



Health & Family Services Policy Council

**Tuesday, April 13, 2010
9:15 AM - 11:15 AM
Webster Hall (212 Knott)**

**Larry Cretul
Speaker**

**Ed Homan
Chair**

Council Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Family Services Policy Council

Start Date and Time: Tuesday, April 13, 2010 09:15 am
End Date and Time: Tuesday, April 13, 2010 11:15 am
Location: Webster Hall (212 Knott)
Duration: 2.00 hrs

Consideration of the following bill(s):

CS/HB 509 Blood Establishments by Health Care Regulation Policy Committee, Tobia
CS/HB 645 Community Residential Homes by Military & Local Affairs Policy Committee, Stargel
CS/HB 729 Practice of Tattooing by Health Care Regulation Policy Committee, Brandenburg
CS/HB 1503 Health Care by Health Care Regulation Policy Committee, Flores

Pursuant to rule 7.13, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Monday, April 12, 2010.

By request of the Chair, all council members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, April 12, 2010.

NOTICE FINALIZED on 04/09/2010 16:29 by Alison.Cindy



The Florida House of Representatives

Health & Family Services Policy Council

A G E N D A

April 13, 2010
9:15 AM – 11:15 AM
Webster Hall (212 Knott)

- I. Opening Remarks by Chair Homan

- II. Consideration of the following Bill(s):
 - CS/HB 509 – Blood Establishments by Health Care Regulation Policy Committee, Rep. Tobia

 - CS/HB 645 – Community Residential Homes by Military & Local Affairs Policy Committee, Rep. Stargel

 - CS/HB 729 – Practice of Tattooing by Health Care Regulation Policy Committee, Rep. Brandenburg

 - CS/HB 1503 – Health Care by Health Care Regulation Policy Committee, Rep. Flores

- III. Closing Remarks

- IV. Adjournment

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

A blood establishment is defined in s. 381.06014, F.S., to mean any person, entity, or organization, operating within Florida, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.

The state of Florida does not issue a specific license as a blood establishment. Florida law¹ requires a blood establishment operating in Florida to operate in a manner consistent with the provisions of federal law in Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600-640, relating to the manufacture and regulation of blood and blood components. If the blood establishment does not operate accordingly, and is operating in a manner that constitutes a danger to the health or well-being of blood donors or recipients, the Agency for Health Care Administration (AHCA), or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the establishment.

Federal law classifies blood establishments as follows:² community (non-hospital) blood bank ("community blood center"), hospital blood bank, plasmapheresis center, product testing laboratory, hospital transfusion service, component preparation facility, collection facility, distribution center, broker/warehouse, and other. Community blood centers are primarily engaged in collecting blood and blood components from voluntary donors to make a safe and adequate supply of these products available to hospitals and other health care providers in the community for transfusion. Blood establishments that focus on the collection of plasma that is not intended for transfusion, but is intended to be sold for the manufacture of blood derivatives³ routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by AHCA, unless otherwise exempt.⁴ As a part of the clinical laboratory license, the facility is inspected at least every two years.

¹ s. 381.06014, F.S.

² A description of these classifications may be found at:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (last visited March 29, 2010).

³ Blood derivatives are classified as prescription drugs.

⁴ Rule 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.

AHCA may accept surveys or inspections conducted by a private accrediting organization in lieu of conducting its own inspection. The clinical laboratory personnel are required to maintain professional licensure by the Department of Health (DOH). Community blood centers must also have appropriate licenses issued by DOH and must comply with laws related to biomedical waste⁵ and radiation services.

Blood and Blood Components

Blood may be transfused to patients as whole blood or as one of its primary components: red blood cells (RBCs), plasma, platelets, and cryoprecipitated antihemophilic factor (AHF).⁶

RBCs are prepared from whole blood by removing the plasma, and are given to surgery and trauma patients, along with patients with blood disorders like anemia and sickle cell disease. RBCs have a shelf life of 42 days, or they may be treated and frozen for storage of up to 10 years. Leukoreduced RBCs are filtered to contain a lesser amount of white blood cells than would normally be present in whole blood or RBC units. Leukoreduction is recommended to improve the safety of blood transfusions by reducing the possibility of post-transfusion infection or reaction that may result from pathogens concentrated in white blood cells.

Plasma is the liquid portion of the blood that carries clotting factors and nutrients. It may be obtained through apheresis⁷ or separated from whole blood, which is referred to as recovered plasma. It is given to trauma patients, organ transplant recipients, newborns and patients with clotting disorders. Fresh frozen plasma (FFP) is plasma frozen within hours after donation in order to preserve clotting factors and may be stored up to seven years. It is thawed before it is transfused.

Cryoprecipitated AHF is the portion of plasma that is rich in certain clotting factors. It is removed from plasma by freezing and then slowly thawing the plasma. Cryoprecipitated AHF is used to prevent or control bleeding in individuals with hemophilia and von Willebrand's disease.

Platelets control blood clotting in the body, and are used to stop bleeding associated with cancer and surgery. Units of platelets are prepared by using a centrifuge to separate the platelet-rich plasma from the donated unit of whole blood. Platelets also may be obtained from a donor by the process of apheresis, which results in about six times as many platelets as a unit of platelets obtained from the whole blood. Platelets are stored at room temperature for up to five days.

Florida Community Blood Centers

Many blood banks operate, collect and distribute in a local community, and any excess blood is distributed to other communities in Florida, or nationally, as needed. Accordingly, the community blood centers generally collect and provide blood services to health care facilities in the same geographic area. Community blood centers occasionally overlap in their collection in certain counties. This generally occurs when a county is contiguous to the general region in which two or more blood centers are located.

Currently, there are six not-for-profit corporations that operate community blood centers in Florida and one for-profit corporation. The not-for-profit corporations include: Community Blood Centers of South Florida; Florida Blood Services (includes the recent mergers of Bloodnet USA, Northwest Florida Blood Services, and Southeastern Community Blood Center); Florida's Blood Centers; LifeSouth Community Blood Centers; Suncoast Communities Blood Bank; and The Blood Alliance, formerly Florida Georgia

⁵ Rule ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.

⁶ Blood component definitions from: AABB "Whole Blood and Blood Components" available at:

http://www.aabb.org/Content/About_Blood/Facts_About_Blood_and_Blood_Banking/fabloodwhole.htm (last visited on March 29, 2010).

⁷ *Ibid.* Apheresis is a process in which blood is drawn from the donor into an apheresis instrument that separates the blood into its components, retains the desired component, and returns the remainder of the blood to the donor.

Blood Alliance and the Blood Center of the St. Johns. The for-profit corporation is United States Blood Bank (USBB). Several hospital-owned blood centers operate in this state as well, primarily collecting for their own use. At least one community blood center that does not have a fixed location in Florida collects blood and blood components using a mobile blood-collection vehicle from volunteer donors and distributes blood and blood components to health care providers in Florida.

Recently, the USBB, the for-profit community blood center in south Florida, received notification of a policy that impairs its ability to engage in blood collection activities and compete with the not-for-profit community blood centers. According to correspondence dated October 13, 2009, between officials within the Miami Parking Authority, that policy statement provides, "Meter rentals for blood mobile agencies will only be granted to non-profit companies conducting a blood drive ..."⁸

Community blood centers collect about 93–94 percent, hospitals collect 5–6 percent, and the military collects 1-2 percent of the national blood supply.⁹

Pricing

The cost of blood and blood components is primarily based on the cost of labor and required testing to ensure the safety of the blood collected. A donor must be educated and screened to ensure they are in good health prior to making a donation. Each specimen of blood taken is subject to an initial test, which can cost \$52 - \$66 per unit. If an initial test reveals a positive condition that would make the unit unusable, the unit is subject to confirmatory testing. The price of a confirmatory test varies considerably depending upon the test(s) that must be run, one of which may cost as much as \$170.

In addition to screening, collecting, processing (separation), and testing, blood centers must ensure that they implement procedures for labeling, including expiration dating; tracking and tracing the donation; deferral; public health reporting and donor follow-up as applicable; blood component quarantining in temperature-controlled environments until testing indicates the unit may be released for use; continued storage in temperature-controlled environments for released units; transportation and handling; and environmentally appropriate disposal of supplies and unusable units.

Generally, the median fees charged by community blood centers in Florida are at, or near, the lowest median fees nationally.¹⁰

The chart below reflects the range of costs reported by Florida hospitals responding to the Senate Committee on Health Regulation's interim survey.¹¹ The questionnaire asked for the average cost of a unit of the specified component paid by the hospital over the last 12 months. The cost to hospitals for a unit of RBCs and Leukoreduced RBCs might vary depending upon the blood type. Costs overall tended to be higher in south Florida.

	For-Profit Hospitals		Not-For-Profit Hospitals	
	Low	High	Low	High
RBCs	\$ 147.50	\$ 241.00	\$ 148.00	\$ 220.00
Plasma	\$ 47.50	\$ 77.00	\$ 49.00	\$ 59.00
Platelets	\$ 520.00	\$ 653.00	\$ 506.00	\$ 618.00
Leukoreduced RBCs	\$ 178.50	\$ 261.00	\$ 175.00	\$ 263.00

⁸ A copy of the correspondence is on file with the Florida Senate Health Regulation Committee. A representative from the Miami Parking Authority indicated in a telephone conversation with professional committee staff that they had received complaints concerning staff from blood centers standing in the middle of the street harassing people to donate and blood drives that were not conducted in cooperation with a business in the vicinity.

⁹ The Florida Senate, Committee on Health Regulation, Interim Report 2010-119 (December 2009).

¹⁰ The regional median fees were provided by ABC in an email to staff in the Florida Senate Health Regulation Committee dated November 17, 2009. The median fees for Florida were obtained from information submitted by the community blood centers in response to a committee survey.

¹¹ See The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, found at: http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-119hr.pdf (last visited on April 1, 2010).

Licensure to Handle Prescription Drugs

Human blood and blood products are characterized as both “biologics,”¹² for purposes of regulation under the federal Public Health Service Act, as amended, and also as “drugs,” subject to regulation under applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).¹³ Some of the community blood centers are licensed by the Department of Health (DOH) as a prescription drug wholesaler since they purchase and distribute prescription drugs, such as blood, blood components, blood derivatives, and other prescription drugs used in the collection, processing, and therapeutic activities conducted by the community blood centers.¹⁴

The Florida Drug and Cosmetic Act (the Act),¹⁵ as well as federal law,¹⁶ prohibits the sale, purchase or trade (wholesale distribution) of a prescription drug that was purchased by... a health care entity. A community blood center is a health care entity,¹⁷ however, some of the community blood centers in this state are licensed as prescription drug wholesalers in order to purchase and distribute certain prescription drugs that are needed by community blood centers and hospitals to deliver health care services that are traditionally performed by, or in cooperation with, community blood centers. For example, some community blood centers offer hospitals the full range of blood-related products, such as albumin (to replace fluid), Rh Immune Globulin (to prevent incompatible maternal-fetal blood admixture), and erythropoietin (to stimulate the production of RBCs), as well as trained personnel and expertise in handling those products. The Act and licensure of community blood centers under the Act are at odds with providing critical health care services by community blood centers.¹⁸

In November 2008, the FDA’s rule to address this dilemma in federal law became effective.¹⁹ That rule allows limited distribution of prescription drugs by blood establishments that would otherwise be prohibited. The types of drugs that may be distributed under the rule are limited to the following: a prescription drug that is indicated for a bleeding disorder, clotting disorder, or anemia; a blood collection container that is approved under s. 505 of the federal FD&C Act related to new drugs; a drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative. In order for this exception to apply, all health care services being provided must be related to a registered blood establishment’s activities.

Prescription Drug Manufacturer Permit

Florida law requires a prescription drug manufacturer permit for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.²⁰ The DOH recently noted that blood establishments have not been permitted under the Act as a prescription drug manufacturer and have not registered the prescription drugs that they manufacture (the blood and blood components) with the DOH, notwithstanding the fact that blood establishments are considered manufacturers of prescription drugs under federal law. The distribution of the prescription drugs that blood establishments manufacture are exempt from the definition of wholesale distribution under s.

¹² The term “biologics” or “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product,... applicable to the prevention, treatment, or cure of a disease or condition of human beings. See: http://www.law.cornell.edu/uscode/42/uscode_sec_42_00000262----000-.html (last visited on April 1, 2010).

¹³ The FDA “CPG 230.120 – Human Blood and Blood Products as Drugs” “Inspections, Compliance, Enforcement, and Criminal Investigations” available at: <http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm073863.htm> (last visited on April 1, 2010). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.

¹⁴ Ch. 499, F.S., related to Drugs, Devices, Cosmetics, and Household Products.

¹⁵ s. 499.005(21), F.S.

¹⁶ 21 U.S.C. 353(c)(3)(A)(ii)(I) (Section 503(c)(3)(A)(ii)(I) of the FD&C Act).

¹⁷ A health care entity is defined as a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. See s. 499.003(23), F.S. The federal definition, found at 21 C.F.R. 203.3(q), is similar.

¹⁸ The DOH indicated in an email to Florida Senate Health Regulation Committee staff, dated November 12, 2009, that at the present time, they are not aware of any serious abuses or action by the licensed community blood centers that may pose a public health threat.

¹⁹ The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published on October 9, 2008, is available at:

<http://edocket.access.gpo.gov/2008/pdf/E8-24050.pdf> (last visited on April 1, 2010).

²⁰ s. 499.01(a), F.S.

499.003(53) (d), F.S. This situation applies to the community blood centers as well as other types of blood establishments, such as the establishments that collect plasma from paid donors.

Senate Interim Project Report 2010-119

During the 2009-2010 interim, the Senate Committee on Health Regulation reviewed the regulation of blood banks (a.k.a. community blood centers). The recommendations concerning legislative action in the resulting report included:

- Prohibiting public agencies from restricting the access to public facilities based on the tax status of the community blood center.
- Addressing the statutory obstacle that prohibits a community blood center, because it is a health care entity, from maintaining licensure as a prescription drug wholesale distributor and engaging in the wholesale distribution of prescription drugs.
- Prohibiting a community blood center from using the tax status of a hospital or other health care facility as the sole factor when determining the price for the sale of blood or blood components.

Effect of Proposed Changes

The bill prohibits a local government from restricting access to or use of a public facility or public infrastructure for collecting blood or blood components from voluntary donors based on whether the blood establishment is a for-profit or not-for-profit corporation. The bill prohibits blood establishments from determining the price to sell blood or blood components, received from volunteer donors, solely on the tax status of hospitals or other health care providers.

The bill allows blood establishments to engage in the distribution of certain prescription drugs without having to obtain a distributors license. Specifically, the bill mirrors FDA's rule by creating a limited exemption to the definition of "Wholesale distribution" for the sale, purchase, or trade by a registered blood establishment that qualifies as a health care entity of any:

- Drug indicated for bleeding, clotting disorder, anemia, or blood collection container approved under section 505 of the Prescription Drug Marketing Act.
- Drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative, as long as the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services provided by the blood establishment consist of collecting, processing, storing, or administering human hematopoietic stem or progenitor cells or performing diagnostic testing of specimens that are tested together with specimens undergoing routine donor testing.

The bill expands the state's exemption from whole distribution beyond FDA's rule by including drugs necessary for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of either a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician. This expansion creates a conflict between state and federal law. A blood establishment who performs the above therapeutic activities would be disqualified from the federal exclusion provided under 21 CFR § 203.22 (h), and would be considered a health care entity under federal law. Both state and federal law prohibits the sale, purchase or trade of a prescription drug that was purchased by... a health care entity.²¹

The bill requires a blood establishment that utilizes the exemption created above, to satisfy all other requirements of Part I Chapter 499, F.S., applicable to a wholesale distributor or retail pharmacy, which includes: prohibited acts; criminal acts; permits; storage and handling of prescription drugs; pedigree paper; registration of drugs, etc...

²¹ *Id.*

Finally, the bill amends s. 499.01, F.S., relating to prescription drug manufacturer permit. It provides an exemption to the permitting requirement for a drug manufacturer for a blood establishment that is operating in a manner consistent with Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600-640 and manufactures prescription drugs described in the newly created exemption under "wholesale distribution". The bill authorizes a blood establishment to manufacture a wide range of prescription drugs beyond blood and blood components. For example a blood establishment could manufacture prescription drugs such as epinephrine, erythropoietin, and other recombinant DNA drugs without a Prescription Drug Manufacturer permit.

B. SECTION DIRECTORY:

Section 1. Amends s. 381.06014, F.S., relating to blood establishments.

Section 2. Amends s. 499.003, F.S., relating to definitions.

Section 3. Amends s. 499.01, F.S., relating to permits.

Section 4. Provides that the bill takes effect upon becoming a law.

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:

Not Applicable, the bill does not appear to affect municipal or county governments.

2. Other:

None

B. RULE-MAKING AUTHORITY:

None

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill excludes "blood establishment" from the definition of "wholesale distribution" under Part I Chapter 499, F.S., and requires a "blood establishment" to meet all the other requirements of Part I Chapter 499, F.S., pertaining to wholesale distributor or retail pharmacy. As drafted, it is unclear which provisions of Part I Chapter 499, F.S., specifically permits, recordkeeping, and pedigree papers, are to be complied with by the blood establishment. It is also unclear as to whether these provisions are to be applied to the "blood establishment" as a "wholesale distributor" or a "retail pharmacy".

Under ss. 499.005 (14), (15), F.S., it is unlawful for a person to perform or cause the performance of any of the following acts in this state:

- The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.
- The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

As currently drafted, the bill does not require a blood establishment to obtain a permit to distribute certain prescription drugs. Without such a permit, a blood establishment is not expressly authorized to perform the prohibited activities outlined above.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 31, 2010, the Health Care Regulation Policy Committee considered the bill, adopted a strike-all amendment, and reported the bill favorably. The amendment accomplishes the following:

- Prohibits local governments from restricting access to public facilities or infrastructure for volunteer blood drives based on the tax status of a blood establishment conducting the blood drive.
- Prohibits a blood establishment from determining the price to sell blood or blood components, received from volunteer donors, solely on the tax status of hospitals or other health care providers.
- Excludes from the definition of "wholesale distribution" certain drugs utilized in blood related services provided by blood establishment.
- Exempts a blood establishment that manufactures blood and blood components from the requirement to be permitted as a prescription drug manufacturer.

1 A bill to be entitled
 2 An act relating to blood establishments; amending s.
 3 381.06014, F.S.; prohibiting a local government from
 4 restricting access to or use of public facilities or
 5 infrastructure for the collection of blood or blood
 6 components from volunteer donors based on certain
 7 criteria; prohibiting blood establishments from
 8 determining the price of blood or blood components based
 9 on certain criteria; amending s. 499.003, F.S.; revising
 10 the definition of the term "wholesale distribution" to
 11 exclude certain drugs and products distributed by blood
 12 establishments; amending s. 499.01, F.S.; excluding
 13 certain blood establishments from the requirement to
 14 obtain a prescription drug manufacturer permit; providing
 15 an effective date.

16
 17 Be It Enacted by the Legislature of the State of Florida:

18
 19 Section 1. Subsections (5) and (6) are added to section
 20 381.06014, Florida Statutes, to read:

21 381.06014 Blood establishments.—

22 (5) A local government may not restrict the access to or
 23 use of any public facility or infrastructure for the collection
 24 of blood or blood components from volunteer donors based on
 25 whether the blood establishment is operating as a for-profit
 26 organization or a not-for-profit organization.

27 (6) In determining the price of blood or blood components
 28 that are received from volunteer donors and sold to hospitals or

29 other health care providers, a blood establishment may not base
 30 the price of the blood or blood component solely on whether the
 31 purchasing entity is a for-profit organization or a not-for-
 32 profit organization.

33 Section 2. Paragraphs (e) and (f) of subsection (53) of
 34 section 499.003, Florida Statutes, are redesignated as
 35 paragraphs (f) and (g), respectively, and a new paragraph (e) is
 36 added to that subsection to read:

37 499.003 Definitions of terms used in this part.—As used in
 38 this part, the term:

39 (53) "Wholesale distribution" means distribution of
 40 prescription drugs to persons other than a consumer or patient,
 41 but does not include:

42 (e) The sale, purchase, or trade or the offer to sell,
 43 purchase, or trade, by a registered blood establishment that
 44 qualifies as a health care entity of any:

45 1. Drug indicated for a bleeding or clotting disorder or
 46 anemia;

47 2. Blood collection container approved under section 505
 48 of the Prescription Drug Marketing Act;

49 3. Drug that is a blood derivative, or a recombinant or
 50 synthetic form of a blood derivative, as long as the health care
 51 services provided by the blood establishment are related to its
 52 activities as a registered blood establishment or the health
 53 care services provided by the blood establishment consist of
 54 collecting, processing, storing, or administering human
 55 hematopoietic stem or progenitor cells or performing diagnostic
 56 testing of specimens that are tested together with specimens

57 undergoing routine donor testing; or
 58 4. Drug necessary to collect blood or blood components
 59 from volunteer blood donors; for blood establishment personnel
 60 to perform therapeutic procedures under the direction and
 61 supervision of a licensed physician; and to diagnose, treat,
 62 manage, and prevent any reaction of either a volunteer blood
 63 donor or a patient undergoing a therapeutic procedure performed
 64 under the direction and supervision of a licensed physician.

65
 66 A blood establishment whose distribution of products is excluded
 67 under this paragraph must satisfy all other requirements of this
 68 part applicable to a wholesale distributor or retail pharmacy.

69 Section 3. Paragraph (a) of subsection (2) of section
 70 499.01, Florida Statutes, is amended to read:

71 499.01 Permits.—

72 (2) The following permits are established:

73 (a) Prescription drug manufacturer permit.—A prescription
 74 drug manufacturer permit is required for any person that is a
 75 manufacturer of a prescription drug and that manufactures or
 76 distributes such prescription drugs in this state.

77 1. A person that operates an establishment permitted as a
 78 prescription drug manufacturer may engage in wholesale
 79 distribution of prescription drugs manufactured at that
 80 establishment and must comply with all of the provisions of this
 81 part, except s. 499.01212, and the rules adopted under this
 82 part, except s. 499.01212, that apply to a wholesale
 83 distributor.

84 2. A prescription drug manufacturer must comply with all

85 | appropriate state and federal good manufacturing practices.
86 | 3. A blood establishment, as defined in s. 381.06014,
87 | operating in a manner consistent with 21 C.F.R. parts 211 and
88 | 660-640 and manufacturing only the prescription drugs described
89 | in s. 499.003(53) (d) and (e) is not required to obtain a permit
90 | as a prescription drug manufacturer under this paragraph or
91 | register products under s. 499.015.

