licensed under this part. A resident of a facility that obtains a home health license may contract with a home health agency of his or her choice, provided that the home health agency provides liability insurance and workers' compensation coverage for its employees. Facilities covered by this exemption may establish policies that give residents the option of contracting for services and care beyond that which is provided by the facility to enable them to age in place. For purposes of this section, a retirement community consists of a facility licensed under this part or under part II of chapter 400, and apartments designed for independent living located on the same campus.

Section 31. Subsection (5) of section 483.285, Florida Statutes, is amended to read:

483.285 Application of part; exemptions.--This part applies to all multiphasic health testing centers within the state, but does not apply to:

(5) A home health agency licensed under ss. 400.461-400.518 ~~part IV of chapter 400~~.

Section 32. Subsection (1) of section 627.6617, Florida Statutes, is amended to read:

627.6617 Coverage for home health care services.--

(1) Any group health insurance policy providing coverage on an expense-incurred basis shall provide coverage for home health care by a home health care agency licensed pursuant to ss. 400.461-400.518 ~~part IV of chapter 400~~. Such coverage may be limited to home health care under a plan of treatment prescribed by a licensed physician. Services may be performed by a registered graduate nurse, a licensed practical nurse, a physical therapist, a speech therapist, an occupational therapist, or a home health aide. Provisions for utilization review may be imposed, provided that similar provisions apply to all other types of health care services.

Section 33. This act shall take effect July 1, 2007.

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