92 | Section 4. This act shall take effect upon becoming a law.

COUNCIL/COMMITTEE AMENDMENT

Bill No. CS/HB 509 (2010)

Amendment No. 1

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 _____

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council

3 Representative(s) Tobia offered the following:

4
5 **Amendment**

6 Remove lines 49-68 and insert:

7 3. Drug that is a blood derivative, or a recombinant or
8 synthetic form of a blood derivative; or

9 4. Drug necessary to collect blood or blood components
10 from volunteer blood donors; for blood establishment personnel
11 to perform therapeutic procedures under the direction and
12 supervision of a licensed physician; and to diagnose, treat,
13 manage, and prevent any reaction of either a volunteer blood
14 donor or a patient undergoing a therapeutic procedure performed
15 under the direction and supervision of a licensed physician.

16
17 A blood establishment's distribution of products are excluded
18 under this paragraph as long as all health care services
19 provided by the blood establishment are related to its

COUNCIL/COMMITTEE AMENDMENT

Bill No. CS/HB 509 (2010)

Amendment No. 1

20 activities as a registered blood establishment or the health
21 care services provided by the blood establishment consisting of
22 collecting, processing, storing, or administering human
23 hematopoietic stem or progenitor cells or performing diagnostic
24 testing of specimens that are tested together with specimens
25 undergoing routine donor testing. A blood establishment must
26 satisfy the requirements of s. 499.0121, F.S., and s.499.01212,
27 F.S.

COUNCIL/COMMITTEE AMENDMENT

Bill No. CS/HB 509 (2010)

Amendment No. 2

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 _____

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council
3 Representative(s) Tobia offered the following:

4
5 **Amendment**

6 Remove line 89 and insert:
7 in s. 499.003(53)(d) is not required to obtain a permit

HOUSE PRINCIPLES

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FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Chapter 89-372, F.O.F., established the framework for what is currently s. 419.001, F.S. Its purpose was to prevent or reduce inappropriate institutional care by providing for community-based care, home-based care, or other forms of less intensive care. The goal was to follow a deinstitutionalization model for placement of persons with special needs in the least restrictive setting and for the encouragement of placement of such individuals in community residential facilities.

Currently, s. 419.001, F.S., requires the local government to approve the location of certain residential homes which provide for a living environment for seven to fourteen unrelated residents. When a site for a community residential home has been selected by a sponsoring agency¹ in an area zoned for multifamily use, the agency must notify the Chief Executive Officer of the local government in writing. The local government then has up to 60 days to respond. If no response is given within 60 days, the sponsoring agency may establish the home at the site in question. Currently, homes with six or fewer residents are deemed a single family unit and do not require approval by the local government, provided that the home does not exist within a 1,000 feet radius of another six or fewer resident home.

Section 419.001(1)(d), F.S., defines a "resident" as a:

- "Developmentally disabled person" pursuant to s.393.063, F.S., which includes a person with a disorder or syndrome that is attributable to retardation, cerebral palsy, autism, spina bifida, or Prader-Willi syndrome and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.
- "Frail elder" pursuant to s. 429.65(9), F.S., which includes a functionally impaired person who is over the age of 60 who has physical and mental limitations that restricts the ability of that person to live independently and perform normal activities of daily living.
- "Physically disabled or handicapped person" pursuant to s. 760.22(7)(a), F.S., which includes a person that has a physical or mental impairment which substantially limits one or more major life activities, or he or she has a record of having, or is regarded as having, such physical or mental impairment.

¹ s. 419.001(1)(e), F.S., defines "sponsoring agency" as "an agency or unit of government, a profit or nonprofit agency, or any other person or organization which intends to establish or operate a community residential home."

- Nondangerous “mentally ill person” pursuant to s. 394.455(18), F.S., which includes an impairment of the mental or emotional processes that exercise conscious control of one's actions or of the ability to perceive or understand reality, which impairment substantially interferes with a person's ability to meet the ordinary demands of living, regardless of etiology. For the purposes of this part, the term does not include retardation or developmental disability as defined in Chapter 393, F.S., intoxication, or conditions manifested only by antisocial behavior or substance abuse impairment.
- “Child” who is found to be dependent by the court pursuant to ss. 39.01(14), and 984.03 F.S., and a “child” in need of services pursuant to ss. 984.03(9) and 985.03(8), F.S.

Effect of Proposed Changes

Committee Substitute for House Bill 645 amends s. 419.001(1), F.S., to define a “planned residential community” as a planned unit development which is:

- under unified control;
- planned and developed as a whole;
- has a minimum gross lot area of 10 acres; and
- has amenities that are designed to serve residents with a developmental disability; but
- which may also provide housing options for other individuals; and
- residents may enjoy unrestricted freedom of movement within and outside of the community.

The bill establishes that local government approval must be based on criteria that includes, but is not limited to, compliance with appropriate land use, zoning, and building codes. The bill prohibits the local government from basing approval on proximity limitations based upon the type of residents the planned unit development is anticipated to serve.

The bill creates s. 419.001(4), F.S., which provides that homes that have six or fewer residents that would otherwise meet the definition of a community residential home, and that are within a planned residential community, are not subject to the proximity limitations of s. 419.001, F.S. This means that if a home within a planned residential community will not be subject to the proximity requirements that would be otherwise enforceable on homes outside the planned residential community, if such limitations are based solely on the types of residents anticipated to be living in the community.

The practical effect of the bill is to allow the planning and development of special needs communities in areas adjacent to residential areas.

The bill also amends s. 393.501(2), F.S., creating an exception within the rulemaking authority of the Agency for Persons with Disabilities. The exception provides that there is no restriction on the number of facilities designated as community residential homes located within a planned residential community as defined by s. 419.001(1), F.S.

B. SECTION DIRECTORY:

- Section 1.** Amends s. 393.501(2), F.S., relating to rulemaking.
- Section 2.** Amends s. 419.001, F.S., relating to site selection of community residential homes..
- Section 3.** Provides an effective date of July 1, 2010.

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:

Not applicable because this bill does not appear to: require the counties or cities to spend funds or take an action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None

B. RULE-MAKING AUTHORITY:

The bill amends s. 393.501(2), F.S., to restrict the rulemaking authority of the Agency for Persons with Disabilities.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The term "under unified control" is ambiguous and may need to be clarified as to what is intended to be achieved. Similarly the language "residents may enjoy unrestricted freedom of movement" is drafted in the permissive form and may not achieve the intended effect.

Proponents of the bill emphasize that this would not be an institutional setting, since other adults, including family members, friends, and other caregivers may also live in the community. Qualifying persons will still be eligible for supported living services, and proponents advocate that these "planned residential communities" would allow the service providers better access to their clients and save the state money by not requiring the providers to drive further distances to their clients.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 25, 2010, HB 645 was amended in the Military & Local Affairs Policy Committee upon adoption of one amendment. The analysis reflects the bill as amended. Specifically, the amendment does the following:

- Modifies the definition of planned community development to require that the development be under unified control.
- Modifies the definition of planned community development to include minimum acreage requirements
- Modifies the definition of planned community development to state that residents may enjoy unrestricted freedom of movement within and outside of the community.
- Requires that a planned residential community must comply with the applicable local government's land development code and other local ordinances.
- Prohibits a local government from imposing proximity limitations between homes within a planned residential community if such limitations are based solely on the types of residents anticipated to be living in the community.

1 A bill to be entitled
 2 An act relating to community residential homes; amending
 3 s. 393.501, F.S.; prohibiting certain rules adopted by the
 4 Agency for Persons with Disabilities from restricting the
 5 number of facilities designated as community residential
 6 homes located within a planned residential community;
 7 amending s. 419.001, F.S.; defining the term "planned
 8 residential community"; providing that community
 9 residential homes located within a planned residential
 10 community may be contiguous to one another; prohibiting a
 11 local government from imposing proximity limitations under
 12 certain circumstances; providing an effective date.

13
 14 WHEREAS, individuals who have development disabilities have
 15 the same rights and freedoms as every other citizen in the
 16 United States, and

17 WHEREAS, the Developmental Disabilities Assistance and Bill
 18 of Rights Act of 2000, Pub. L. No. 106-402, found that
 19 individuals who have developmental disabilities and their
 20 families are the primary decisionmakers regarding the services
 21 and supports such individuals and their families receive,
 22 including choosing where the individuals live, and play
 23 decisionmaking roles in policies and programs that affect the
 24 lives of such individuals and their families, and

25 WHEREAS, individuals who have developmental disabilities
 26 should be able to select a home with the same freedom of choice
 27 as other United States citizens, and

28 WHEREAS, such selection should have no bearing on

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29 eligibility for services or supports that an individual may
 30 otherwise be entitled to receive, NOW, THEREFORE,

31

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

33

34 Section 1. Subsection (2) of section 393.501, Florida
 35 Statutes, is amended to read:

36 393.501 Rulemaking.—

37 (2) Such rules must ~~shall~~ address the number of facilities
 38 on a single lot or on adjacent lots, except that there is no
 39 restriction on the number of facilities designated as community
 40 residential homes located within a planned residential community
 41 as those terms are defined in s. 419.001(1). In adopting rules,
 42 an alternative living center and an independent living education
 43 center, as described in s. 393.18, are ~~shall be~~ subject to the
 44 ~~provisions of~~ s. 419.001, except that such centers are ~~shall be~~
 45 exempt from the 1,000-foot-radius requirement of s. 419.001(2)
 46 if:

47 (a) The centers are located on a site zoned in a manner
 48 that permits all the components of a comprehensive transitional
 49 education center to be located on the site; or

50 (b) There are no more than three such centers within a
 51 radius of 1,000 feet.

52 Section 2. Subsection (1) of section 419.001, Florida
 53 Statutes, is amended, present subsections (4) through (11) of
 54 that section are redesignated as subsections (5) through (12),
 55 respectively, and a new subsection (4) is added to that section,
 56 to read:

57 419.001 Site selection of community residential homes.—

58 (1) For the purposes of this section, the term ~~following~~
 59 ~~definitions shall apply:~~

60 (a) "Community residential home" means a dwelling unit
 61 licensed to serve residents, ~~as defined in paragraph (d),~~ who
 62 are clients of the Department of Elderly Affairs, the Agency for
 63 Persons with Disabilities, the Department of Juvenile Justice,
 64 or the Department of Children and Family Services or a dwelling
 65 unit licensed by the Agency for Health Care Administration which
 66 provides a living environment for 7 to 14 unrelated residents
 67 who operate as the functional equivalent of a family, including
 68 such supervision and care by supportive staff as may be
 69 necessary to meet the physical, emotional, and social needs of
 70 the residents.

71 (b) "Licensing entity" or "licensing entities" means the
 72 Department of Elderly Affairs, the Agency for Persons with
 73 Disabilities, the Department of Juvenile Justice, the Department
 74 of Children and Family Services, or the Agency for Health Care
 75 Administration, all of which are authorized to license a
 76 community residential home to serve residents, ~~as defined in~~
 77 ~~paragraph (d).~~

78 (c) "Local government" means a county as set forth in
 79 chapter 7 or a municipality incorporated under the provisions of
 80 chapter 165.

81 (d) "Planned residential community" means a planned unit
 82 development which is under unified control, is planned and
 83 developed as a whole, has a minimum gross lot area of 10 acres,
 84 and has amenities that are designed to serve residents with a

85 developmental disability as defined in s. 393.063 but which may
 86 also provide housing options for other individuals. This
 87 community shall provide choices with regard to housing
 88 arrangements, support providers, and activities. The residents
 89 may enjoy unrestricted freedom of movement within and outside of
 90 the community. For the purposes of this paragraph, local
 91 government approval must be based on criteria that include, but
 92 are not limited to, compliance with appropriate land use,
 93 zoning, and building codes. A planned residential community may
 94 contain two or more community residential homes that are
 95 contiguous to one another.

96 (e)~~(d)~~ "Resident" means any of the following: a frail
 97 elder as defined in s. 429.65; a person who has a handicap
 98 ~~physically disabled or handicapped person~~ as defined in s.
 99 760.22 (7) (a); a ~~developmentally disabled~~ person who has a
 100 developmental disability as defined in s. 393.063; a
 101 nondangerous ~~mentally ill~~ person who has a mental illness as
 102 defined in s. 394.455~~(18)~~; or a child who is found to be
 103 dependent as defined in s. 39.01 or s. 984.03, or a child in
 104 need of services as defined in s. 984.03 or s. 985.03.

105 (f)~~(e)~~ "Sponsoring agency" means an agency or unit of
 106 government, a profit or nonprofit agency, or any other person or
 107 organization which intends to establish or operate a community
 108 residential home.

109 (4) Community residential homes, including homes of six or
 110 fewer residents which would otherwise meet the definition of a
 111 community residential home, which are located within a planned
 112 residential community are not subject to the proximity

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113 | requirements of this section and may be contiguous to each
 114 | other. A planned residential community must comply with the
 115 | applicable local government's land development code and other
 116 | local ordinances. A local government may not impose proximity
 117 | limitations between homes within a planned residential community
 118 | if such limitations are based solely on the types of residents
 119 | anticipated to be living in the community.

120 | Section 3. This act shall take effect July 1, 2010.

COUNCIL/COMMITTEE AMENDMENT

Bill No. CS/HB 645 (2010)

Amendment No. 1

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	_____	

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council
3 Representative Stargel offered the following:

4
5 **Amendment**

6 Remove lines 70-108 and insert:
7 the residents or a dwelling unit that operates as a sober house-
8 transitional living home that is established July 1, 2010 or
9 thereafter.

10 (b) "Licensing entity" or "licensing entities" means the
11 Department of Elderly Affairs, the Agency for Persons with
12 Disabilities, the Department of Juvenile Justice, the Department
13 of Children and Family Services, or the Agency for Health Care
14 Administration, all of which are authorized to license a
15 community residential home to serve residents, ~~as defined in~~
16 ~~paragraph (d).~~

17 (c) "Local government" means a county as set forth in
18 chapter 7 or a municipality incorporated under the provisions of
19 chapter 165.

Amendment No. 1

20 (d) "Planned residential community" means a local
21 government approved planned unit development which is under
22 unified control, is planned and developed as a whole, has a
23 minimum gross lot area of 8 acres, and has amenities that are
24 designed to serve residents with a developmental disability as
25 defined in s. 393.063 but which may also provide housing options
26 for other individuals. This community shall provide choices with
27 regard to housing arrangements, support providers, and
28 activities. The residents may enjoy unrestricted freedom of
29 movement within and outside of the community. For the purposes
30 of this paragraph, local government approval must be based on
31 criteria that include, but are not limited to, compliance with
32 appropriate land use, zoning, and building codes. A planned
33 residential community may contain two or more community
34 residential homes that are contiguous to one another.

35 (e)-(d) "Resident" means any of the following: a frail
36 elder as defined in s. 429.65; a person who has a handicap
37 physically disabled or handicapped person as defined in s.
38 760.22(7)(a); a developmentally disabled person who has a
39 handicap as defined in s. 393.063; a nondangerous mentally ill
40 person who has a mental illness as defined in s. 394.455(18); or
41 a child who is found to be dependent as defined in s. 39.01 or
42 s. 984.03, or a child in need of services as defined in s.
43 984.03 or s. 985.03.

44 (f) "Sober house-transitional living home" means a
45 community residential home that provides a peer supported and
46 managed alcohol and drug-free living environment for no more
47 than 6 unrelated residents that are recovering from substance

Amendment No. 1

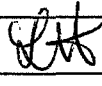

48 abuse and are actively participating in licensed substance abuse
49 treatment, non-licensed peer support services, or are
50 transitioning back in the community from residential treatment
51 programs or incarceration. Sober houses-transitional living
52 homes are supervised by a House Manager who ensures that the
53 sober living environments offer structure and strong peer
54 support. Residents pay weekly or monthly rent and other living
55 expenses associated with operation of the sober house-
56 transitional living home while working, attending treatment, or
57 attending school during the day and engaging in recovery
58 activities in the evenings.

59 (g) ~~(e)~~ "Sponsoring agency" means an agency or unit of
60 government, a profit or nonprofit agency, or any other person or
61 organization which intends to establish or operate a community
62 residential home.

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 729 Practice of Tattooing
SPONSOR(S): Health Care Regulation Policy Committee; Brandenburg
TIED BILLS: IDEN./SIM. BILLS: CS/SB 942

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	12 Y, 0 N, As CS	Holt	Calamas
2)	Health Care Appropriations Committee	13 Y, 0 N	Clark	Massengale
3)	Health & Family Services Policy Council		Holt 	Gormley 
4)				
5)				

SUMMARY ANALYSIS

Committee Substitute for House Bill 729 creates a new regulation for licensure as a tattoo artist, registration as a guest tattoo artist, licensure for tattoo establishments, and licensure for temporary tattoo establishments. A person may not tattoo the body of a human being in this state except in a tattoo establishment and the person performing the tattooing must be licensed as a tattoo artist or registered as a guest tattoo artist.

Because the bill establishes regulation of a new profession, the Sunrise Act criteria apply. Section 11.62, Florida Statutes, states that no profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage; and no profession or occupation be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation.

The bill specifies that a person may not tattoo a child younger than 16 years of age unless it is performed for medical or dental purposes. A minor child over the age of 16 may receive a tattoo under certain circumstances.

The bill appears to have a significant fiscal impact; however, the expenditures incurred will be offset by the revenues collected (See fiscal analysis).

The bill has an effective date of January 1, 2012.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Tattooing

A tattoo is a permanent mark or design made on the skin by a process of pricking and ingraining an indelible ink pigment. Tattoos are made by using needles to inject colored ink below the skin's surface. Typically, a tattoo artist uses a hand-held machine with one or more needles piercing the skin repeatedly. With every puncture, the needles insert ink into the skin.

National Trends and Regulations

At least 38 states have implemented laws regarding tattooing and 28 states have laws that prohibit tattooing on minors without parental permission.¹ Parental permission requirements vary among states ranging from signed notarized documentation to explicit in-person consent of the child's parent or guardian. The majority of states laws establish financial penalties, incarceration time, or both for violators.

The U.S. Food and Drug Administration (USFDA) and the Department of Health and Human Services, Centers for Disease Control and Prevention's (CDC) literature speak to a variety of potential risks in acquiring a tattoo on the body. Such risks include:

- Infection – Dirty needles can pass infections, such as hepatitis and HIV.
- Allergies – Allergies to different ink pigments can cause problems.

¹ Ala. Code § 420-3-23; Alaska Stat. § 08.13.217; Ariz. Rev. Stat. §13-3721; Cal. [Health & Safety] Code §119300; Col. Rev. Stat. Ann. §25-4-2103; Conn. Gen. Stat. §19a-92a; Del. Code Ann. Title 11, Ch 5 §1114(a); Ga. Code §16-12-71; Ga. Code §16-5-71; Haw. Rev. Stat. § 321-372 to 383; Idaho Code § 18-1523; Idaho Code § 39-2001; Idaho Code § 39-2003; Ill. Comp. Stat. 720§5/12-10; Ind. Code Ann. §35-42-2-7; Iowa Code §135.37; Kan. Admin. Regs. §69-15; Ky. Rev. Stat. §211.760; La. Admin. Code 29§2741-2744; Me. Rev. Stat. Ann. Title 32, Ch. 63 §4201-4301; Me. Rev. Stat. Ann. Title 32-A, Ch. 63 §4311-4317; Md. Code Regs. 09.22.02.01-03; Mich. Comp. Laws Ann. §333.131; Minn. Stat. §609.2246; Miss. Laws §73-61-1; Mo. Rev. Stat. §324.520; Mont. Code Ann. §45-5-623; Mont. Admin. R. 37.112.100; Neb. Rev. Stat. § Sec. 427 71-3; Neb. Rev. Stat. § Sec. 433 71-3; Nev. Admin. Code §29.17.080; N.H. Rev. Stat. Ann. §314-A:3; N.J. Admin. Code §8:27-8; N.Y. Codes R. & Regs. 160.7; N.C. Gen. Stat. §14-400; N.C. Gen. Stat. §130A-283; N.D. Cent. Code §12.1-31; Ohio Rev. Code Ann. §3730.02-.11; Okla. Stat. Title 21 §842.1-2; Or. Admin. R. 331-550-0000-0020; Pa. Cons. Stat. Title 18 §4729; Pa. Cons. Stat. Title 18 §6311; RI General Laws §11-9-15; RI General Laws §23-1-39; S.C. Code Ann. §40-47-60; S.C. Code Ann. §44-34-60; S.D. Codified Laws Ann. §26-10-19; S.D. Admin. R. 44:12:01:01-35; Tenn. Code Ann. §62-38-207; Tenn. Code Ann. §39-15-403; Texas Health and Safety Code Ann. §146.012; Tex. Admin. Code §229.401; Utah Code Ann. §76-10-2201; Vt. Stat. Ann. Title 26 §4101-4108; Va. Code Ann. §18.2-371.3; Va. Code Ann. §15.2-912; Wash. Rev. Code §26.28.085; Wash. Admin. Code 246-145-010; W. Va. Code §16-38-1-7; Wis. Stat. §252.23; Wis. Stat. §948.70; Wyo. Stat. §14-3-107.

- Scarring – Unwanted scar tissue may form on an initial or removed tattoo.
- MRI complications – Though rare, swelling or burning in the tattoo area when having a magnetic resonance image can occur.

The USFDA has not approved any tattoo pigments for injection into the skin. This applies to all tattoo pigments, including those used for ultraviolet and glow-in-the dark tattoos. Many pigments used in tattoo inks are industrial-grade colors suitable for printers' ink or automobile paint. In addition, the use of henna in temporary tattoos has also not been approved by the USFDA.

The CDC notes that a risk of HIV transmission exists if instruments contaminated with blood are not sterilized or disinfected, or are used inappropriately between clients. The CDC recommends that single-use instruments intended to penetrate the skin be used once, then discarded. In addition, reusable instruments or devices that penetrate the skin or contact a client's blood should be thoroughly cleaned and sterilized between clients. The CDC stresses that tattooists should be educated regarding HIV transmission and take precautions to prevent this transmission in their setting.

Biomedical Waste Permitting

Section 381.0098(1), F.S., establishes legislative intent relating to protecting the public's health by establishing safety standards for the packaging, transport, storage, treatment and disposal of biomedical waste. Biomedical waste is defined as "any solid or liquid waste which may present a threat of infection to humans, including waste products that include discarded disposable sharps, human blood, blood products and body fluids." A biomedical waste generator is defined as "a facility, or person that produces or generates biomedical waste." The statute directs the Department of Health (DOH) and the Department of Environmental Protection to develop an interagency agreement to ensure maximum efficiency in coordinating, administering, and regulating biomedical waste. While DOH has no authority to issue a license to a tattooist or a tattoo studio, it does have authority to issue a biomedical waste-generator permit to a tattooist and a tattoo studio.

Rule 64E-16.011, F.A.C., DOH prescribes minimum sanitary practices relating to the management of biomedical waste and the regulation of biomedical waste generators. Tattoo studios are considered biomedical waste generators and as such are required to obtain an annual permit from DOH. These studios are inspected by DOH personnel at least once a year and re-inspections may be conducted when a facility is found to be noncompliant with sanitation practices. Current law does not provide authorization for DOH to inspect these establishments relating to other sanitation aspects of tattoo studios, or to license or register tattoo artists.

The Department of Health estimates that there are approximately 900 permanent make-up and tattoo establishments in Florida.² The American Tattooing Institute offers an on-line or mail order certification course that includes studies in skin anatomy and physiology, blood borne pathogens, Occupational Safety and Health Administration standards, food and drug administration information, and body art specialist's code of ethics training.³

Regulation of Tattooing in Florida

Section 877.04, F.S., governs the practice of tattooing. Generally, a tattoo may only be performed by:

- A physician licensed under chapters 458 and 459, F.S.;
- A dentist licensed under chapter 466, F.S.; or
- A person under the general supervision of a physician or dentist.

Any person who tattoos must either be licensed as, or work under the "general supervision," as defined in Rule 64B8-2.002, F.A.C., of a physician or dentist. Additionally, it is unlawful for the body of a minor to be tattooed without the written, notarized consent of the parent or legal guardian. Any person who

² Department of Health, Bill Analysis, Economic Statement and Fiscal Note of House Bill 729 (February 8, 2010).

³ American Tattooing Institute, Body Art Specialist's Code of Ethics, available at: http://www.tatsmart.com/code_of_ethics (last viewed March 20, 2010).

violates this section is guilty of a misdemeanor of the second degree, punishable under ss. 775.082 and 775.083, F.S.

Professional Regulation and the Florida Sunrise Act

There are three different types or levels of regulation:⁴

1. Licensure is the most restrictive form of state regulation. Under licensure laws, it is illegal for a person to practice a profession without first meeting all of the standards imposed by the state.
2. Certification grants title protection to those who meet training and other standards. Those who do not meet certification standards cannot use the title, but can still perform the services.
3. Registration the least restrictive form of regulation, and usually only requires individuals to file their name, address and qualifications with a government agency before practicing the occupation.

Section 456.003, F.S., specifies that health care professions be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions shall be regulated when:

- Their unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation;
- The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation; and
- Less restrictive means of regulation are not available.

Section 11.62, F.S., the Sunrise Act, provides legislative intent regarding the regulation of new professions and occupations:⁵

- No profession or occupation is subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose; and
- No profession or occupation is regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

In determining whether to regulate a profession or occupation, section 11.62(3), F.S., requires the Legislature to consider the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;

⁴ Schmitt, K. & Shimberg, B. (1996). *Demystifying Occupational and Professional Regulation: Answers to Questions You May Have Been Afraid to Ask. Council on Licensure, Enforcement, and Regulation.*

⁵ s. 11.62(2), F.S.

- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The Sunrise Act requires proponents of regulation to submit information documenting the need for the proposed regulation. A sunrise questionnaire was submitted by the Florida Professional Tattoo Artist's Guild (guild). The guild represents approximately 1,800 tattooists. According to the guild, they have met very little resistance to the proposed regulation contained in Committee Substitute for House Bill 729 and estimate that 75 percent of the professional tattoo industry support this legislation.

Sunrise Act Criteria

Substantial Harm or Endangerment

Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.⁶

The practice of tattooing has the potential of exposing clients and tattoo artists to blood borne pathogens if proper universal precautions⁷ are not practiced. According to the guild, there is a growth in underground tattooing (called "scratchers") where tattoo services are provided at homes, bars, flea markets, camp sites, and similar sites. Scratchers are most likely not practicing universal precautions, concerned with cross contamination, or properly disposing of biomedical waste.⁸

According to the guild, DOH has no database to document the number of complaints received. The following is a comment from an employee with the Department of Health, Division of Environmental Health, provided by the guild:

"I can say that seldom a day goes by when our staff here in Community Environmental Health do not receive a phone call or e-mail pertaining to tattoo regulations in Florida, both licensure inquiries and complaints about pertaining to unexpected outcomes." 2/2/10

Specialized Skill or Training, and Measurability

Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability.⁹

Tattooing is a specialized field that is based on peer review of a tattooist artistic ability. A tattoo artist may only work with specific colors or specialize in special designs (i.e., wild life or portraits). The bill does not require tattoo artists to possess formal institutional classroom training that provides them with

⁶ s. 11.62(3), F.S.

⁷ "Universal precautions," as defined by CDC, are a set of precautions designed to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens when providing first aid or health care. Under universal precautions, blood and certain body fluids of all patients are considered potentially infectious for HIV, HBV and other bloodborne pathogens. See Centers for Disease Control and Prevention, Universal Precautions for Prevention of Transmission of HIV and Other Bloodborne Infections, available at: http://www.cdc.gov/ncidod/dhqp/bp_universal_precautions.html (last viewed March 19, 2010).

⁸ Rule 64E-16, F.A.C., requires facilities that generate biomedical waste to ensure proper management of that waste. Biomedical waste is any solid or liquid waste which may present a threat of infection to humans, including non-liquid tissue, body parts, blood, blood products, and body fluids from humans and other primates; laboratory and veterinary wastes which contain human disease-causing agents; and discarded sharps. The following are also included: (a) used, absorbent materials saturated with blood, blood products, body fluids, or excretions or secretions contaminated with visible blood; and absorbent materials saturated with blood or blood products that have dried. (b) non-absorbent, disposable devices that have been contaminated with blood, body fluids or, secretions or excretions visibly contaminated with blood, but have not been treated by an approved method.

⁹ s. 11.62(3), F.S.

a specialized skill that is measurable or quantifiable. According to the guild, "at this time it is left up to the individual tattoo establishment to set their standards." About 90 percent of the beginner tattoo artists receive training through an apprenticeship.

The Alliance of Professional Tattooists (alliance) provides a blood borne pathogen course at the majority of the conventions in the United States. This course is a total of six hours for training and an examination. According to the guild, "this course is highly regarded in the tattoo industry as a must complete course and test." According to the guild, "there is a great deal of knowledge passed from tattooist to tattooist at some of the conventions where training seminars are offered." The guild and the alliance do have rules pertaining to codes of practice for their members; however, the only recourse for enforcement of the codes is to revoke a membership.

Unreasonable Effect on Job Creation or Job Retention

Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment.¹⁰

The guild is unaware of any other unregulated occupation that performs similar services. Establishments that offer body piercing services and operate as tattoo establishments will be required to have dual licensure. According to the guild, the training in blood borne pathogens and cross contamination is a necessary requirement.

Can the Public Be Effectively Protected by Other Means?

Whether the public is or can be effectively protected by other means.¹¹

Current law¹² requires tattoo artists to work under the general supervision of a licensed medical doctor or doctor of osteopathic medicine. According to the guild, supervising doctors develop their own procedures regarding the medical conditions of individuals receiving tattoos, treatment of problems resulting during or from tattooing, and procedures in the event an emergency situation developed during the performance or as a result of tattooing. Thus, these standards vary from doctor to doctor. If the supervising doctor is negligent in his or her duties, the Board of Medicine can review the license of the doctor and, if necessary, take disciplinary action on their license.¹³ If there is a complaint that a tattoo facility violated the terms of its biomedical waste permit, county health department staff has the authority to investigate and enforce compliance when necessary.¹⁴

Favorable Cost-effectiveness and Economic Impact

Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.¹⁵

According to the guild, there are approximately 900 tattoo establishments and approximately 1,800 tattoo artists in Florida.¹⁶ Usually there are two tattoo artists practicing in each tattoo establishment and on average each tattoo establishment will complete 25 to 30 tattoos in one week. The average minimum cost of a tattoo is \$30. If these values are applied statewide, there is a potential of approximately one million tattoos applied annually, which the guild believes will increase as a result of the "security the public will feel because of the enforcement provisions." In addition, the guild believes the cost of regulation will cost tattoo establishments less than what they are paying to a doctor to provide his services of general supervision. Fees doctors charge for supervision vary. According to members of the guild, some doctors charge \$300 per tattoo artist.

¹⁰ *Id.*

¹¹ *Id.*

¹² s. 877.04, F.S.

¹³ ss. 458.331 and 459.015, F.S.

¹⁴ Rule 64E-16.013, F.A.C.

¹⁵ *Id.*

¹⁶ DOH supplied the Guild with a recent registration list of biomedical waste permittees to assist in calculating the number of tattoo establishments.

Effect of Proposed Changes

The bill creates definitions for active license or registration, department, guest tattoo artist, operator, stop use order, tattoo, tattoo artists, tattoo establishment, and temporary establishment.

The bill specifies that a person may not tattoo a child younger than 16 years of age unless it is performed for medical or dental purposes. A minor child over the age of 16 may receive a tattoo if the minor is accompanied by a parent or legal guardian; provides proof of identity in the form of a government issued photo identification; provides proof that he/she is the parent or legal guardian of the minor; the parent submits a written notarized consent; and the tattooing may only be performed by a tattoo artist, guest tattoo artist, medical doctor, doctor of osteopathic medicine, or dentist. The bill exempts a person from criminal prosecution if a minor falsely presents as being 18 years of age, the artist checks identification, and a person of reasonable average intelligence person would believe the minor is at least 18 years of age.

General Licensure Provisions

The bill specifies that a person may not tattoo the body of a human being in this state except in a tattoo establishment and the person performing the tattooing must be licensed as a tattoo artist or registered as a guest tattoo artist. The bill exclusively applies to the tattooing of human beings and does not apply to the tattooing of animals.

The bill exempts licensed medical doctors, doctors of osteopathic medicine, and dentists who perform tattooing exclusively for medical or dental purposes from having to be licensed as a tattoo artist. The bill specifies that these provisions do not preempt any local law or ordinance of a county or municipality that imposes regulations on tattoo establishments, temporary establishments, tattoo artists, or the practice of tattooing.

The bill authorizes DOH to enforce and discipline individuals who:

- provide false information on a DOH application;
- violate state or local health code or ordinances;
- practice tattooing without a valid license or registration issued by DOH;
- are found guilty or plead nolo contendere to a crime in any jurisdiction that relates to the practice of tattooing or operation of a tattoo establishment;
- commit fraud, deceit, negligence, or misconduct in the practice or operation of tattooing; or
- aid, procure, or assist a person in unlawfully practicing tattooing or operating a tattoo establishment.

The bill authorizes DOH to:

- refuse to issue a license or registration;
- suspend or revoke a license or registration;
- issue a reprimand;
- place an individual on probation;
- issue a stop-use order;
- order corrective action;
- impose stricter penalties for repeat violations; or
- consider the severity of the violation distinguishing lesser violations from those that endanger public health.

The bill requires DOH to establish fees and authorizes DOH to annually adjust the maximum fees authorized according to the rate of inflation or deflation indicated by the Consumer Price Index for All Urban Consumers, U.S. City Average, All Items, as reported by the U.S. Department of Labor.

The bill authorizes DOH to promulgate rules and consult with representatives of the tattooing industry during rule development. The bill specifies that the rules adopted may include, but are not limited to: defining terms; prescribing educational requirements for tattoo artists and guest tattoo artists; health and safety requirements; sanitation and sterilization practices; equipment requirements; customer notification, contents and retention of customer records; and physical plants.

The bill specifies requirements for the following:

1. licensure as a tattoo artist,
2. registration as a guest tattoo artist, and
3. licensure of tattoo establishments and temporary establishments.

Individuals who practice tattooing without a tattoo artist license, guest tattoo artist registration, tattoo establishment license, or temporary establishment license commit a misdemeanor of the second degree.¹⁷

1. Tattoo Artist Licensure

The bill specifies that a person seeking to practice as a licensed tattoo artist must apply to DOH for licensure. An applicant for licensure must:

- be at least 18 years of age;
- submit a completed application to DOH;
- pay a fee that may not exceed \$150;
- submit proof of successful completion of a DOH approved education course in blood borne pathogens and communicable disease; and
- submit proof of passage of a DOH approved examination that tests the materials contained in the education course.

The DOH application must capture the following information:

- name and address of residence of the applicant; and
- name and address of each tattoo establishment to include temporary establishments in which the person intends to practice.

The bill requires a licensed tattoo artist to notify DOH within 30 days of a name or address change and of practice as a tattoo artist for more than 14 days at a tattooing establishment that was not disclosed on the most recent application for licensure.

A licensed tattoo artist must display their registration in a manner that is easily visible to the public at all times while practicing tattooing, comply with all state and local health codes, and maintain sanitary conditions at all times. The bill requires DOH to approve one or more education courses and examinations that are to be made accessible through an Internet website. Licensure as a tattoo artist is valid for one year, is not transferable, and must be renewed annually.

2. Guest Tattoo Artist Registration

The bill requires DOH to issue a guest tattoo artist registration to an applicant who:

- is at least 18 years of age;
- submits a completed DOH application;
- pays the applicable registration fee that may not exceed \$45; and

¹⁷ Misdemeanors of the second degree are punishable by a term of imprisonment not to exceed 60 days or a fine not to exceed \$500 (ss. 775.082 and 775.083, F.S.).

- holds an active license, registration, or certification issued by a jurisdiction outside of Florida that meets the education and examination requirements for licensure and submits proof of successful completion of an DOH approved education course and examination.

A guest tattoo artist must display the registration in a manner that is easily visible to the public at all times while practicing tattooing, comply with all state and local health codes, and maintain sanitary conditions at all times. Registration as a guest tattoo artist is valid for 14 days and is not transferable. A person seeking re-registration as a guest tattoo artist may re-register before or after their current registration expires.

3. Licensed Tattoo Establishments and Temporary Establishments

The bill specifies that a person may not operate a tattoo establishment or temporary establishment unless it is licensed by DOH. The Department of Health must issue a tattoo establishment license to applicants if they:

- submit a completed DOH application;
- pay the applicable licensure fee that may not exceed \$250; and
- comply with all applicable local building, occupational, zoning, and health codes.

The bill requires the DOH application to capture the following information:

- name under which the tattoo establishment will conduct business;
- physical address and phone number;
- name, mailing address, and telephone number of the tattoo establishment operator; and
- name and address of the tattoo establishment's registered agent for service of process.

The bill requires a licensed tattoo establishment or temporary establishment to:

- visibly display the establishment license to the public at all times when tattooing is being performed;
- ensure that all tattoo artists and guest tattoo artists practicing within the establishments meet registration or licensure requirements;
- maintain sanitary conditions at all times;
- comply with state and local health codes and ordinances;
- comply with the biomedical waste requirements in s. 381.0098, F.S.; and
- allow periodic inspections and enforcement by DOH.

A tattoo establishment license is only valid for the location listed on the license and the establishment must notify DOH prior to any change in location. Tattoo establishments with more than one location must obtain a separate license for each location. A tattoo establishment license is valid for one year, is not transferrable, and must be renewed annually. The bill specifies that temporary tattoo establishments must meet the same licensure requirements as permanent tattoo establishments; however, the license is only valid for 14 consecutive days.

The bill requires DOH to inspect each tattoo establishment at least annually and each temporary establishment before and, if necessary, during the event.

The bill has an effective date of January 1, 2012.

B. SECTION DIRECTORY:

Section 1. Creates s. 381.00771, F.S., relating to definitions and terms.

Section 2. Creates s. 381.00773, F.S., relating to applicability.

Section 3. Creates s. 381.00775, F.S., relating to tattoo artists; licensure; and registration of guest tattoo artists.

- Section 4.** Creates s. 381.00777, F.S., relating to tattoo establishments; licensure; and temporary establishments.
- Section 5.** Creates s. 381.00779, F.S., relating to practice requirements.
- Section 6.** Creates s. 381.00781, F.S., relating to fees and disposition.
- Section 7.** Creates s. 381.00783, F.S., relating to grounds for discipline and administrative penalties.
- Section 8.** Creates s. 381.00785, F.S., relating to criminal penalties.
- Section 9.** Transfers and renumbers s. 877.04, F.S., to s. 381.00787, F.S., relating to prohibited tattooing and penalties.
- Section 10.** Amends s. 381.00789, F.S., relating to rulemaking.
- Section 11.** Creates s. 381.00791, F.S., relating to local laws and ordinances.
- Section 12.** Provides an effective date of January 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Department of Health, Division of Environmental Health, estimates that 900 permanent tattoo establishments and 150 temporary establishments would be required to pay an annual license fee not to exceed \$250. Assuming an estimated average of two artists per tattoo establishment, 1,800 artists will be required to pay a fee not to exceed \$150 annually. An estimated 250 guest tattoo artist will be required to pay registration fee not to exceed \$45.¹⁸ These revenue estimates presented in this fiscal analysis are calculated using the maximum allowable license fee amounts. DOH has the authority to set the fee lower than the cap.

Estimated Revenue	1st Year	2nd Year
Licenses for 1050 establishments @ \$250 each	\$262,500	\$262,500
Licenses for 1800 artists @ \$150 each	\$ 270,000	\$ 270,000
Licenses for 250 guest artists @ \$45	\$ 11,250	\$ 11,250
Total Estimated Revenue	\$543,750	\$543,750

2. Expenditures:

The Department of Health, Division of Environmental Health, will incur the costs of rule promulgation, development, and presentation of training for DOH county health departments (CHDs) who will inspect the establishments. The Department of Health will also incur the costs of training and examination approval for the tattoo industry. County Health Departments will incur the costs associated with processing applications, issuing licenses, and conducting inspections, re-inspections, and enforcement. The estimated expenditures reflect the cost of performing the inspections. Hourly rate for salaries includes the fringe benefits.

Estimated Expenditures	1st Year	2nd Year (Annualized/Recurr.)
Salaries		
Inspection of 900 permanent and 150 temporary establishments @ \$130 per inspection	\$ 136,500	\$ 136,500
Reinspection of 25% of Establishments	\$ 34,125	\$ 34,125
Complaint investigation of 20% of establishments	\$ 27,300	\$ 27,300

¹⁸ Department of Health, Bill Analysis, Economic Statement and Fiscal Note of House Bill 729 (February 8, 2010).

Processing 1050 establishment applications, 2100 artists applications/registrations, issuing 3150 licenses	\$40,000	\$ 40,000
Training development for county health department staff	\$ 2,500	\$ 1,500
Rule Promulgation	\$ 10,000	-0-
Expenses		
Travel for staff to provide training at 10 sites	\$ 5,000	-0-
Site visits from Central Office staff to perform site evaluations	-0-	\$ 5,000
Data support and information distribution	\$5,000	\$5,000
Total Estimated Expenditures	\$260,425	\$249,425

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

Not applicable.

2. Expenditures:

The fiscal impact to county governments as a result of the second degree misdemeanor penalty is indeterminate. This is a likely low volume offense and is therefore anticipated to have an insignificant fiscal effect to the counties.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There may be an additional cost to tattoo artists for licensure and possibly training if they have not already taken a course.

D. FISCAL COMMENTS:

Section 216.0236, F.S., states that it is the intent of the Legislature that all costs of providing a regulatory service or regulating a profession or business be borne solely by those who receive the service or who are subject to regulation. It is also the intent of the Legislature that the fees charged for providing a regulatory service or regulating a profession or business is reasonable and takes into account the differences between the types of professions or businesses being regulated.

The bill does not include, nor does it require, a fiscal appropriation for DOH to meet the requirements of the bill. Approximately 10% of the estimated expenditures incurred by DOH will be incurred by the central office and are administrative in nature. The remaining expenditures will be incurred by the county health departments for regulatory purposes. These expenditures will be offset by the revenues earned in annual licensure and registration fees. These fees will be deposited into the County Health Department Trust Fund for use of regulatory functions of the county health departments. Approximately 10 percent of the revenues will be transferred to the Administrative Trust Fund to cover the functions of the DOH central office.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the department sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill places the provisions for regulation of tattoo artists and guest tattoo artists into Chapter 381, F.S., relating to public health. Most regulated professions and persons are governed under Chapter 456, F.S.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 22, 2010, the Health Care Regulation Policy Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all:

- changes the effective date to January 1, 2012;
- reorganizes the bill by combining provisions and moving language around within the bill;
- requires licensed tattoo establishments to comply with state biomedical waste requirements;
- requires DOH to inspect tattoo establishments at least once annually;
- specifies that tattooing applies exclusively to humans, not animals;
- requires DOH to inspect temporary tattoo establishments prior to the event and, if necessary, during the event;
- decreases the penalty from a felony of the third degree felony to a misdemeanor of the second degree;
- authorizes specific rule making; and
- exempts artists from criminal prosecution if the minor falsely presents as being 18 years of age, the artist checks identification, and a person of reasonable average intelligence person would believe the minor is at least 18 years of age.

This analysis is drafted to the committee substitute.

1 A bill to be entitled
2 An act relating to the practice of tattooing; creating s.
3 381.00771, F.S.; defining terms; creating s. 381.00773,
4 F.S.; exempting certain personnel who perform tattooing
5 for medical or dental purposes from regulation under
6 specified provisions; creating s. 381.00775, F.S.;
7 prohibiting the practice of tattooing except by a person
8 licensed or registered by the Department of Health;
9 requiring tattoo artists to complete a department-approved
10 education course and pass an examination; providing for
11 the licensure of tattoo artists and the registration of
12 guest tattoo artists licensed in jurisdictions outside
13 this state; creating s. 381.00777, F.S.; requiring the
14 licensure of permanent tattoo establishments and temporary
15 establishments; creating s. 381.00779, F.S.; providing
16 practice requirements for tattoo artists, guest tattoo
17 artists, tattoo establishments, and temporary
18 establishments; requiring the department to inspect the
19 establishments at specified intervals; creating s.
20 381.00781, F.S.; providing for fees for initial licensure
21 or registration and the renewal or reactivation thereof;
22 authorizing the adjustment of fees according to inflation
23 or deflation; creating s. 381.00783, F.S.; specifying acts
24 that constitute grounds for which the department may take
25 disciplinary action; providing penalties; creating s.
26 381.00785, F.S.; providing penalties for certain
27 violations involving the practice of tattooing;
28 transferring, renumbering, and amending s. 877.04, F.S.;

29 prohibiting the tattooing of a minor child except under
 30 certain circumstances; providing penalties; providing
 31 exceptions; creating s. 381.00789, F.S.; requiring the
 32 department to adopt rules to administer the act; creating
 33 s. 381.00791, F.S.; providing that specified provisions do
 34 not preempt certain local laws and ordinances; providing
 35 an effective date.

36
 37 Be It Enacted by the Legislature of the State of Florida:

38
 39 Section 1. Section 381.00771, Florida Statutes, is created
 40 to read:

41 381.00771 Definitions of terms used in ss. 381.00771-
 42 381.00791.—As used in ss. 381.00771-381.00791, the term:

43 (1) "Active license or registration" means a current
 44 license or registration issued by the department that is not
 45 suspended or revoked.

46 (2) "Department" means the Department of Health.

47 (3) "Guest tattoo artist" means a person who is licensed,
 48 registered, or certified to practice tattooing in a jurisdiction
 49 outside of this state who is registered with the department to
 50 practice tattooing in this state.

51 (4) "Operator" means a person designated by a tattoo
 52 establishment or temporary establishment to control the
 53 operation of the establishment.

54 (5) "Stop-use order" means a written notice from the
 55 department to a licensee or registrant requiring him or her to
 56 remove any tattooing equipment or supplies, or cease conducting

57 | any particular procedures, because the equipment or supplies are
 58 | not being used or the procedures are not being conducted in
 59 | accordance with ss. 381.00771-381.00791 or any rule adopted
 60 | under those sections.

61 | (6) "Tattoo" means a mark or design made on or under the
 62 | skin of a human being by a process of piercing and ingraining a
 63 | pigment, dye, or ink in the skin.

64 | (7) "Tattoo artist" means a person licensed under ss.
 65 | 381.00771-381.00791 to practice tattooing.

66 | (8) "Tattoo establishment" means any permanent location,
 67 | place, area, structure, or business where tattooing is
 68 | performed.

69 | (9) "Temporary establishment" means any location, place,
 70 | area, or structure where tattooing is performed during, and in
 71 | conjunction with, a convention or other similar event that does
 72 | not exceed 14 consecutive days.

73 | Section 2. Section 381.00773, Florida Statutes, is created
 74 | to read:

75 | 381.00773 Application of ss. 381.00771-381.00791;
 76 | exemption.-

77 | (1) Except for s. 381.00787, which applies to all persons,
 78 | ss. 381.00771-381.00791 do not apply to a person licensed to
 79 | practice medicine or dentistry under chapter 458, chapter 459,
 80 | or chapter 466 who performs tattooing exclusively for medical or
 81 | dental purposes.

82 | (2) Sections 381.00771-381.00791 apply exclusively to the
 83 | tattooing of human beings and do not apply to the tattooing of
 84 | any animal.

85 Section 3. Section 381.00775, Florida Statutes, is created
86 to read:

87 381.00775 Tattoo artists; licensure; registration of guest
88 tattoo artists.—

89 (1) Except as provided in s. 381.00773, a person may not
90 tattoo the body of any human being in this state unless the
91 person is licensed as a tattoo artist or registered as a guest
92 tattoo artist under this section.

93 (2) (a) A person seeking licensure as a tattoo artist must
94 apply to the department in the format prescribed by the
95 department. An application must include:

- 96 1. The name and residence address of the applicant.
97 2. The name and street address of each tattoo
98 establishment and temporary establishment at which the applicant
99 intends to practice tattooing in this state.

100 (b) The department shall issue a license to an applicant
101 who:

- 102 1. Is 18 years of age or older.
103 2. Submits a completed application.
104 3. Pays the applicable license fee established in s.
105 381.00781.
106 4. Submits proof of successful completion of an education
107 course approved by the department on blood-borne pathogens and
108 communicable diseases.
109 5. Submits proof of passage of an examination approved by
110 the department on the material presented in the education
111 course.

112 (c) The department shall approve one or more education

113 courses and examinations that allows a person to complete the
 114 requirements of subparagraphs (b)4. and 5. in person or through
 115 an Internet website.

116 (d) A tattoo artist must, within 30 days after a change,
 117 notify the department of any change in the following information
 118 disclosed in his or her most recent application for issuance or
 119 renewal of his or her tattoo artist license in the format
 120 prescribed by the department:

121 1. The name and residence address of the tattoo artist.

122 2. The name and street address of each tattoo
 123 establishment in this state at which the tattoo artist has
 124 practiced tattooing for more than 14 days since the most recent
 125 renewal of his or her tattoo artist license or, if the license
 126 has not been renewed, since the license was issued.

127 (3) (a) A person seeking registration as a guest tattoo
 128 artist must apply to the department in the format prescribed by
 129 the department. An application must include:

130 1. The name and residence address of the applicant.

131 2. The name and street address of each tattoo
 132 establishment and temporary establishment at which the applicant
 133 will practice under the guest tattoo artist registration.

134 (b) The department shall issue a guest tattoo artist
 135 registration to an applicant who:

136 1. Is 18 years of age or older.

137 2. Submits a completed application.

138 3. Pays the applicable registration fee established in s.
 139 381.00781.

140 4. Holds an active license, registration, or certification

141 issued by a jurisdiction outside this state, whether by another
 142 state, the District of Columbia, any possession or territory of
 143 the United States, or any foreign jurisdiction, if:

144 a. The education and examination requirements of the
 145 license, registration, or certification substantially meet or
 146 exceed the requirements of subparagraphs (2)(b)4. and 5.; or

147 b. The applicant submits proof of successful completion of
 148 an education course approved by the department under
 149 subparagraph (2)(b)4. and proof of passage of an examination
 150 approved by the department under subparagraph (2)(b)5.

151 (4)(a) A tattoo artist license is valid for 1 year and
 152 must be renewed annually.

153 (b) A guest tattoo artist registration is valid for 14
 154 days. A guest tattoo artist may apply for reregistration before
 155 or after expiration of his or her current registration.

156 (5) A license or registration issued by the department
 157 under this section is not transferable.

158 Section 4. Section 381.00777, Florida Statutes, is created
 159 to read:

160 381.00777 Tattoo establishments; licensure; temporary
 161 establishments.—

162 (1)(a) Except as provided in s. 381.00773, a person may
 163 not tattoo the body of any human being in this state except at a
 164 tattoo establishment or temporary establishment licensed under
 165 this section.

166 (b) A person may not operate a tattoo establishment or
 167 temporary establishment in this state unless the establishment
 168 is licensed under this section.

169 (2) A person seeking licensure of a tattoo establishment
 170 must apply to the department in the format prescribed by the
 171 department. An application must include:

172 (a) The registered business name, including any fictitious
 173 names under which the tattoo establishment conducts business in
 174 the state.

175 (b) The street address and telephone number of the tattoo
 176 establishment.

177 (c) The name, mailing address, and telephone number of the
 178 tattoo establishment's operator.

179 (d) The name and address of the tattoo establishment's
 180 registered agent for service of process in the state.

181 (3) The department shall issue a tattoo establishment
 182 license to an applicant, if:

183 (a) The applicant submits a completed application.
 184 (b) The applicant pays the applicable license fee
 185 established in s. 381.00781.

186 (c) The establishment complies with all applicable local
 187 building, occupational, zoning, and health codes.

188 (4) A temporary establishment must meet the same
 189 requirements for licensure as a permanent tattoo establishment.

190 (5) (a) A license is valid only for the location listed on
 191 the license. A tattoo establishment must notify the department
 192 in the format prescribed by the department before any change of
 193 the licensed location. A tattoo establishment with more than one
 194 location must obtain a separate license for each location.

195 (b) A tattoo establishment license is valid for 1 year and
 196 must be renewed annually.

197 (c) A temporary establishment license is valid for the
 198 duration of a convention or other similar event for which the
 199 license is issued not to exceed 14 consecutive days.

200 (6) A license issued by the department under this section
 201 is not transferable.

202 Section 5. Section 381.00779, Florida Statutes, is created
 203 to read:

204 381.00779 Practice requirements.-

205 (1) A tattoo establishment or temporary establishment
 206 must:

207 (a) Display an active license for the establishment in a
 208 manner that is easily visible to the public at all times while
 209 tattooing is performed at the establishment.

210 (b) Ensure that each tattoo artist and guest tattoo
 211 artist, while practicing tattooing at the establishment, meets
 212 all applicable requirements of ss. 381.00771-381.00791.

213 (c) Maintain sanitary conditions of the establishment at
 214 all times.

215 (d) Comply with all state and local health codes and
 216 ordinances.

217 (e) Allow the department to inspect the establishment
 218 pursuant to subsection (4).

219 (f) Comply with s. 381.0098 and rules adopted under that
 220 section.

221 (2) A tattoo artist or guest tattoo artist must:

222 (a) Display his or her active license in a manner that is
 223 easily visible to the public at all times while practicing
 224 tattooing.

225 (b) Practice tattooing exclusively at an establishment
 226 licensed under ss. 381.00771-381.00791.

227 (c) Maintain sanitary conditions of the establishment at
 228 all times.

229 (d) Comply with all state and local health codes and
 230 ordinances.

231 (3) A tattoo artist or guest tattoo artist may tattoo the
 232 body of a minor child only to the extent authorized in s.
 233 381.00787. A tattoo establishment or temporary establishment
 234 must keep, for the period prescribed by the department, each
 235 written notarized consent submitted under s. 381.00787(2)(c) by
 236 the parent or legal guardian of a minor child who is tattooed at
 237 the establishment.

238 (4) The department may inspect and investigate each tattoo
 239 establishment and temporary establishment as necessary to ensure
 240 compliance with ss. 381.00771-381.00791. However, the department
 241 shall inspect each tattoo establishment at least annually and
 242 shall inspect each temporary establishment before and, as
 243 necessary, during a convention or similar event with which the
 244 establishment is connected.

245 Section 6. Section 381.00781, Florida Statutes, is created
 246 to read:

247 381.00781 Fees; disposition.-

248 (1) The department shall establish by rule the following
 249 fees:

250 (a) Fee for the initial licensure of a tattoo
 251 establishment and the renewal of such license, which, except as
 252 provided in subsection (2), may not exceed \$250 per year.

253 (b) Fee for licensure of a temporary establishment, which,
 254 except as provided in subsection (2), may not exceed \$250.

255 (c) Fee for the initial licensure of a tattoo artist and
 256 the renewal of such license, which, except as provided in
 257 subsection (2), may not exceed \$150 per year.

258 (d) Fee for registration or reregistration of a guest
 259 tattoo artist, which, except as provided in subsection (2), may
 260 not exceed \$45.

261 (e) Fee for reactivation of an inactive tattoo
 262 establishment license or tattoo artist license. A license
 263 becomes inactive if it is not renewed before the expiration of
 264 the current license.

265 (2) The department may annually adjust the maximum fees
 266 authorized under subsection (1) according to the rate of
 267 inflation or deflation indicated by the Consumer Price Index for
 268 All Urban Consumers, U.S. City Average, All Items, as reported
 269 by the United States Department of Labor.

270 Section 7. Section 381.00783, Florida Statutes, is created
 271 to read:

272 381.00783 Grounds for discipline; administrative
 273 penalties.-

274 (1) The following acts constitute grounds for which
 275 disciplinary action specified in subsection (2) may be taken by
 276 the department against any tattoo establishment, temporary
 277 establishment, tattoo artist, guest tattoo artist, operator of a
 278 tattoo establishment, or unlicensed person engaged in activities
 279 regulated under ss. 381.00771-381.00791:

280 (a) Providing false information on an application for

281 licensure or registration.
 282 (b) Violating a state or local health code or ordinance.
 283 (c) Violating any provision of ss. 381.00771-381.00791,
 284 rule adopted under those sections, or lawful order of the
 285 department.
 286 (d) Being found guilty of or pleading nolo contendere to,
 287 regardless of adjudication, a crime in any jurisdiction which
 288 relates to the practice of tattooing or the operation of a
 289 tattoo establishment or temporary establishment.
 290 (e) Committing fraud, deceit, negligence, or misconduct in
 291 the practice of tattooing or the operation of a tattoo
 292 establishment or temporary establishment.
 293 (f) Aiding, procuring, or assisting a person to unlawfully
 294 practice tattooing or unlawfully operate a tattoo establishment
 295 or temporary establishment.
 296 (g) Failing to keep the written notarized consent of the
 297 parent or legal guardian of a minor child who is tattooed at a
 298 tattoo establishment or temporary establishment for the period
 299 specified pursuant to s. 381.00779(3) or knowingly making false
 300 entries in a parent's or legal guardian's written notarized
 301 consent.
 302 (2) When the department determines that a person commits
 303 any of the acts set forth in subsection (1), the department may
 304 enter an order imposing one or more of the following penalties:
 305 (a) Refusal to issue a license or registration or renew a
 306 license.
 307 (b) Suspension or revocation of a license or registration.
 308 (c) Imposition of an administrative fine not to exceed

309 \$1,500 for each count or separate violation.

310 (d) Issuance of a reprimand.

311 (e) Placement of the licensee or registrant on probation
 312 for a specified period and subject to the conditions that the
 313 department may specify.

314 (f) Issuance of a stop-use order.

315 (g) Corrective action.

316 (3) The department shall impose stricter penalties for the
 317 repetition of violations and as the severity of violations
 318 escalate, distinguishing lesser violations from those that
 319 endanger the public health.

320 (4) Disciplinary proceedings shall be conducted as
 321 provided in chapter 120.

322 Section 8. Section 381.00785, Florida Statutes, is created
 323 to read:

324 381.00785 Criminal penalties.-

325 (1) A person may not:

326 (a) Operate a tattoo establishment or temporary
 327 establishment in this state without a license.

328 (b) Practice tattooing in this state without a tattoo
 329 artist license or guest tattoo artist registration, except as
 330 provided in s. 381.00773.

331 (c) Practice tattooing in this state at any place other
 332 than a tattoo establishment or temporary establishment, except
 333 as provided in s. 381.00773.

334 (d) Obtain or attempt to obtain a license or registration
 335 by means of fraud, misrepresentation, or concealment.

336 (2) A person who violates this section commits a

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337 misdemeanor of the second degree, punishable as provided in s.
 338 775.082 or s. 775.083.

339 Section 9. Section 877.04, Florida Statutes, is
 340 transferred, renumbered as section 381.00787, Florida Statutes,
 341 and amended to read:

342 381.00787 877.04 Tattooing prohibited; penalty.—

343 (1) A ~~It is unlawful for any person may not to~~ tattoo the
 344 body of a minor child younger than 16 years of age unless the
 345 ~~any human being; except that~~ tattooing is may be performed for
 346 medical or dental purposes by a person licensed to practice
 347 medicine or dentistry under chapter chapters 458, chapter and
 348 459, or chapter 466, ~~or by a person under his or her general~~
 349 ~~supervision as defined by the Board of Medicine.~~

350 ~~(2) Any person who violates the provisions of this section~~
 351 ~~shall be guilty of a misdemeanor of the second degree,~~
 352 ~~punishable as provided in s. 775.082 or s. 775.083.~~

353 (2)(3) A person may not tattoo the ~~No~~ body of a minor
 354 child who is at least 16 years of age, but younger than 18 years
 355 of age, unless:

356 (a) The minor child is accompanied by his or her parent or
 357 legal guardian;

358 (b) The minor child and his or her parent or legal
 359 guardian each submit proof of his or her identity by producing a
 360 government-issued photo identification;

361 (c) The parent or legal guardian submits his or her ~~shall~~
 362 ~~be tattooed without the~~ written notarized consent in the format
 363 prescribed by the department; of

364 (d) The parent or legal guardian submits proof that he or

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365 she is the parent or legal guardian of the minor child; and

366 (e) The tattooing is performed by a tattoo artist or guest
367 tattoo artist licensed under ss. 381.00771-381.00791 or a person
368 licensed to practice medicine or dentistry under chapter 458,
369 chapter 459, or chapter 466.

370 (3) A person who violates this section commits a
371 misdemeanor of the second degree, punishable as provided in s.
372 775.082 or s. 775.083. However, a person who tattoos the body of
373 a minor child younger than 18 years of age does not violate this
374 section, if:

375 (a) The person carefully inspects what appears to be a
376 government-issued photo identification that represents that the
377 minor child is 18 years of age or older.

378 (b) The minor child falsely represents himself or herself
379 as being 18 years of age or older and presents a fraudulent
380 identification.

381 (c) A reasonable person of average intelligence would
382 believe that the minor child is 18 years of age or older and
383 that the photo identification is genuine, was issued to the
384 minor child, and truthfully represents the minor child's age.

385 Section 10. Section 381.00789, Florida Statutes, is
386 created to read:

387 381.00789 Rulemaking.—The department shall adopt rules to
388 administer ss. 381.00771-381.00791. Such rules may include, but
389 are not limited to, rules defining terms; prescribing
390 educational requirements for tattoo artists and guest tattoo
391 artists, health and safety requirements, sanitation practices,
392 and sterilization requirements and procedures; and providing

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393 requirements for tattoo equipment, customer notification, the
 394 contents of customer records, the retention of records, and
 395 physical plants. The department shall consult with
 396 representatives of the tattooing industry in this state during
 397 the development of such rules.

398 Section 11. Section 381.00791, Florida Statutes, is
 399 created to read:

400 381.00791 Local laws and ordinances.--Sections 381.00771-
 401 381.00791 do not preempt any local law or ordinance of a county
 402 or municipality that imposes regulations on tattoo
 403 establishments, temporary establishments, tattoo artists, or the
 404 practice of tattooing which are in addition to those sections.

405 Section 12. This act shall take effect January 1, 2012.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1503 Health Care
SPONSOR(S): Health Care Regulation Policy Committee; Flores
TIED BILLS: IDEN./SIM. BILLS: SB 2138

Table with 4 columns: REFERENCE, ACTION, ANALYST, STAFF DIRECTOR. Row 1: Health Care Regulation Policy Committee, 12 Y, 0 N, As CS, Holt, Calamas. Row 2: Health & Family Services Policy Council, Holt, Gormley.

SUMMARY ANALYSIS

The bill repeals obsolete or duplicative provisions in licensing laws, to include expired reports and unnecessary documentation requirements regulated by the Agency for Health Care Administration (AHCA).

The bill makes various changes to the regulation of home health agencies. The bill provides a home health agency patient a bill of rights. Home health agency administrators are required to direct the operation of the home health agency and have qualified alternate administrators. The director of nursing must be available during the hours the home health agency is open. The bill specifies the duties of the director of nursing, registered nurse, licensed practical nurse, therapists and therapist's assistants in providing home health care and supervision. Home health aides must be competent to provide care to patients. Skilled services must be performed in compliance with state practice acts and the patient's plan of care. The plan of care is to be reviewed and updated according to specified time frames. The home health agency must provide one type of service directly and may provide other services through arrangements with others if they have a written contract.

The bill establishes a new requirement that dentists and dental hygienist complete a dental workforce survey at the time of licensure renewal. Beginning with the 2014 licensure renewal cycle, individuals will not be permitted to renew their license if they do not complete the survey. The bill requires the Department of Health to assume responsibilities for collecting, updating, and disseminating dental workforce data and serve as the coordinating and strategic planning body. The bill creates a dental workforce advisory body.

The bill exempts licensed dentists who are part of a professional corporation or Limited Liability Company comprised of dentists from having to obtain a health care clinic establishment permit. The bill provides that the dentist is deemed the purchaser and owner of the prescription drugs.

The bill adds a representative of the Florida Dental Association to the Florida Healthy Kids Corporation board of directors.

This bill does not appear to have a fiscal impact on state or local government revenues or expenditures.

The bill has an effective date of July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Health Care Licensing Procedures Act

The Agency for Health Care Administration (AHCA) regulates over 41,000 health care providers under various regulatory programs. Regulated providers include:

- Laboratories authorized to perform testing under the Drug-Free Workplace Act (ss. 112.0455, 440.102, F.S.)
- Birth centers (Ch. 383, F.S.).
- Abortion clinics (Ch. 390, F.S.).
- Crisis stabilization units (Pts. I and IV of Ch. 394, F.S.).
- Short-term residential treatment facilities (Pt. I and IV of Ch. 394, F.S.).
- Residential treatment facilities (Pt. IV of Ch. 394, F.S.).
- Residential treatment centers for children and adolescents (Pt. IV of Ch. 394, F.S.).
- Hospitals (Part I of Ch. 395, F.S.).
- Ambulatory surgical centers (Pt. I of Ch. 395, F.S.).
- Mobile surgical facilities (Pt. I of Ch. 395, F.S.).
- Health care risk managers (Pt. I of Ch. 395, F.S.).
- Nursing homes (Pt. II of Ch. 400, F.S.).
- Assisted living facilities (Pt. I of Ch. 429, F.S.).
- Home health agencies (Pt. III of Ch. 400, F.S.).
- Nurse registries (Pt. III of Ch. 400, F.S.).
- Companion services or homemaker services providers (Pt. III of Ch. 400, F.S.).
- Adult day care centers (Pt. III of Ch. 429, F.S.).
- Hospices (Pt. IV of Ch. 400, F.S.).
- Adult family-care homes (Pt. II of Ch. 429, F.S.).
- Homes for special services (Pt. V of Ch. 400, F.S.).
- Transitional living facilities (Pt. V of Ch. 400, F.S.).
- Prescribed pediatric extended care centers (Pt. VI of Ch. 400, F.S.).
- Home medical equipment providers (Pt. VII of Ch. 400, F.S.).
- Intermediate care facilities for persons with developmental disabilities (Pt. VIII of Ch. 400, F.S.).
- Health care services pools (Pt. IX of Ch. 400, F.S.).
- Health care clinics (Pt. X of Ch. 400, F.S.).

- Clinical laboratories (Pt. I of Ch. 483, F.S.).
- Multiphasic health testing centers (Pt. II of Ch. 483, F.S.).
- Organ, tissue, and eye procurement organizations (Pt. V of Ch. 765, F.S.).

Providers are regulated under individual licensing statutes and the Health Care Licensing Procedures Act (Act) in Part II of Chapter 408, Florida Statutes. The Act provides uniform licensing procedures and standards applicable to most AHCA-regulated entities. The Act contains basic licensing standards for 29 provider types in areas such as licensure application requirements, ownership disclosure, staff background screening, inspections, and administrative sanctions, license renewal notices, and bankruptcy and eviction notices.

Hospital Licensure

Currently, Florida law allows AHCA to consider and use hospital accreditation by certain accrediting organizations for various purposes, including accepting accreditation surveys in lieu of AHCA survey, requiring accreditation for designation as certain specialty hospitals, and setting standards for quality improvement programs. Section 395.002, F.S., defines “accrediting organizations” as the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc.

Complaint investigation procedures for hospitals exist in the hospital authorizing chapter as well as in the Act. Section 395.1046, F.S., provides special procedures for hospital complaints regarding emergency access issues. For example, AHCA must: investigate emergency access complaints even if the complaint is withdrawn; prepare an investigative report; and make a probable cause determination. According to AHCA, the federal process for emergency access complaints dictates that these complaints should not be handled any differently from other types of complaints, thereby creating two separate processes for emergency access complaints, one state and one federal.

The bill broadens the definition of “accrediting organizations” for hospitals and ambulatory surgery centers to include any nationally recognized accrediting organization which has standards comparable to AHCA’s licensure standards, as determined by AHCA. This gives AHCA and providers greater flexibility to accept new or improving accrediting organizations, and reconsider existing ones based on current statutory and rule-based standards.

The bill repeals s. 395.1046, F.S., which modifies the procedures for investigations in hospital emergency access complaints. Under the bill, AHCA would use existing hospital complaint investigation procedures used for all other types of complaints.

Home Health Agency Licensure

Currently, services provided by a home health agency must be covered by an agreement between the home health agency and the patient or the patient’s legal representative. The agreement must specify the services being provided, rates or charges for services paid with private funds, and sources of payment.¹ The bill provides that the home health agency must provide a copy of the agreement to the patient or patient’s representative.

Patient Rights

In addition, the bill creates new provisions requiring a home health agency to protect and promote the rights of each individual under its care. The home health agency is required to provide the patient a written notice of the patients rights prior to the initiation of treatment. The provisions are:

- The patient has the right to exercise their rights as a patient;
- The patient has the right to have their property treated with respect;

¹ s. 400.487(1), F.S.

- The patient has the right to voice grievances regarding treatment, care, or lack of respect for personal property;
- The patient must be informed of the right to report complaints via the statewide toll-free telephone number;
- The patient has the right to be informed prior to receiving care and any changes in the plan of care; and
- The patient has the right to participate in the planning of care and they must be advised in advance.

The home health agency must investigate any complaint about patient care and failure to respect the patient's property and document both the existence and resolution of the complaint. The patient must be informed of the disciplines (such as registered nurse, home health aide, physical therapist) that will provide the care; notified in advance of the individuals who will provide treatment and care; and the frequency of visits.

Personnel

The bill amends s. 400.476, F.S., to provide additional requirements and limitations of staffing services for home health agencies.

The bill amends the responsibilities of a home health agency administrator. It requires that an alternate administrator meet the same qualifications as an administrator which includes not working for multiple unrelated home health agencies. It prohibits delegation of supervisory and administrative functions to another agency or organization.

The bill requires the director of nursing or a similarly qualified alternate to be available at all times during operating hours; to oversee the assignment of personnel and nursing services, home health aides and certified nursing assistants; and to participate in all activities related to the provision of professional services by the home health agency.

The bill provides that a home health agency's professional staff must comply with applicable state practice acts, accepted professional standards and principles, and the home health agency's policies and procedures. According to AHCA, by referencing the professional practice acts in state law, AHCA surveyors can cite for non-compliance, and follow up to see if a correction is made.²

The bill provides that a home health agency may not use a home health aide unless the individual has successfully completed a training and competency evaluation program to ensure they are adequately trained. All aides must be competent and cannot perform tasks for which they received an unsatisfactory evaluation except under direct supervision of a licensed practical nurse.

The bill amends s. 400.487, F.S., to require home health aides and certified nursing assistants to be supervised by a registered nurse. However, supervision may be provided by therapists if therapy services are only provided. The bill requires that a supervisory visit be made to the home of a patient at least once every 60 days while the home health aide or certified nursing is providing care to a patient. If a patient receiving skilled nursing or therapy services a nurse or therapist is required to visit at least once every two weeks, however, the visit does not have to be made while the aide or certified nursing assistant is providing care. The bill requires that home health aides and certified nursing assistants to receive written patient care instructions from their supervisors.

Provision of Services

The bill provides in s. 400.476, F.S., that a home health agency must provide at least one of the types of services directly. The services provided by individuals that are not direct employees and by other organizations under arrangements must have a written contract that specifies the services to be

² Agency for Health Care Administration 2010 Bill Analysis & Economic Impact Statement of House Bill 1503 (March 24, 2010).
 STORAGE NAME: h1503b.HFPC.doc
 DATE: 4/9/2010

provided, procedures for scheduling visits, submitting notes, evaluating patients, and payment for services.

The bill specifies in s. 400.487, F.S., the services to be provided by a registered nurse, licensed practical nurse, home health aide, certified nursing assistant, therapist and therapist assistant are specified. All personnel serving patients must coordinate their efforts to provide care and show this communication in the patient's record. Verbal orders must be put in writing and plans of care are to be reviewed every 60 days or more frequently if there is a significant change in the patient's condition. The bill specifies that drugs and treatments can only be provided as ordered by a physician, or advanced registered nurse practitioner or physician's assistant who works under the supervision of a physician. Flu and pneumonia vaccines may be administered to patients in accordance with home health agency policy that is developed in consultation with a physician.

The bill amends the definition of "admission" in s. 400.462, F.S., so that the evaluation of the patient does not have to occur when the patient gets home, but can be done while the patient is still at a hospital or rehabilitation facility. In addition, "home health services" is revised to include the provision of durable medical equipment. The bill provides a new definition for "primary home health agency" designating the agency that is responsible for the services provided as well as the plan of care since many home health agencies contract with other agencies for services.

Nursing Home Licensure

Litigation Notices

Since 2001, nursing homes have been required by s. 400.147(10), F.S., to report civil notices of intent to litigate (required by s. 400.0233, F.S.) and civil complaints filed with clerks of courts by a resident or representative of a resident. This information has been used to produce the Semi-Annual Report on Nursing Homes required by s. 400.195, F.S. Information is reported in aggregate for all facilities.

The bill eliminates the requirement to report notices of intent to litigate and civil complaints.

Assisted Living Facility Licensure

Assisted Living Facilities (ALFs) are not currently required to submit resident population data to AHCA. However, there is a requirement to submit disaster/emergency information electronically via AHCA's Emergency Status System (ESS).³ Submission of ESS data was a result of SB 1986 (Ch. 2009-223 L.O.F), and is being required at the time of licensure renewal. Currently, 42.1 percent (1197) of ALFs are currently enrolled in this system.

Section 429.23, F.S., requires each ALF to submit a monthly report on civil liability claims filed against the facility, and provides that the reports are not discoverable on civil or administrative actions.

Pilot Projects

The Medicaid "Up-or-Out" Quality of Care Contract Management Program in s. 400.148, F.S., was created as a pilot program in 2001 to improve care in poor performing nursing homes and assisted living facilities by assigning trained medical personnel to facilities in select counties similar to Medicare models for managing the medical and supportive-care needs of long-term nursing home residents. The pilot was subject to appropriation; however, an appropriation was not allocated to this program and it was never implemented. According to AHCA, the criteria specified to identify poor performing facilities has been replaced by more comprehensive information for consumers to make informed choices for care.

The bill repeals the Medicaid Up or Out Pilot Quality of Care Contract Management Program.

³ The Emergency Status System is a web-based system for reporting and tracking health care facility status before, during and after an emergency.

Reports

The semi-annual report on nursing homes in s. 400.195, F.S., was provided from December 2002 through June 2005 as a tool to provide information about litigation in Florida nursing homes. The report included demographic and regulatory information about nursing homes in Florida and aggregate numbers of notices of intent to litigate and civil complaints filed with the clerks of courts against Florida nursing homes. The reporting requirement ended June 2005 by law. The statutory obligation to publish this report has been met and by law expired on June 30, 2005.

The Comprehensive Review for Long Term Care Services program report was required to be submitted to the Legislature by July 1, 2005. However, the language requiring the report still exists in s. 409.912(15)(g), F.S.

The bill repeals these two report requirements.

Dental Workforce

In January of 2008, the State Surgeon General established the Florida Health Practitioner Oral Healthcare Workforce Ad Hoc Committee (Ad Hoc Committee).⁴ The mission of the Ad Hoc Committee was to evaluate and address the complex range of oral health workforce concerns that impact Florida's ability to recruit or retain available practicing dental providers (dentists, dental hygienists, and dental assistants), especially for Florida's disadvantaged and underserved populations.⁵ The Ad Hoc Committee published the Health Practitioner Oral Healthcare Workforce Ad Hoc Committee Report (report) in February 2009, which provided recommendations on dental workforce and access to oral health care. The 2009 report the committee suggested "monitoring dental workforce trends through surveys that accompany licensure renewal and assessing dental needs of all persons in Florida through a statewide oral health needs assessment or a statewide oral health surveillance system."⁶

The Department of Health (DOH) is conducting a voluntary workforce survey as a part of the current renewal cycle for all Florida licensed dentists and dental hygienists. During the 2010 licensure renewal cycle 10,240 of 11,214 dentists or 91 percent participated in the survey.⁷ And 11,026 of 11,710 dental hygienists or 94 percent participated in the survey.⁸

The bill requires that beginning in 2012, at the time of licensure renewal dentist and dental hygienist will be requested to provide information in a dental workforce survey. If the dentist or dental hygienist does not complete the survey within 90 days after renewal, then the Board of Dentistry is required to issue a non-disciplinary citation stating that their license will not be renewed unless the survey is completed. In addition the dentist or dental hygienist must submit a statement that the information they provided in the survey is true and accurate to the best of their knowledge and belief.

The bill provides that DOH:

- Maintain a database to serve as a statewide source of dental workforce data;
- Act as a clearinghouse and coordinator for the collection, and dissemination of dental workforce data;
- Work with stakeholders to assess and share all data collected in a timely fashion;
- Work in conjunction with the Board of Dentistry to develop strategies to maximize federal and state programs that provide incentives for dentists to practice in federally designated shortage areas;
- Work in conjunction with the Board of Dentistry and the advisory body to address matters relating to the state's dental workforce; and

⁴ Florida Department of Health, Health Practitioner Oral healthcare Workforce Ad Hoc Committee Report, February 2009.

⁵ *Id.*

⁶ Florida Department of Health, Health Practitioner Oral healthcare Workforce Ad Hoc Committee Report (February 2009).

⁷ Telephone conversation with the Executive Director for the Florida Board of Dentistry (March 2010).

⁸ Email correspondence with the Executive Director for the Florida Board of Dentistry (April 1, 2010).

- Adopt rules to administer the provisions of the bill.

The bill creates an advisory body tasked with providing input on the development of questions for the dental workforce survey. The bill provides that the advisory body be comprised of:

- State Surgeon General or designee;
- Dean of each accredited dental school in the state;
- Representative of the Florida Dental Hygiene Association;
- Representative of the Florida Dental Association;
- Representative from the Board of Dentistry;
- A dentist from each of the dental specialties⁹ recognized by the American Dental Association's Commission on Dental Accreditation.

The bill provides that DOH create a dental workforce survey that contains, but is not limited, to the following questions that are codified into statute:

- Questions Related to the Licensee:
 - Name of dental school or dental hygiene program that individual graduated from and the year of graduation;
 - Geographic location of the practice;
 - Anticipated plans of the dentist to change license or practice status;
 - Dentists areas of specialty or certification;
 - Year that the dentist completed specialty program recognized by the American Dental Association;
 - Dentist's membership in professional organizations;
 - Number of pro bono hours provided by the dentist or dental hygienist during the last biennium;
 - Dentists in private practice:
 - Number of full-time dentists and dental hygienists employed by the dentist during the reporting period;
 - Average number of patients treated per week by the dentist during the reporting period;
 - For dental hygienists:
 - Average number of patients treated per week during the reporting period; and
 - Settings where dental care was delivered.
- Questions Concerning the Availability and Trends of Critically Needed Services Provided by the Dentist or Dental Hygienist:
 - Dental care to children having special needs;
 - Geriatric dental care;
 - Dental services in emergency departments;
 - Medicaid services; and
 - Other critically needed specialty areas, as determined by the advisory body.

The bill provides that members of the advisory body are required to serve without compensation. The bill provides legislative intent specifying that DOH implement the provisions of the bill within existing resources.

Health Care Clinic Establishment Permit

The Florida Drug and Cosmetic Act (Act) is found in part I of ch. 499, F.S. DOH is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in

⁹ Currently there are nine recognized specialties: Dental Public Health, Endodontics, Oral and Maxillofacial Surgery, Oral and Maxillofacial Pathology, Oral and Maxillofacial Radiology, Orthodontics and Dentofacial Orthopedics, Pediatric Dentistry, Periodontics, and Prosthodontics.

the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics. The regulatory structure provides for prescription drugs to be under the responsibility of a permit at all times, until a prescription drug is dispensed to a patient.¹⁰

One of the permits issued by DOH under the Act is the Health Care Clinic Establishment (HCCE) permit. The biennial fee for the HCCE permit is \$255¹¹ and the permit is valid for 2 years, unless suspended or revoked.¹²

The HCCE permit was established in 2008 to enable a business entity to purchase prescription drugs.¹³ The HCCE permit is a permit that a medical practice may obtain in order to purchase and own prescription drugs in the business entity's name. The HCCE permit is not required if a practitioner in the clinic or practice wants to purchase and own prescription drugs in his or her own name using his or her professional license that authorizes that practitioner to prescribe prescription drugs.

Under the requirements of the permit, a qualifying practitioner or a veterinarian licensed under ch. 474, F.S., is designated to be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs purchased and possessed by the business entity.¹⁴ Both the qualifying practitioner and the permitted health care clinic must notify the DOH within 10 days after any change in the qualifying practitioner.

The bill exempts licensed dentists who are part of a professional corporation or Limited Liability Company comprised of dentists from having to obtain a health care clinic establishment permit. The bill provides that the dentist is deemed the purchaser and owner of the prescription drugs.

Florida Healthy Kids Corporation

The Florida Healthy Kids Corporation ("Corporation"), under contract with the Agency, performs administrative functions for the overall Florida KidCare program and administers the SCHIP HealthyKids program. The Corporation handles eligibility determination, premium billing and collection, refunds, and customer service for KidCare, except for the large Medicaid component, which is administered by the Agency and the Department of Children and Families.

The corporation is governed by a 12-member board of directors (board) who serve for 3-year terms of office. The current membership includes:¹⁵

- The Chief Financial Officer, or designee;
- The Secretary of Health Care Administration, or designee;
- One member appointed by the Commissioner of Education from the Office of School Health Programs of the Florida Department of Education;
- One member appointed by the Chief Financial Officer from among three members nominated by the Florida Pediatric Society;
- One member, appointed by the Governor, who represents the Children's Medical Services Program;
- One member appointed by the Chief Financial Officer from among three members nominated by the Florida Hospital Association;
- One member, appointed by the Governor, who is an expert on child health policy;
- One member, appointed by the Chief Financial Officer, from among three members nominated by the Florida Academy of Family Physicians;
- One member, appointed by the Governor, who represents the state Medicaid program;
- One member, appointed by the Chief Financial Officer, from among three members nominated by the Florida Association of Counties;

¹⁰ s. 499.01, F.S.

¹¹ The fee for a HCCE permit may not be less than \$125 or more than \$250 annually. See s. 499.041(2)(c), F.S.

¹² 64F-12.018, F.A.C.

¹³ s. 499.01(2)(t), F.S.

¹⁴ s. 499.01(2)(t)1., F.S.

¹⁵ s. 624.91(6), F.S.

- The State Health Officer or designee; and
- The Secretary of Children and Family Services, or designee.

In 2009, the Legislature passed two separate bills that amended the membership to the board.¹⁶ The first bill HB 185, was approved by the Governor on May 20, 2009.¹⁷ This bill added a representative nominated by the Florida Dental Association to the board. The second bill SB 918, was approved by the Governor on June 2, 2009.¹⁸ This bill added the Secretary of Children and Family Services or designee to the board. According to provisions of statutory construction, the law “last passed” by the Legislature is published with a footnote in statute noting the conflict.¹⁹

The bill adds a representative of the dental community to the Florida Healthy Kids Corporation board of directors. The member will be appointed by the Governor from three candidates nominated by the Florida Dental Association.

B. SECTION DIRECTORY:

- Section 1.** Repeals paragraph (e) of subsection (10) of s. 112.0455, F.S., relating to disciplinary remedies in the drug-free workplace act.
- Section 2.** Repeals s. 383.325, F.S., relating to inspection reports.
- Section 3.** Repeals s. 395.1046, F.S., relating to complaint investigation procedures.
- Section 4.** Repeals s. 395.3037, F.S., relating to definitions.
- Section 5.** Amends s. 400.0239, F.S., relating to quality of long-term care facility improvement trust fund.
- Section 6.** Repeals subsection (10) of s. 400.147, F.S., relating to required reporting to the internal risk management and quality assurance program.
- Section 7.** Repeals s. 400.148, F.S., relating to the Medicaid “Up-or-Out” Quality of Care Contract Management Program.
- Section 8.** Repeals s. 400.195, F.S., relating to agency reporting requirements for nursing homes.
- Section 9.** Amends s. 400.476, F.S., relating to staffing requirements, notifications, and limitations on staffing services.
- Section 10.** Amends s.400.487, F.S., relating to home health 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; and orders not to resuscitate.
- Section 11.** Repeals subsection (11) of s. 408.802, F.S., relating to applicability of private review agents.
- Section 12.** Repeals paragraphs (e), (f), and (g) of subsection (15) of s. 409.912, F.S., relating to the report on the CARES program and impact of modifying the level of care to eliminate the Intermediate II level of care.
- Section 13.** Repeals subsection (2) of s. 429.12, F.S., relating to requirement for a plan of corrective action pending sale or transfer of ownership of a facility.
- Section 14.** Repeals subsection (5) of s. 429.23, F.S., relating to the reporting requirements of any liability claim.
- Section 15.** Repeals s. 429.911, F.S., relating to adult day care facilities grounds for action when intentional or negligent acts occur that affect the safety and health of a resident.
- Section 16.** Creates an unnumbered section relating to dental workforce survey.
- Section 17.** Creates an unnumbered section relating to dental workforce advisory body.
- Section 18.** Creates an unnumbered section relating to legislative intent.
- Section 19.** Amends s. 499.01, F.S., relating to health care clinic establishment permit.
- Section 20.** Amends s. 624.91, F.S., relating to the Florida Healthy Kids Corporation Act.
- Section 21.** Provides that the bill takes effect July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

¹⁶ See chapters 2009-41 and 2009-113, L.O.F.

¹⁷ ch. 2009-41, L.O.F.

¹⁸ ch. 2009-113, L.O.F.

¹⁹ See preface to the Florida Statutes, “Statutory Construction.”

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:

According to AHCA as of March 31, 2010, 63 percent (1,485) of the 2,361 licensed home health agencies are also Medicare and/or Medicaid certified. Approximately one-third of these agencies are in the process of becoming certified.²⁰ Certified agencies are already required to meet the new requirements in this bill. Non-certified home health agencies may be impacted if they are not doing the following:²¹

- Supervisory visits for home health aides and certified nursing assistants
- Reviewing plans of care
- Investigating complaints from patients
- Preparing written contracts for individuals not directly employed and other agencies that are providing services under arrangements
- Having a director of nursing or alternate available during operating hours
- Having a registered nurse provide written instructions on patient care to home health aides and certified nursing assistants

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

None.

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:

AHCA and DOH have sufficient rule-making authority to implement the provisions of the bill.

²⁰ Agency for Health Care Administration 2010 Bill Analysis & Economic Impact Statement of House Bill 1503 (March 24, 2010).

²¹ *Id.*

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill creates a dental workforce advisory body. The bill is silent on the terms of membership terms and how members will be appointed. However s. 20.052(5), F.S., provides that private citizen members must be appointed by the Governor, the head of the department, the executive director of the department, or a Cabinet officer and members must be appointed for 4-year staggered terms. Staff recommends adding a statutory cross reference to s. 20.052, F.S., or providing membership terms and appointment provisions into the bill.

On line 629, the bill provides that the Board of Dentistry is required to issue a non-disciplinary citation or renew a license. This is usually a function of the department, not the board. Staff recommends amending the language to provide this authority to the department

According to the proponents for the dental workforce survey, one of the reasons for supporting the legislation was to provide confidentiality to dentist and dental hygienists who provided information concerning their practice in a survey. However, Committee Substitute for HB 1503, does not provide a public records exemption. House Bill 537, which was amended into House Bill 1503, was tied to House bill 539, which provided a public records exemption for the information contained in dental workforce surveys.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 31, 2010, the Health Care Regulation Policy Committee adopted a strike-all amendment and an amendment to the amendment. The bill was reported favorably as a committee substitute. The amendments:

Amendment 1: Conforms to SB 2138.

- Retains original bill's repeals of the Medicaid 'Up or Out' program, AHCA reporting and investigative requirements, and various regulatory functions.
- Eliminates all other bill provisions except those related to home health agencies:
 - Creates a patient bill of rights for home health agency clients;
 - Delineates the duties of the director of nursing and any alternates;
 - Delineates the duties of the administrator;
 - Provides detailed requirements for supervision of various services;
 - Specifies service functions and duties of various professionals;
 - Prohibits employment of home health aides without certain scores on competency tests, as set by rule; and
 - Requires various contracts and contract terms.

Amendment to Amendment:

- Amends the provisions of HB 537, modified, onto the bill.
 - Requires dentists and dental hygienists to complete a dental workforce survey to at the time of licensure renewal;
 - Dentists and hygienists who fail to complete the survey will receive a non-disciplinary citation;
 - Beginning with 2014 licensure renewal cycle, individuals will not be permitted to renew their license if they do not complete the survey;
 - DOH must maintain a database of dental workforce data;
 - Creates an advisory body to provide input in the development of survey questions;
 - Members of the advisory body are required to serve without compensation;
 - DOH must implement the provisions of the bill within existing resources;
 - Exempts dental practices from the health care clinic establishment permit and deems such dentists are the purchaser and owner of prescription drugs (regardless of who pays for the drugs); and
- Adds a member nominated by the Florida Dental Association to the Florida Healthy Kids Corporation Board of Directors.

This analysis is drafted to the committee substitute.

1 A bill to be entitled
 2 An act relating to health care; amending s. 112.0455,
 3 F.S., and repealing paragraph (10)(e), relating to a
 4 prohibition against applying the Drug-Free Workplace Act
 5 retroactively; conforming a cross-reference; repealing s.
 6 383.325, F.S., relating to the requirement of a licensed
 7 facility under s. 383.305, F.S., to maintain inspection
 8 reports; repealing s. 395.1046, F.S., relating to the
 9 investigation of complaints regarding hospitals; repealing
 10 s. 395.3037, F.S.; deleting definitions relating to
 11 obsolete provisions governing primary and comprehensive
 12 stroke centers; amending s. 400.0239, F.S.; deleting an
 13 obsolete provision; repealing s. 400.147(10), F.S.,
 14 relating to a requirement that a nursing home facility
 15 report any notice of a filing of a claim for a violation
 16 of a resident's rights or a claim of negligence; repealing
 17 s. 400.148, F.S., relating to the Medicaid "Up-or-Out"
 18 Quality of Care Contract Management Program; repealing s.
 19 400.195, F.S., relating to reporting requirements for the
 20 Agency for Health Care Administration; amending s.
 21 400.476, F.S.; providing requirements for an alternate
 22 administrator of a home health agency; revising the duties
 23 of the administrator; revising the requirements for a
 24 director of nursing for a specified number of home health
 25 agencies; prohibiting a home health agency from using an
 26 individual as a home health aide unless the person has
 27 completed training and an evaluation program; requiring a
 28 home health aide to meet certain standards in order to be

29 | competent in performing certain tasks; requiring a home
 30 | health agency and staff to comply with accepted
 31 | professional standards; providing certain requirements for
 32 | a written contract between certain personnel and the
 33 | agency; requiring a home health agency to provide certain
 34 | services through its employees; authorizing a home health
 35 | agency to provide additional services with another
 36 | organization; providing responsibilities of a home health
 37 | agency when it provides home health aide services through
 38 | another organization; requiring the home health agency to
 39 | coordinate personnel who provide home health services;
 40 | requiring personnel to communicate with the home health
 41 | agency; amending s. 400.487, F.S.; requiring a home health
 42 | agency to provide a patient or the patient's legal
 43 | representative a copy of the agreement between the agency
 44 | and the patient which specifies the home health services
 45 | to be provided; providing the rights that are protected by
 46 | the home health agency; requiring the home health agency
 47 | to furnish nursing services by or under the supervision of
 48 | a registered nurse; requiring the home health agency to
 49 | provide therapy services through a qualified therapist or
 50 | therapy assistant; providing the duties and qualifications
 51 | of a therapist and therapy assistant; requiring
 52 | supervision by a physical therapist or occupational
 53 | therapist of a physical therapist assistant or
 54 | occupational therapy assistant; providing duties of a
 55 | physical therapist assistant or occupational therapy
 56 | assistant; providing for speech therapy services to be

57 | provided by a qualified speech-language pathologist or
 58 | audiologist; providing for a plan of care; providing that
 59 | only the staff of a home health agency may administer
 60 | drugs and treatments as ordered by certain health
 61 | professionals; providing requirements for verbal orders;
 62 | providing duties of a registered nurse, licensed practical
 63 | nurse, home health aide, and certified nursing assistant
 64 | who work for a home health agency; providing for
 65 | supervisory visits of services provided by a home health
 66 | agency; repealing s. 408.802(11), F.S., relating to the
 67 | applicability of the Health Care Licensing Procedures Act
 68 | to private review agents; repealing s. 409.912(15)(e),
 69 | (f), and (g), F.S., relating to a requirement for the
 70 | Agency for Health Care Administration to submit a report
 71 | to the Legislature regarding the operations of the CARE
 72 | program; repealing s. 429.12(2), F.S., relating to the
 73 | sale or transfer of ownership of an assisted living
 74 | facility; repealing s. 429.23(5), F.S., relating to each
 75 | assisted living facility's requirement to submit a report
 76 | to the agency regarding liability claims filed against it;
 77 | repealing s. 429.911(2)(a), F.S., relating to an
 78 | intentional or negligent act materially affecting the
 79 | health or safety of center participants as grounds for
 80 | which the agency may take action against the owner of an
 81 | adult day care center or its operator or employee;
 82 | requiring persons who apply for licensure renewal as a
 83 | dentist or dental hygienist to furnish certain information
 84 | to the Department of Health in a dental workforce survey;

85 requiring the Board of Dentistry to issue a
 86 nondisciplinary citation and a notice for failure to
 87 complete the survey within a specified time; providing
 88 notification requirements for the citation; requiring the
 89 department to serve as the coordinating body for the
 90 purpose of collecting, disseminating, and updating dental
 91 workforce data; requiring the department to maintain a
 92 database regarding the state's dental workforce; requiring
 93 the department to develop strategies to maximize federal
 94 and state programs and to work with an advisory body to
 95 address matters relating to the state's dental workforce;
 96 providing membership of the advisory body; providing for
 97 members of the advisory body to serve without
 98 compensation; requiring the department to act as a
 99 clearinghouse for collecting and disseminating information
 100 regarding the dental workforce; requiring the department
 101 and the board to adopt rules; providing legislative intent
 102 regarding implementation of the act within existing
 103 resources; amending s. 499.01, F.S.; authorizing certain
 104 business entities to pay for prescription drugs obtained
 105 by practitioners licensed under ch. 466, F.S.; amending s.
 106 624.91, F.S.; revising the membership of the board of
 107 directors of the Florida Healthy Kids Corporation to
 108 include a member nominated by the Florida Dental
 109 Association and appointed by the Governor; providing an
 110 effective date.

111
 112 Be It Enacted by the Legislature of the State of Florida:

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Section 1. Paragraph (e) of subsection (10) of section 112.0455, Florida Statutes, is repealed, and paragraph (e) of subsection (14) of that section is amended to read:

112.0455 Drug-Free Workplace Act.—

(14) DISCIPLINE REMEDIES.—

(e) Upon resolving an appeal filed pursuant to paragraph (c), and finding a violation of this section, the commission may order the following relief:

1. Rescind the disciplinary action, expunge related records from the personnel file of the employee or job applicant and reinstate the employee.
2. Order compliance with paragraph (10) (f) ~~(g)~~.
3. Award back pay and benefits.
4. Award the prevailing employee or job applicant the necessary costs of the appeal, reasonable attorney's fees, and expert witness fees.

Section 2. Section 383.325, Florida Statutes, is repealed.

Section 3. Section 395.1046, Florida Statutes, is repealed.

Section 4. Section 395.3037, Florida Statutes, is repealed.

Section 5. Paragraph (g) of subsection (2) of section 400.0239, Florida Statutes, is amended to read:

400.0239 Quality of Long-Term Care Facility Improvement Trust Fund.—

(2) Expenditures from the trust fund shall be allowable for direct support of the following:

141 (g) Other initiatives authorized by the Centers for
 142 Medicare and Medicaid Services for the use of federal civil
 143 monetary penalties, ~~including projects recommended through the~~
 144 ~~Medicaid "Up or Out" Quality of Care Contract Management Program~~
 145 ~~pursuant to s. 400.148.~~

146 Section 6. Subsection (10) of section 400.147, Florida
 147 Statutes, is repealed.

148 Section 7. Section 400.148, Florida Statutes, is repealed.

149 Section 8. Section 400.195, Florida Statutes, is repealed.

150 Section 9. Section 400.476, Florida Statutes, is amended
 151 to read:

152 400.476 Staffing requirements; notifications; limitations
 153 on staffing services.—

154 (1) ADMINISTRATOR.—

155 (a) An administrator may manage only one home health
 156 agency, except that an administrator may manage up to five home
 157 health agencies if all five home health agencies have identical
 158 controlling interests as defined in s. 408.803 and are located
 159 within one agency geographic service area or within an
 160 immediately contiguous county. If the home health agency is
 161 licensed under this chapter and is part of a retirement
 162 community that provides multiple levels of care, an employee of
 163 the retirement community may administer the home health agency
 164 and up to a maximum of four entities licensed under this chapter
 165 or chapter 429 which all have identical controlling interests as
 166 defined in s. 408.803. An administrator shall designate, in
 167 writing, for each licensed entity, a qualified alternate
 168 administrator to serve during the administrator's absence. An

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169 | alternate administrator must meet the requirements in this
170 | paragraph and s. 400.462(1).

171 | (b) An administrator of a home health agency who is a
172 | licensed physician, physician assistant, or registered nurse
173 | licensed to practice in this state may also be the director of
174 | nursing for a home health agency. An administrator may serve as
175 | a director of nursing for up to the number of entities
176 | authorized in subsection (2) only if there are 10 or fewer full-
177 | time equivalent employees and contracted personnel in each home
178 | health agency.

179 | (c) The administrator shall organize and direct the
180 | agency's ongoing functions, maintain an ongoing liaison with the
181 | board members and the staff, employ qualified personnel and
182 | ensure adequate staff education and evaluations, ensure the
183 | accuracy of public informational materials and activities,
184 | implement an effective budgeting and accounting system, and
185 | ensure that the home health agency operates in compliance with
186 | this part and part II of chapter 408 and rules adopted for these
187 | laws.

188 | (d) The administrator shall clearly set forth in writing
189 | the organizational chart, services furnished, administrative
190 | control authority, and lines of authority for the delegation of
191 | responsibilities for patient care. These responsibilities must
192 | be readily identifiable. Administrative and supervisory
193 | functions may not be delegated to another agency or
194 | organization, and the primary home health agency shall monitor
195 | and control all services that are not furnished directly,
196 | including services provided through contracts.

197 (2) DIRECTOR OF NURSING.—
 198 (a) A director of nursing may be the director of nursing
 199 for:
 200 1. Up to two licensed home health agencies if the agencies
 201 have identical controlling interests as defined in s. 408.803
 202 and are located within one agency geographic service area or
 203 within an immediately contiguous county; or
 204 2. Up to five licensed home health agencies if:
 205 a. All of the home health agencies have identical
 206 controlling interests as defined in s. 408.803;
 207 b. All of the home health agencies are located within one
 208 agency geographic service area or within an immediately
 209 contiguous county; ~~and~~
 210 c. Each home health agency has a registered nurse who
 211 meets the qualifications of a director of nursing and who has a
 212 written delegation from the director of nursing to serve as the
 213 director of nursing for that home health agency when the
 214 director of nursing is not present; ~~and~~—
 215 d. This person, or a similarly qualified alternate, is
 216 available at all times during operating hours and participates
 217 in all activities relevant to the professional services
 218 furnished, including, but not limited to, the oversight of
 219 nursing services, home health aides, and certified nursing
 220 assistants and the assignment of personnel.
 221
 222 If a home health agency licensed under this chapter is part of a
 223 retirement community that provides multiple levels of care, an
 224 employee of the retirement community may serve as the director

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225 of nursing of the home health agency and up to a maximum of four
226 entities, other than home health agencies, licensed under this
227 chapter or chapter 429 which all have identical controlling
228 interests as defined in s. 408.803.

229 (b) A home health agency that provides skilled nursing
230 care may not operate for more than 30 calendar days without a
231 director of nursing. A home health agency that provides skilled
232 nursing care and the director of nursing of a home health agency
233 must notify the agency within 10 business days after termination
234 of the services of the director of nursing for the home health
235 agency. A home health agency that provides skilled nursing care
236 must notify the agency of the identity and qualifications of the
237 new director of nursing within 10 days after the new director is
238 hired. If a home health agency that provides skilled nursing
239 care operates for more than 30 calendar days without a director
240 of nursing, the home health agency commits a class II
241 deficiency. In addition to the fine for a class II deficiency,
242 the agency may issue a moratorium in accordance with s. 408.814
243 or revoke the license. The agency shall fine a home health
244 agency that fails to notify the agency as required in this
245 paragraph \$1,000 for the first violation and \$2,000 for a repeat
246 violation. The agency may not take administrative action against
247 a home health agency if the director of nursing fails to notify
248 the department upon termination of services as the director of
249 nursing for the home health agency.

250 (c) A home health agency that is not Medicare or Medicaid
251 certified and does not provide skilled care or provides only
252 physical, occupational, or speech therapy is not required to

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253 have a director of nursing and is exempt from paragraph (b).

254 (3) TRAINING.—A home health agency shall ensure that each
 255 certified nursing assistant employed by or under contract with
 256 the home health agency and each home health aide employed by or
 257 under contract with the home health agency is adequately trained
 258 to perform the tasks of a home health aide in the home setting.

259 (a) The home health agency may not use as a home health
 260 aide on a full-time, temporary, per diem, or other basis any
 261 individual to provide services unless the individual has
 262 completed a training and competency evaluation program, or a
 263 competency evaluation program, as permitted in s. 400.497, which
 264 meets the minimum standards established by the agency in state
 265 rules.

266 (b) A home health aide is not competent in any task for
 267 which he or she is evaluated as "unsatisfactory." The aide must
 268 perform any such task only under direct supervision by a
 269 licensed nurse until he or she receives training in the task and
 270 satisfactorily passes a subsequent evaluation in performing the
 271 task. A home health aide has not successfully passed a
 272 competency evaluation if the aide does not have a passing score
 273 on the test as specified by agency rule.

274 (4) STAFFING.—Staffing services may be provided anywhere
 275 within the state.

276 (5) PERSONNEL.—

277 (a) The home health agency and its staff must comply with
 278 accepted professional standards and principles that apply to
 279 professionals, including, but not limited to, the state practice
 280 acts and the home health agency's policies and procedures.

281 (b) If personnel under hourly or per-visit contracts are
 282 used by the home health agency, there must be a written contract
 283 between those personnel and the agency which specifies the
 284 following requirements:

285 1. Acceptance for care only of patients by the primary
 286 home health agency.

287 2. The services to be furnished.

288 3. The necessity to conform to all applicable agency
 289 policies, including personnel qualifications.

290 4. The responsibility for participating in developing
 291 plans of care.

292 5. The manner in which services are controlled,
 293 coordinated, and evaluated by the primary home health agency.

294 6. The procedures for submitting clinical and progress
 295 notes, scheduling visits, and providing periodic patient
 296 evaluations.

297 7. The procedures for payment for services furnished under
 298 the contract.

299 (c) A home health agency shall directly provide at least
 300 one of the types of authorized services through home health
 301 agency employees, but may provide additional services under
 302 arrangements with another agency or organization. Services
 303 furnished under such arrangements must have a written contract
 304 conforming to the requirements specified in paragraph (b).

305 (d) If home health aide services are provided by an
 306 individual who is not employed directly by the home health
 307 agency, the services of the home health aide must be provided
 308 under arrangements as stated in paragraphs (b) and (c). If the

309 home health agency chooses to provide home health aide services
 310 under arrangements with another organization, the
 311 responsibilities of the home health agency include, but are not
 312 limited to:

313 1. Ensuring the overall quality of the care provided by
 314 the aide.

315 2. Supervising the aide's services as described in s.
 316 400.487.

317 3. Ensuring that each home health aide providing services
 318 under arrangements with another organization has met the
 319 training requirements or competency evaluation requirements of
 320 s. 400.497.

321 (e) The home health agency shall coordinate the efforts of
 322 all personnel furnishing services, and the personnel shall
 323 maintain communication with the home health agency to ensure
 324 that personnel efforts support the objectives outlined in the
 325 plan of care. The clinical record or minutes of case conferences
 326 shall ensure that effective interchange, reporting, and
 327 coordination of patient care occurs.

328 Section 10. Section 400.487, Florida Statutes, is amended
 329 to read:

330 400.487 Home health service agreements; physician's,
 331 physician assistant's, and advanced registered nurse
 332 practitioner's treatment orders; patient assessment;
 333 establishment and review of plan of care; provision of services;
 334 orders not to resuscitate.—

335 (1) Services provided by a home health agency must be
 336 covered by an agreement between the home health agency and the

337 patient or the patient's legal representative specifying the
 338 home health services to be provided, the rates or charges for
 339 services paid with private funds, and the sources of payment,
 340 which may include Medicare, Medicaid, private insurance,
 341 personal funds, or a combination thereof. The home health agency
 342 shall provide a copy of the agreement to the patient or the
 343 patient's legal representative. A home health agency providing
 344 skilled care must make an assessment of the patient's needs
 345 within 48 hours after the start of services.

346 (2) When required by the provisions of chapter 464; part
 347 I, part III, or part V of chapter 468; or chapter 486, the
 348 attending physician, physician assistant, or advanced registered
 349 nurse practitioner, acting within his or her respective scope of
 350 practice, shall establish treatment orders for a patient who is
 351 to receive skilled care. The treatment orders must be signed by
 352 the physician, physician assistant, or advanced registered nurse
 353 practitioner before a claim for payment for the skilled services
 354 is submitted by the home health agency. If the claim is
 355 submitted to a managed care organization, the treatment orders
 356 must be signed within the time allowed under the provider
 357 agreement. The treatment orders shall be reviewed, as frequently
 358 as the patient's illness requires, by the physician, physician
 359 assistant, or advanced registered nurse practitioner in
 360 consultation with the home health agency.

361 (3) A home health agency shall arrange for supervisory
 362 visits by a registered nurse to the home of a patient receiving
 363 home health aide services as specified in subsection (9) in
 364 ~~accordance with the patient's direction, approval, and agreement~~

365 ~~to pay the charge for the visits.~~

366 (4) The home health agency shall protect and promote the
 367 rights of each individual under its care, including each of the
 368 following rights:

369 (a) Notice of rights.—The home health agency shall provide
 370 the patient with a written notice of the patient's rights in
 371 advance of furnishing care to the patient or during the initial
 372 evaluation visit before the initiation of treatment. The home
 373 health agency must maintain documentation showing that it has
 374 complied with the requirements of this section.

375 (b) Exercise of rights and respect for property and
 376 person.—

377 1. The patient has the right to exercise his or her rights
 378 as a patient of the home health agency.

379 2. The patient has the right to have his or her property
 380 treated with respect.

381 3. The patient has the right to voice grievances regarding
 382 treatment or care that is or fails to be furnished, or regarding
 383 the lack of respect for property by anyone who is furnishing
 384 services on behalf of the home health agency, and not be
 385 subjected to discrimination or reprisal for doing so.

386 4. The home health agency must investigate complaints made
 387 by a patient or the patient's family or guardian regarding
 388 treatment or care that is or fails to be furnished or regarding
 389 the lack of respect for the patient's property by anyone
 390 furnishing services on behalf of the home health agency. The
 391 home health agency shall document the existence of the complaint
 392 and its resolution.

393 5. The patient and his or her immediate family or
 394 representative must be informed of the right to report
 395 complaints via the statewide toll-free telephone number to the
 396 agency as required in s. 408.810.

397 (c) Right to be informed and to participate in planning
 398 care and treatment.-

399 1. The patient has the right to be informed, in advance,
 400 about the care to be furnished and of any changes in the care to
 401 be furnished. The home health agency shall advise the patient in
 402 advance of which disciplines will furnish care and the frequency
 403 of visits proposed to be furnished. The home health agency must
 404 advise the patient in advance of any change in the plan of care
 405 before the change is made.

406 2. The patient has the right to participate in the
 407 planning of the care. The home health agency must advise the
 408 patient in advance of the right to participate in planning the
 409 care or treatment and in planning changes in the care or
 410 treatment. Each patient has the right to be informed of and to
 411 participate in the planning of his or her care. Each patient
 412 must be provided, upon request, a copy of the plan of care
 413 established and maintained for that patient by the home health
 414 agency.

415 (5) When nursing services are ordered, the home health
 416 agency to which a patient has been admitted for care must
 417 provide the initial admission visit, all service evaluation
 418 visits, and the discharge visit by a direct employee. Services
 419 provided by others under contractual arrangements to a home
 420 health agency must be monitored and managed by the admitting

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421 home health agency. The admitting home health agency is fully
 422 responsible for ensuring that all care provided through its
 423 employees or contract staff is delivered in accordance with this
 424 part and applicable rules.

425 (6) The skilled care services provided by a home health
 426 agency, directly or under contract, must be supervised and
 427 coordinated in accordance with the plan of care. The home health
 428 agency shall furnish skilled nursing services by or under the
 429 supervision of a registered nurse and in accordance with the
 430 plan of care. Any therapy services offered directly or under
 431 arrangement by the home health agency must be provided by a
 432 qualified therapist or by a qualified therapy assistant under
 433 the supervision of a qualified therapist and in accordance with
 434 the plan of care.

435 (a) Duties and qualifications.—A qualified therapist shall
 436 assist the physician in evaluating the level of function, help
 437 develop or revise the plan of care, prepare clinical and
 438 progress notes, advise and consult with the family and other
 439 agency personnel, and participate in in-service programs. The
 440 therapist or therapy assistant must meet the qualifications in
 441 the state practice acts and applicable rules.

442 (b) Physical therapist assistants and occupational therapy
 443 assistants.—Services provided by a physical therapist assistant
 444 or occupational therapy assistant must be under the supervision
 445 of a qualified physical therapist or occupational therapist as
 446 required in chapter 486 and part III of chapter 468,
 447 respectively, and applicable rules. A physical therapist
 448 assistant or occupational therapy assistant shall perform

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449 services planned, delegated, and supervised by the therapist,
450 assist in preparing clinical notes and progress reports,
451 participate in educating the patient and his or her family, and
452 participate in in-service programs.

453 (c) Speech therapy services.—Speech therapy services shall
454 be furnished only by or under supervision of a qualified speech-
455 language pathologist or audiologist as required in part I of
456 chapter 468 and applicable rules.

457 (d) Care follows a written plan of care.—The plan of care
458 shall be reviewed by the physician or health professional who
459 provided the treatment orders pursuant to subsection (2) and
460 home health agency personnel as often as the severity of the
461 patient's condition requires, but at least once every 60 days or
462 more when there is a patient-elected transfer, a significant
463 change in condition, or a discharge and return to the same home
464 health agency during the 60-day episode. Professional staff of a
465 home health agency shall promptly alert the physician or other
466 health professional who provided the treatment orders of any
467 change that suggests a need to alter the plan of care.

468 (e) Administration of drugs and treatment.—Only
469 professional staff of a home health agency may administer drugs
470 and treatments as ordered by the physician or health
471 professional pursuant to subsection (2), with the exception of
472 influenza and pneumococcal polysaccharide vaccines, which may be
473 administered according to the policy of the home health agency
474 developed in consultation with a physician and after an
475 assessment for contraindications. Verbal orders shall be in
476 writing and signed and dated with the date of receipt by the

477 registered nurse or qualified therapist who is responsible for
 478 furnishing or supervising the ordered service. A verbal order
 479 may be accepted only by personnel who are authorized to do so by
 480 applicable state laws, rules, and internal policies of the home
 481 health agency.

482 (7) A registered nurse shall conduct the initial
 483 evaluation visit, regularly reevaluate the patient's nursing
 484 needs, initiate the plan of care and necessary revisions,
 485 furnish those services requiring substantial and specialized
 486 nursing skill, initiate appropriate preventive and
 487 rehabilitative nursing procedures, prepare clinical and progress
 488 notes, coordinate services, inform the physician and other
 489 personnel of changes in the patient's condition and needs,
 490 counsel the patient and his or her family in meeting nursing and
 491 related needs, participate in in-service programs, and supervise
 492 and teach other nursing personnel, unless the home health agency
 493 providing the home health aide services is not Medicare-
 494 certified or Medicaid-certified and does not provide skilled
 495 care.

496 (8) A licensed practical nurse shall furnish services in
 497 accordance with agency policies, prepare clinical and progress
 498 notes, assist the physician and registered nurse in performing
 499 specialized procedures, prepare equipment and materials for
 500 treatments observing aseptic technique as required, and assist
 501 the patient in learning appropriate self-care techniques.

502 (9) A home health aide and certified nursing assistant
 503 shall provide services that are in the service provision plan
 504 provided in s. 400.491 and other services that the home health

505 aide or certified nursing assistant is permitted to perform
 506 under state law. The duties of a home health aide or certified
 507 nursing assistant include the provision of hands-on personal
 508 care, performance of simple procedures as an extension of
 509 therapy or nursing services, assistance in ambulation or
 510 exercises, and assistance in administering medications that are
 511 ordinarily self-administered and are specified in agency rules.
 512 Any services by a home health aide which are offered by a home
 513 health agency must be provided by a qualified home health aide
 514 or certified nursing assistant.

515 (a) Assignment and duties.-A home health aide or certified
 516 nursing assistant shall be assigned to a specific patient by a
 517 registered nurse, unless the home health agency providing the
 518 home health aide services is not Medicare-certified or Medicaid-
 519 certified and does not provide skilled care. Written patient
 520 care instructions for the home health aide and certified nursing
 521 assistant must be prepared by the registered nurse or other
 522 appropriate professional who is responsible for the supervision
 523 of the home health aide and certified nursing assistant as
 524 stated in this section.

525 (b) Supervision.-If a patient receives skilled nursing
 526 care, the registered nurse shall perform the supervisory visit.
 527 If the patient is not receiving skilled nursing care but is
 528 receiving physical therapy, occupational therapy, or speech-
 529 language pathology services, the appropriate therapist may
 530 provide the supervision. A registered nurse or other
 531 professional must make an onsite visit to the patient's home at
 532 least once every 2 weeks. The visit is not required while the

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533 aide is providing care.

534 (c) Supervisory visits.—If home health aide services are
 535 provided to a patient who is not receiving skilled nursing care,
 536 physical or occupational therapy, or speech-language pathology
 537 services, a registered nurse must make a supervisory visit to
 538 the patient's home at least once every 60 days, unless the home
 539 health agency providing the home health aide services is not
 540 Medicare-certified or Medicaid-certified and does not provide
 541 skilled care, either directly or through contracts. The
 542 registered nurse shall ensure that the aide is properly caring
 543 for the patient and each supervisory visit must occur while the
 544 home health aide is providing patient care. In addition to the
 545 requirements in this subsection, a home health agency shall
 546 arrange for additional supervisory visits by a registered nurse
 547 to the home of a patient receiving home health aide services in
 548 accordance with the patient's direction, approval, and agreement
 549 to pay the charge for the visits.

550 (10)-(7) Home health agency personnel may withhold or
 551 withdraw cardiopulmonary resuscitation if presented with an
 552 order not to resuscitate executed pursuant to s. 401.45. The
 553 agency shall adopt rules providing for the implementation of
 554 such orders. Home health personnel and agencies shall not be
 555 subject to criminal prosecution or civil liability, nor be
 556 considered to have engaged in negligent or unprofessional
 557 conduct, for withholding or withdrawing cardiopulmonary
 558 resuscitation pursuant to such an order and rules adopted by the
 559 agency.

560 Section 11. Subsection (11) of section 408.802, Florida

561 Statutes, is repealed.

562 Section 12. Paragraphs (e), (f), and (g) of subsection
 563 (15) of section 409.912, Florida Statutes, are repealed.

564 Section 13. Subsection (2) of section 429.12, Florida
 565 Statutes, is repealed.

566 Section 14. Subsection (5) of section 429.23, Florida
 567 Statutes, is repealed.

568 Section 15. Paragraph (a) of subsection (2) of section
 569 429.911, Florida Statutes, is repealed.

570 Section 16. Dental workforce survey.—

571 (1) Beginning in 2012, each person who applies for
 572 licensure renewal as a dentist or dental hygienist under chapter
 573 466, Florida Statutes, must, in conjunction with the renewal of
 574 such license under procedures and forms adopted by the Board of
 575 Dentistry and in addition to any other information that may be
 576 required from the applicant, furnish the following information
 577 to the Department of Health, working in conjunction with the
 578 board, in a dental workforce survey:

579 (a) Licensee information, including, but not limited to:

580 1. The name of the dental school or dental hygiene program
 581 that the dentist or dental hygienist graduated from and the year
 582 of graduation.

583 2. The year that the dentist or dental hygienist began
 584 practicing or working in this state.

585 3. The geographic location of the dentist's or dental
 586 hygienist's practice or address within the state.

587 4. For a dentist in private practice:

588 a. The number of full-time dental hygienists employed by

- 589 the dentist during the reporting period.
- 590 b. The number of full-time dental assistants employed by
- 591 the dentist during the reporting period.
- 592 c. The average number of patients treated per week by the
- 593 dentist during the reporting period.
- 594 d. The settings where the dental care was delivered.
- 595 5. Anticipated plans of the dentist to change the status
- 596 of his or her license or practice.
- 597 6. The dentist's areas of specialty or certification.
- 598 7. The year that the dentist completed a specialty program
- 599 recognized by the American Dental Association.
- 600 8. For a hygienist:
- 601 a. The average number of patients treated per week by the
- 602 hygienist during the reporting period.
- 603 b. The settings where the dental care was delivered.
- 604 9. The dentist's memberships in professional
- 605 organizations.
- 606 10. The number of pro bono hours provided by the dentist
- 607 or dental hygienist during the last biennium.
- 608 (b) Information concerning the availability and trends
- 609 relating to critically needed services, including, but not
- 610 limited to, the following types of care provided by the dentist
- 611 or dental hygienist:
- 612 1. Dental care to children having special needs.
- 613 2. Geriatric dental care.
- 614 3. Dental services in emergency departments.
- 615 4. Medicaid services.
- 616 5. Other critically needed specialty areas, as determined

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617 by the advisory body.

618 (2) In addition to the completed survey, the dentist or
619 dental hygienist must submit a statement that the information
620 provided is true and accurate to the best of his or her
621 knowledge and belief.

622 (3) Beginning in 2012, renewal of a license by a dentist
623 or dental hygienist licensed under chapter 466, Florida
624 Statutes, is not contingent upon the completion and submission
625 of the dental workforce survey; however, for any subsequent
626 license renewal, the board may not renew the license of any
627 dentist or dental hygienist until the survey required under this
628 section is completed and submitted by the licensee.

629 (4)(a) Beginning in 2012, the Board of Dentistry shall
630 issue a nondisciplinary citation to any dentist or dental
631 hygienist licensed under chapter 466, Florida Statutes, who
632 fails to complete the survey within 90 days after the renewal of
633 his or her license to practice as a dentist or dental hygienist.

634 (b) The citation must notify a dentist or dental hygienist
635 who fails to complete the survey required by this section that
636 his or her license will not be renewed for any subsequent
637 license renewal unless the dentist or dental hygienist completes
638 the survey.

639 (c) In conjunction with issuing the license renewal notice
640 required by s. 456.038, Florida Statutes, the board shall notify
641 each dentist or dental hygienist licensed under chapter 466,
642 Florida Statutes, who fails to complete the survey that the
643 survey must be completed before the subsequent license renewal.

644 Section 17. (1) The Department of Health shall serve as

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645 the coordinating body for the purpose of collecting and
646 regularly updating and disseminating dental workforce data. The
647 department shall work with multiple stakeholders, including the
648 Florida Dental Association and the Florida Dental Hygiene
649 Association, to assess and share with all communities of
650 interest all data collected in a timely fashion.

651 (2) The Department of Health shall maintain a current
652 database to serve as a statewide source of data concerning the
653 dental workforce. The department, in conjunction with the Board
654 of Dentistry, shall also:

655 (a) Develop strategies to maximize federal and state
656 programs that provide incentives for dentists to practice in
657 shortage areas that are federally designated. Strategies shall
658 include programs such as the Florida Health Services Corps
659 established under s. 381.0302, Florida Statutes.

660 (b) Work in conjunction with an advisory body to address
661 matters relating to the state's dental workforce. The advisory
662 body shall provide input on developing questions for the dentist
663 workforce survey. The advisory body shall include, but need not
664 be limited to, the State Surgeon General or his or her designee,
665 the dean of each dental school accredited in the United States
666 and based in this state or his or her designee, a representative
667 from the Florida Dental Association, a representative from the
668 Florida Dental Hygiene Association, a representative from the
669 Board of Dentistry, and a dentist from each of the dental
670 specialties recognized by the American Dental Association's
671 Commission on Dental Accreditation. Members of the advisory body
672 shall serve without compensation.

673 (c) Act as a clearinghouse for collecting and
 674 disseminating information concerning the dental workforce.

675 (3) The Department of Health and the Board of Dentistry
 676 shall adopt rules necessary to administer this section.

677 Section 18. It is the intent of the Legislature that the
 678 Department of Health and the Board of Dentistry implement the
 679 provisions of sections 16 through 20 of this act within existing
 680 resources.

681 Section 19. Paragraph (t) of subsection (2) of section
 682 499.01, Florida Statutes, is amended to read:

683 499.01 Permits.—

684 (2) The following permits are established:

685 (t) Health care clinic establishment permit.—Effective
 686 January 1, 2009, a health care clinic establishment permit is
 687 required for the purchase of a prescription drug by a place of
 688 business at one general physical location that provides health
 689 care or veterinary services, which is owned and operated by a
 690 business entity that has been issued a federal employer tax
 691 identification number. For the purpose of this paragraph, the
 692 term "qualifying practitioner" means a licensed health care
 693 practitioner defined in s. 456.001, or a veterinarian licensed
 694 under chapter 474, who is authorized under the appropriate
 695 practice act to prescribe and administer a prescription drug.

696 1. An establishment must provide, as part of the
 697 application required under s. 499.012, designation of a
 698 qualifying practitioner who will be responsible for complying
 699 with all legal and regulatory requirements related to the
 700 purchase, recordkeeping, storage, and handling of the

701 prescription drugs. In addition, the designated qualifying
 702 practitioner shall be the practitioner whose name, establishment
 703 address, and license number is used on all distribution
 704 documents for prescription drugs purchased or returned by the
 705 health care clinic establishment. Upon initial appointment of a
 706 qualifying practitioner, the qualifying practitioner and the
 707 health care clinic establishment shall notify the department on
 708 a form furnished by the department within 10 days after such
 709 employment. In addition, the qualifying practitioner and health
 710 care clinic establishment shall notify the department within 10
 711 days after any subsequent change.

712 2. The health care clinic establishment must employ a
 713 qualifying practitioner at each establishment.

714 3. In addition to the remedies and penalties provided in
 715 this part, a violation of this chapter by the health care clinic
 716 establishment or qualifying practitioner constitutes grounds for
 717 discipline of the qualifying practitioner by the appropriate
 718 regulatory board.

719 4. The purchase of prescription drugs by the health care
 720 clinic establishment is prohibited during any period of time
 721 when the establishment does not comply with this paragraph.

722 5. A health care clinic establishment permit is not a
 723 pharmacy permit or otherwise subject to chapter 465. A health
 724 care clinic establishment that meets the criteria of a modified
 725 Class II institutional pharmacy under s. 465.019 is not eligible
 726 to be permitted under this paragraph.

727 6. This paragraph does not apply to the purchase of a
 728 prescription drug by a licensed practitioner under his or her

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729 | license. A professional corporation or limited liability company
 730 | composed of dentists and operating as authorized in s. 466.0285
 731 | may pay for prescription drugs obtained by a practitioner
 732 | licensed under chapter 466, and the licensed practitioner is
 733 | deemed the purchaser and owner of the prescription drugs.

734 | Section 20. Paragraph (a) of subsection (6) of section
 735 | 624.91, Florida Statutes, is amended to read:

736 | 624.91 The Florida Healthy Kids Corporation Act.—

737 | (6) BOARD OF DIRECTORS.—

738 | (a) The Florida Healthy Kids Corporation shall operate
 739 | subject to the supervision and approval of a board of directors
 740 | chaired by the Chief Financial Officer or her or his designee,
 741 | and composed of 12 ~~11~~ other members selected for 3-year terms of
 742 | office as follows:

743 | 1. The Secretary of Health Care Administration, or his or
 744 | her designee.

745 | 2. One member appointed by the Commissioner of Education
 746 | from the Office of School Health Programs of the Florida
 747 | Department of Education.

748 | 3. One member appointed by the Chief Financial Officer
 749 | from among three members nominated by the Florida Pediatric
 750 | Society.

751 | 4. One member, appointed by the Governor, who represents
 752 | the Children's Medical Services Program.

753 | 5. One member appointed by the Chief Financial Officer
 754 | from among three members nominated by the Florida Hospital
 755 | Association.

756 | 6. One member, appointed by the Governor, who is an expert

757 | on child health policy.

758 | 7. One member, appointed by the Chief Financial Officer,
759 | from among three members nominated by the Florida Academy of
760 | Family Physicians.

761 | 8. One member, appointed by the Governor, who represents
762 | the state Medicaid program.

763 | 9. One member, appointed by the Chief Financial Officer,
764 | from among three members nominated by the Florida Association of
765 | Counties.

766 | 10. The State Health Officer or her or his designee.

767 | 11. The Secretary of Children and Family Services, or his
768 | or her designee.

769 | 12. One member, appointed by the Governor, from among
770 | three members nominated by the Florida Dental Association.

771 | Section 21. This act shall take effect July 1, 2010.

Amendment No. 1

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	_____	

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council
3 Representative(s) Flores offered the following:
4

5 **Amendment (with title amendment)**

6 Between lines 129 and 130, insert:

7 Section 2. Subsection (3) is added to section 381.00315,
8 Florida Statutes, to read:

9 381.00315 Public health advisories; public health
10 emergencies.—The State Health Officer is responsible for
11 declaring public health emergencies and issuing public health
12 advisories.

13 (3) To facilitate effective emergency management, when the
14 United States Department of Health and Human Services contracts
15 for the manufacturing and delivery of licensable products in
16 response to a public health emergency and the terms of those
17 contracts are made available to the states, the department shall
18 accept funds provided by cities, counties and other entities
19 designated in the state emergency management plan required under

Amendment No. 1

20 s. 252.35(2)(a) for the purpose of participation in these
21 contracts. The department shall deposit said funds in the Grants
22 and Donations Trust Fund and expend those funds on behalf of the
23 donor city, county or other entity for the purchase the
24 licensable products made available under the contract.
25
26

27 -----
28 **T I T L E A M E N D M E N T**

29 Remove line 5 and insert:

30 retroactively; conforming a cross-reference; amending s.
31 381.00315, F.S., directing the Department of Health to accept
32 funds from counties, municipalities, and certain other entities
33 for the purchase of certain products made available under a
34 contract of the United States Department of Health and Human
35 Services for the manufacture and delivery of such products in
36 response to a public health emergency; repealing s.

Amendment No. 2

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 _____

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council

3 Representative(s) Flores offered the following:
4

5 **Amendment (with title amendment)**

6 Between lines 130 and 131, insert:

7 Section 3. Subsection (20) of section 395.0197, Florida
8 Statutes, is created to read:

9 395.0197 Internal risk management program.—

10 (20) A hospital's implementation of a comprehensive plan
11 to reduce healthcare associated infections prior to a patient
12 becoming infected constitutes a rebuttable presumption against a
13 claim of negligence or malpractice by the hospital or any of its
14 employees or independent contractors. Any such plan must
15 include the following components:

16 (a) A baseline measurement of healthcare associated
17 infections in the hospital that uses the National Healthcare
18 Safety Network and Centers for Disease Control and Prevention
19 surveillance definitions and reports the number of infections in

Amendment No. 2

20 each category relative to the volume of possible cases in the
21 hospital.

22 (b) A goal for reducing the incidence of infections by a
23 specific amount in a defined period of time. The hospital's
24 goals for reduction of infections must be commensurate with the
25 national goal for reducing each type of healthcare associated
26 infection.

27 (c) An action plan for reducing each type of infection,
28 including the use of real time infection surveillance technology
29 or automated infection control or prevention technology.

30 (d) Methods for making information available to patients
31 and the public regarding baseline measurements and periodic
32 reports on the hospital's progress in improving those measures.

33
34
35 -----
36 **T I T L E A M E N D M E N T**

37 Remove line 8 and insert:
38 reports; amending s. 395.0197, F.S., providing for a rebuttable
39 presumption against negligence or malpractice claims for
40 hospitals and their employees or independent contractors under
41 specified circumstances; establishing components for the plan;
42 repealing s. 395.1046, F.S., relating to the

Amendment No. 3

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 _____

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council
3 Representative(s) Flores offered the following:

4
5 **Amendment (with title amendment)**

6 Between lines 563 and 564, insert:

7 Section 13. Section 409.91255, Florida Statutes, is
8 amended to read:

9 409.91255 Federally qualified health center access
10 program.—

11 (1) SHORT TITLE.—This section may be cited as the
12 "Community Health Center Access Program Act."

13 (2) LEGISLATIVE FINDINGS AND INTENT.—

14 (a) The Legislature finds that, despite significant
15 investments in health care programs, nearly 6 ~~more than 2~~
16 million low-income Floridians, primarily the working poor and
17 minority populations, continue to lack access to basic health
18 care services. Further, the Legislature recognizes that
19 federally qualified health centers have a proven record of

Amendment No. 3

20 providing cost-effective, comprehensive primary and preventive
21 health care and are uniquely qualified to address the lack of
22 adequate health care services for the uninsured.

23 (b) It is the intent of the Legislature to recognize the
24 significance of increased federal investments in federally
25 qualified health centers and to leverage that investment through
26 the creation of a program to provide for the expansion of the
27 primary and preventive health care services offered by federally
28 qualified health centers. Further, such a program will support
29 the coordination of federal, state, and local resources to
30 assist such health centers in developing an expanded community-
31 based primary care delivery system.

32 (3) ASSISTANCE TO FEDERALLY QUALIFIED HEALTH CENTERS.—The
33 agency shall administer ~~Department of Health shall develop~~ a
34 program for the expansion of federally qualified health centers
35 for the purpose of providing comprehensive primary and
36 preventive health care and urgent care services that may reduce
37 the morbidity, mortality, and cost of care among the uninsured
38 population of the state. The program shall provide for
39 distribution of financial assistance to federally qualified
40 health centers that apply and demonstrate a need for such
41 assistance in order to sustain or expand the delivery of primary
42 and preventive health care services. In selecting centers to
43 receive this financial assistance, the program:

44 (a) Shall give preference to communities that have few or
45 no community-based primary care services or in which the current
46 services are unable to meet the community's needs. To assist in
47 the assessment and identification of areas of critical need, a

Amendment No. 3

48 federally qualified health center based statewide assessment and
49 strategic plan shall be developed by the Florida Association of
50 Community Health Centers, Inc., every 5 years, beginning January
51 1, 2011.

52 (b) Shall require that primary care services be provided
53 to the medically indigent using a sliding fee schedule based on
54 income.

55 (c) Shall ~~promote~~ allow innovative and creative uses of
56 federal, state, and local health care resources.

57 (d) Shall require that the funds provided be used to pay
58 for operating costs of a projected expansion in patient
59 caseloads or services or for capital improvement projects.
60 Capital improvement projects may include renovations to existing
61 facilities or construction of new facilities, provided that an
62 expansion in patient caseloads or services to a new patient
63 population will occur as a result of the capital expenditures.
64 The agency ~~department~~ shall include in its standard contract
65 document a requirement that any state funds provided for the
66 purchase of or improvements to real property are contingent upon
67 the contractor granting to the state a security interest in the
68 property at least to the amount of the state funds provided for
69 at least 5 years from the date of purchase or the completion of
70 the improvements or as further required by law. The contract
71 must include a provision that, as a condition of receipt of
72 state funding for this purpose, the contractor agrees that, if
73 it disposes of the property before the agency's ~~department's~~
74 interest is vacated, the contractor will refund the

Amendment No. 3

75 proportionate share of the state's initial investment, as
76 adjusted by depreciation.

77 (e) Shall ~~May~~ require in-kind support from other sources.

78 (f) Shall promote ~~May encourage~~ coordination among
79 federally qualified health centers, other private sector
80 providers, and publicly supported programs.

81 (g) Shall promote ~~allow~~ the development of community
82 emergency room diversion programs in conjunction with local
83 resources, providing extended hours of operation to urgent care
84 patients. Diversion programs shall include case management for
85 emergency room followup care.

86 (4) EVALUATION OF APPLICATIONS.—A review panel shall be
87 established, consisting of four persons appointed by the
88 Secretary of Health Care Administration ~~State Surgeon General~~
89 and three persons appointed by the chief executive officer of
90 the Florida Association of Community Health Centers, Inc., to
91 review all applications for financial assistance under the
92 program. Applicants shall specify in the application whether the
93 program funds will be used for the expansion of patient
94 caseloads or services or for capital improvement projects to
95 expand and improve patient facilities. The panel shall use the
96 following elements in reviewing application proposals and shall
97 determine the relative weight for scoring and evaluating these
98 elements:

99 (a) The target population to be served.

100 (b) The health benefits to be provided.

101 (c) The methods that will be used to measure cost-
102 effectiveness.

Amendment No. 3

- 103 (d) How patient satisfaction will be measured.
104 (e) The proposed internal quality assurance process.
105 (f) Projected health status outcomes.
106 (g) How data will be collected to measure cost-
107 effectiveness, health status outcomes, and overall achievement
108 of the goals of the proposal.
109 (h) All resources, including cash, in-kind, voluntary, or
110 other resources that will be dedicated to the proposal.
111 (5) ADMINISTRATION AND TECHNICAL ASSISTANCE.—The agency
112 shall ~~Department of Health may~~ contract with the Florida
113 Association of Community Health Centers, Inc., to develop and
114 coordinate ~~administer~~ the program and provide technical
115 assistance to the federally qualified health centers selected to
116 receive financial assistance. The contracted entity shall be
117 responsible for program support and assume all costs related to
118 administration of this program.

122 **T I T L E A M E N D M E N T**

123 Remove line 72 and insert:
124 program; amending s. 409.91255, F.S.; transferring
125 administrative responsibility for the application
126 procedure for federally qualified health centers from the
127 Department of Health to the Agency for Health Care
128 Administration; requiring the Florida Association of
129 Community Health Centers, Inc., to provide support and

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130 | assume administrative costs for the program; repealing s.
131 | 429.12(2), F.S., relating to the

Amendment No. 4

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 _____

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council

3 Representative(s) Flores offered the following:

4
5 **Amendment (with title amendment)**

6 Between lines 563 and 564, insert:

7 Section 13. Subsection (13) of section 409.9122, Florida
8 Statutes, is repealed.

9
10
11 -----
12 **T I T L E A M E N D M E N T**

13 Remove line 72 and insert:

14 program; repealing s. 409.9122, F.S., relating to Medicaid
15 managed prepaid plan minimum enrollment levels for plans
16 operating in Miami-Dade County; repealing s. 429.12(2), F.S.,
17 relating to the

Amendment No. 5

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 _____

1 Council/Committee hearing bill: Health & Family Services Policy
2 Council
3 Representative(s) Homan offered the following:
4

5 **Amendment (with title amendment)**

6 Between lines 770 and 771, insert:

7 Section 21. Subsections (4) and (9) of section 381.0403,
8 Florida Statutes, are repealed.

9 Section 22. Section 381.4018, Florida Statutes, is amended
10 to read:

11 381.4018 Physician workforce assessment and development.—

12 (1) DEFINITIONS.—As used in this section, the term:

13 (a) "Consortium" or "consortia" means a combination of
14 statutory teaching hospitals, statutory rural hospitals, other
15 hospitals, accredited medical schools, clinics operated by the
16 Department of Health, clinics operated by the Department of
17 Veterans' Affairs, area health education centers, community
18 health centers, federally qualified health centers, prison
19 clinics, local community clinics, or other programs. At least

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20 one member of the consortium shall be a sponsoring institution
21 accredited or currently seeking accreditation by the
22 Accreditation Council for Graduate Medical Education or the
23 American Osteopathic Association.

24 (b) "Council" means the Physician Workforce Advisory
25 Council.

26 (c) "Department" means the Department of Health.

27 (d) "Graduate medical education program" means a program
28 accredited by the Accreditation Council for Graduate Medical
29 Education or the American Osteopathic Association.

30 (e) "Primary care specialty" means emergency medicine,
31 family practice, internal medicine, pediatrics, psychiatry,
32 geriatrics, general surgery, obstetrics and gynecology, and
33 combined pediatrics and internal medicine and other specialties
34 as determined by the Physician Workforce Advisory Council or the
35 Department of Health.

36 (2)-(1) LEGISLATIVE INTENT.—The Legislature recognizes that
37 physician workforce planning is an essential component of
38 ensuring that there is an adequate and appropriate supply of
39 well-trained physicians to meet this state's future health care
40 service needs as the general population and elderly population
41 of the state increase. The Legislature finds that items to
42 consider relative to assessing the physician workforce may
43 include physician practice status; specialty mix; geographic
44 distribution; demographic information, including, but not
45 limited to, age, gender, race, and cultural considerations; and
46 needs of current or projected medically underserved areas in the
47 state. Long-term strategic planning is essential as the period

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48 from the time a medical student enters medical school to
49 completion of graduate medical education may range from 7 to 10
50 years or longer. The Legislature recognizes that strategies to
51 provide for a well-trained supply of physicians must include
52 ensuring the availability and capacity of quality ~~graduate~~
53 medical schools and graduate medical education programs in this
54 state, as well as using new or existing state and federal
55 programs providing incentives for physicians to practice in
56 needed specialties and in underserved areas in a manner that
57 addresses projected needs for physician manpower.

58 (3)~~(2)~~ PURPOSE.—The department ~~of Health~~ shall serve as a
59 coordinating and strategic planning body to actively assess the
60 state's current and future physician workforce needs and work
61 with multiple stakeholders to develop strategies and
62 alternatives to address current and projected physician
63 workforce needs.

64 (4)~~(3)~~ GENERAL FUNCTIONS.—The department shall maximize
65 the use of existing programs under the jurisdiction of the
66 department and other state agencies and coordinate governmental
67 and nongovernmental stakeholders and resources in order to
68 develop a state strategic plan and assess the implementation of
69 such strategic plan. In developing the state strategic plan, the
70 department shall:

71 (a) Monitor, evaluate, and report on the supply and
72 distribution of physicians licensed under chapter 458 or chapter
73 459. The department shall maintain a database to serve as a
74 statewide source of data concerning the physician workforce.

75 (b) Develop a model and quantify, on an ongoing basis, the

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76 adequacy of the state's current and future physician workforce
77 as reliable data becomes available. Such model must take into
78 account demographics, physician practice status, place of
79 education and training, generational changes, population growth,
80 economic indicators, and issues concerning the "pipeline" into
81 medical education.

82 (c) Develop and recommend strategies to determine whether
83 the number of qualified medical school applicants who might
84 become competent, practicing physicians in this state will be
85 sufficient to meet the capacity of the state's medical schools.
86 If appropriate, the department shall, working with
87 representatives of appropriate governmental and nongovernmental
88 entities, develop strategies and recommendations and identify
89 best practice programs that introduce health care as a
90 profession and strengthen skills needed for medical school
91 admission for elementary, middle, and high school students, and
92 improve premedical education at the precollege and college level
93 in order to increase this state's potential pool of medical
94 students.

95 (d) Develop strategies to ensure that the number of
96 graduates from the state's public and private allopathic and
97 osteopathic medical schools is ~~are~~ adequate to meet physician
98 workforce needs, based on the analysis of the physician
99 workforce data, so as to provide a high-quality medical
100 education to students in a manner that recognizes the uniqueness
101 of each new and existing medical school in this state.

102 (e) Pursue strategies and policies to create, expand, and
103 maintain graduate medical education positions in the state based

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104 on the analysis of the physician workforce data. Such strategies
105 and policies must take into account the effect of federal
106 funding limitations on the expansion and creation of positions
107 in graduate medical education. The department shall develop
108 options to address such federal funding limitations. The
109 department shall consider options to provide direct state
110 funding for graduate medical education positions in a manner
111 that addresses requirements and needs relative to accreditation
112 of graduate medical education programs. The department shall
113 consider funding residency positions as a means of addressing
114 needed physician specialty areas, rural areas having a shortage
115 of physicians, and areas of ongoing critical need, and as a
116 means of addressing the state's physician workforce needs based
117 on an ongoing analysis of physician workforce data.

118 (f) Develop strategies to maximize federal and state
119 programs that provide for the use of incentives to attract
120 physicians to this state or retain physicians within the state.
121 Such strategies should explore and maximize federal-state
122 partnerships that provide incentives for physicians to practice
123 in federally designated shortage areas. Strategies shall also
124 consider the use of state programs, such as the Florida Health
125 Service Corps established pursuant to s. 381.0302 and the
126 Medical Education Reimbursement and Loan Repayment Program
127 pursuant to s. 1009.65, which provide for education loan
128 repayment or loan forgiveness and provide monetary incentives
129 for physicians to relocate to underserved areas of the state.

130 (g) Coordinate and enhance activities relative to
131 physician workforce needs, undergraduate medical education, and

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132 graduate medical education, and reentry of retired military and
133 other physicians into the physician workforce provided by the
134 Division of Medical Quality Assurance, ~~the Community Hospital~~
135 ~~Education Program and the Graduate Medical Education Committee~~
136 ~~established pursuant to s. 381.0403,~~ area health education
137 center networks established pursuant to s. 381.0402, and other
138 offices and programs within the department ~~of Health~~ as
139 designated by the State Surgeon General.

140 (h) Work in conjunction with and act as a coordinating
141 body for governmental and nongovernmental stakeholders to
142 address matters relating to the state's physician workforce
143 assessment and development for the purpose of ensuring an
144 adequate supply of well-trained physicians to meet the state's
145 future needs. Such governmental stakeholders shall include, but
146 need not be limited to, the State Surgeon General or his or her
147 designee, the Commissioner of Education or his or her designee,
148 the Secretary of Health Care Administration or his or her
149 designee, and the Chancellor of the State University System or
150 his or her designee ~~from the Board of Governors of the State~~
151 ~~University System,~~ and, at the discretion of the department,
152 other representatives of state and local agencies that are
153 involved in assessing, educating, or training the state's
154 current or future physicians. Other stakeholders shall include,
155 but need not be limited to, organizations representing the
156 state's public and private allopathic and osteopathic medical
157 schools; organizations representing hospitals and other
158 institutions providing health care, particularly those that
159 currently provide or have an interest in providing accredited

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160 medical education and graduate medical education to medical
161 students and medical residents; organizations representing
162 allopathic and osteopathic practicing physicians; and, at the
163 discretion of the department, representatives of other
164 organizations or entities involved in assessing, educating, or
165 training the state's current or future physicians.

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

169 (j) Act as a clearinghouse for collecting and
170 disseminating information concerning the physician workforce and
171 medical education continuum in this state.

172 (5) PHYSICIAN WORKFORCE ADVISORY COUNCIL.—There is created
173 in the department the Physician Workforce Advisory Council, an
174 advisory council as defined in s. 20.03. The council shall
175 comply with the requirements of s. 20.052, except as otherwise
176 provided in this section.

177 (a) The council shall consist of 19 members. Members
178 appointed by the State Surgeon General shall include:

179 1. A designee from the department who is a physician
180 licensed under chapter 458 or chapter 459 and recommended by the
181 State Surgeon General.

182 2. An individual who is affiliated with the Science
183 Students Together Reaching Instructional Diversity and
184 Excellence program and recommended by the area health education
185 center network.

186 3. Two individuals recommended by the Council of Florida
187 Medical School Deans, one representing a college of allopathic

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188 medicine and one representing a college of osteopathic medicine.

189 4. One individual recommended by the Florida Hospital
190 Association, representing a hospital that is licensed under
191 chapter 395, has an accredited graduate medical education
192 program, and is not a statutory teaching hospital.

193 5. One individual representing a statutory teaching
194 hospital as defined in s. 408.07 and recommended by the Safety
195 Net Hospital Alliance.

196 6. One individual representing a family practice teaching
197 hospital as defined in s. 395.805 and recommended by the Council
198 of Family Medicine and Community Teaching Hospitals.

199 7. Two individuals recommended by the Florida Medical
200 Association, one representing a primary care specialty and one
201 representing a nonprimary care specialty.

202 8. Two individuals recommended by the Florida Osteopathic
203 Medical Association, one representing a primary care specialty
204 and one representing a nonprimary care specialty.

205 9. Two individuals who are program directors of accredited
206 graduate medical education programs, one representing a program
207 that is accredited by the Accreditation Council for Graduate
208 Medical Education and one representing a program that is
209 accredited by the American Osteopathic Association.

210 10. An individual recommended by the Florida Association
211 of Community Health Centers representing a federally qualified
212 health center located in a rural area as defined in s.
213 381.0406(2)(a).

214 11. An individual recommended by the Florida Academy of
215 Family Physicians.

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216 12. An individual recommended by the Florida Alliance for
217 Health Professions Diversity.

218 13. The Chancellor of the State University System or his
219 or her designee.

220 14. A layperson member as determined by the State Surgeon
221 General.

222

223 Appointments to the council shall be made by the State Surgeon
224 General. Each entity authorized to make recommendations under
225 this subsection shall make at least two recommendations to the
226 State Surgeon General for each appointment to the council. The
227 State Surgeon General shall name one appointee for each position
228 from the recommendations made by each authorized entity.

229 (b) Each council member shall be appointed to a 4-year
230 term. An individual may not serve more than two terms. Any
231 council member may be removed from office for malfeasance;
232 misfeasance; neglect of duty; incompetence; permanent inability
233 to perform official duties; or pleading guilty or nolo
234 contendere to, or being found guilty of, a felony. Any council
235 member who meets the criteria for removal, or who is otherwise
236 unwilling or unable to properly fulfill the duties of the
237 office, shall be succeeded by an individual chosen by the State
238 Surgeon General to serve out the remainder of the council
239 member's term. If the remainder of the replaced council member's
240 term is less than 18 months, notwithstanding the provisions of
241 this paragraph, the succeeding council member may be reappointed
242 twice by the State Surgeon General.

243 (c) The chair of the council is the State Surgeon General,

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244 who shall designate a vice chair from the membership of the
245 council to serve in the absence of the State Surgeon General. A
246 vacancy shall be filled for the remainder of the unexpired term
247 in the same manner as the original appointment.

248 (d) Council members are not entitled to receive
249 compensation or reimbursement for per diem or travel expenses.

250 (e) The council shall meet at least twice a year in person
251 or by teleconference.

252 (f) The council shall:

253 1. Advise the State Surgeon General and the department on
254 matters concerning current and future physician workforce needs
255 in this state;

256 2. Review survey materials and the compilation of survey
257 information;

258 3. Annually review the number, location, cost, and
259 reimbursement of graduate medical education programs and
260 positions;

261 4. Provide recommendations to the department regarding the
262 survey completed by physicians licensed under chapter 458 or
263 chapter 459;

264 5. Assist the department in preparing the annual report to
265 the Legislature pursuant to ss. 458.3192 and 459.0082;

266 6. Assist the department in preparing an initial strategic
267 plan, conduct ongoing strategic planning in accordance with this
268 section, and provide ongoing advice on implementing the
269 recommendations;

270 7. Monitor and provide recommendations regarding the need
271 for an increased number of primary care or other physician

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272 specialties to provide the necessary current and projected
273 health and medical services for the state; and

274 8. Monitor and make recommendations regarding the status
275 of the needs relating to graduate medical education in this
276 state.

277 (6) PHYSICIAN WORKFORCE GRADUATE MEDICAL EDUCATION
278 INNOVATION PILOT PROJECTS.—

279 (a) The Legislature finds that:

280 1. In order to ensure a physician workforce that is
281 adequate to meet the needs of this state's residents and its
282 health care system, policymakers must consider the education and
283 training of future generations of well-trained health care
284 providers.

285 2. Physicians are likely to practice in the state where
286 they complete their graduate medical education.

287 3. It can directly affect the makeup of the physician
288 workforce by selectively funding graduate medical education
289 programs to provide needed specialists in geographic areas of
290 the state which have a deficient number of such specialists.

291 4. Developing additional positions in graduate medical
292 education programs is essential to the future of this state's
293 health care system.

294 5. It was necessary in 2007 to pass legislation that
295 provided for an assessment of the status of this state's current
296 and future physician workforce. The department is collecting and
297 analyzing information on an ongoing basis to assess this state's
298 physician workforce needs, and such assessment may facilitate
299 the determination of graduate medical education needs and

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300 strategies for the state.

301 (b) There is established under the department a program to
302 foster innovative graduate medical education pilot projects that
303 are designed to promote the expansion of graduate medical
304 education programs or positions to prepare physicians to
305 practice in needed specialties and underserved areas or settings
306 and to provide demographic and cultural representation in a
307 manner that addresses current and projected needs for this
308 state's physician workforce. Funds appropriated annually by the
309 Legislature for this purpose shall be distributed to
310 participating hospitals, medical schools, other sponsors of
311 graduate medical education programs, consortia engaged in
312 developing new graduate medical education programs or positions
313 in those programs, or pilot projects providing innovative
314 graduate medical education in community-based clinical settings.
315 Pilot projects shall be selected on a competitive grant basis,
316 subject to available funds.

317 (c) Pilot projects shall be designed to meet one or more
318 of this state's physician workforce needs, as determined
319 pursuant to this section, including, but not limited to:

320 1. Increasing the number of residencies or fellowships in
321 primary care or other needed specialties.

322 2. Enhancing the retention of primary care physicians or
323 other needed specialties in this state.

324 3. Promoting practice in rural or medically underserved
325 areas of the state.

326 4. Encouraging racial and ethnic diversity within the
327 state's physician workforce.

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328 5. Encouraging practice in community health care or other
329 ambulatory care settings.

330 6. Encouraging practice in clinics operated by the
331 department, including, but not limited to, county health
332 departments, clinics operated by the Department of Veterans'
333 Affairs, prison clinics, or similar settings of need.

334 7. Encouraging the increased production of geriatricians.

335 (d) Priority shall be given to a proposal for a pilot
336 project that:

337 1. Demonstrates a collaboration of federal, state, and
338 local entities that are public or private.

339 2. Obtains funding from multiple sources.

340 3. Focuses on enhancing graduate medical education in
341 rural or underserved areas.

342 4. Focuses on enhancing graduate medical education in
343 ambulatory or community-based settings other than a hospital
344 environment.

345 5. Includes the use of technology, such as electronic
346 medical records, distance consultation, and telemedicine, to
347 ensure that residents are better prepared to care for patients
348 in this state, regardless of the community in which the
349 residents practice.

350 6. Is designed to meet multiple policy needs as enumerated
351 in subsection (3).

352 7. Uses a consortium to provide for graduate medical
353 education experiences.

354 (e) The department shall adopt by rule appropriate
355 performance measures to use in order to consistently evaluate

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356 the effectiveness, safety, and quality of the programs, as well
357 as the impact of each program on meeting this state's physician
358 workforce needs.

359 (f) Participating pilot projects shall submit to the
360 department an annual report on the project in a manner required
361 by the department.

362 (g) Funding provided to a pilot project may be used only
363 for the direct costs of providing graduate medical education.
364 Accounting of such costs and expenditures shall be documented in
365 the annual report.

366 (h) State funds shall be used to supplement funds from any
367 local government, community, or private source. The state may
368 provide up to 50 percent of the funds, and local governmental
369 grants or community or private sources shall provide the
370 remainder of the funds.

371 (7) RULEMAKING.—The department shall adopt rules as
372 necessary to administer this section.

373 Section 23. Section 458.3192, Florida Statutes, is amended
374 to read:

375 458.3192 Analysis of survey results; report.—

376 (1) Each year, the Department of Health shall analyze the
377 results of the physician survey required by s. 458.3191 and
378 determine by geographic area and specialty the number of
379 physicians who:

380 (a) Perform deliveries of children in this state ~~Florida~~.

381 (b) Read mammograms and perform breast-imaging-guided
382 procedures in this state ~~Florida~~.

383 (c) Perform emergency care on an on-call basis for a

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384 hospital emergency department.

385 (d) Plan to reduce or increase emergency on-call hours in
386 a hospital emergency department.

387 (e) Plan to relocate ~~their allopathic or osteopathic~~
388 ~~practice~~ outside the state.

389 (f) Practice medicine in this state.

390 (g) Plan to reduce or modify the scope of their practice.

391 (2) The Department of Health must report its findings to
392 the Governor, the President of the Senate, and the Speaker of
393 the House of Representatives by November 1 each year. The
394 department shall also include in its report findings,
395 recommendations, and strategic planning activities as provided
396 in s. 381.4018. The department may also include other
397 information requested by the Physician Workforce Advisory
398 Council.

399 Section 24. Section 459.0082, Florida Statutes, is amended
400 to read:

401 459.0082 Analysis of survey results; report.—

402 (1) Each year, the Department of Health shall analyze the
403 results of the physician survey required by s. 459.0081 and
404 determine by geographic area and specialty the number of
405 physicians who:

406 (a) Perform deliveries of children in this state Florida.

407 (b) Read mammograms and perform breast-imaging-guided
408 procedures in this state Florida.

409 (c) Perform emergency care on an on-call basis for a
410 hospital emergency department.

411 (d) Plan to reduce or increase emergency on-call hours in

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412 a hospital emergency department.

413 (e) Plan to relocate ~~their allopathic or osteopathic~~
414 ~~practice~~ outside the state.

415 (f) Practice medicine in this state.

416 (g) Plan to reduce or modify the scope of their practice.

417 (2) The Department of Health must report its findings to
418 the Governor, the President of the Senate, and the Speaker of
419 the House of Representatives by November 1 each year. The
420 department shall also include in its report findings,
421 recommendations, and strategic planning activities as provided
422 in s. 381.4018. The department may also include other
423 information requested by the Physician Workforce Advisory
424 Council.

425 Section 25. Section 458.315, Florida Statutes, is amended
426 to read:

427 458.315 Temporary certificate for practice in areas of
428 critical need.—

429 (1) Any physician who:

430 (a) Is licensed to practice in any jurisdiction in the
431 United States and ~~other state,~~ whose license is currently valid;
432 or

433 (b) Has served as a physician in the United States Armed
434 Forces for at least 10 years and received an honorable discharge
435 from the military;

436

437 and who pays an application fee of \$300 may be issued a
438 temporary certificate for ~~to~~ practice in areas of ~~communities of~~
439 ~~Florida where there is a critical need for physicians.~~

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440 (2) A certificate may be issued to a physician who:
441 (a) Practices in an area of critical need;
442 (b) Will be employed by or practice in a county health
443 department, correctional facility, Department of Veterans'
444 Affairs clinic, community health center funded by s. 329, s.
445 330, or s. 340 of the United States Public Health Services Act,
446 or other agency or institution that is approved by the State
447 Surgeon General and provides health care to meet the needs of
448 underserved populations in this state; or

449 (c) Will practice for a limited time to address critical
450 physician-specialty, demographic, or geographic needs for this
451 state's physician workforce as determined by the State Surgeon
452 General entity that provides health care to indigents and that
453 is approved by the State Health Officer.

454 (3) The Board of Medicine may issue this temporary
455 certificate with the following restrictions:

456 (a)-(1) The State Surgeon General board shall determine the
457 areas of critical need, and the physician so certified may
458 practice in any of those areas for a time to be determined by
459 the board. Such areas shall include, but are not be limited to,
460 health professional shortage areas designated by the United
461 States Department of Health and Human Services.

462 1.(a) A recipient of a temporary certificate for practice
463 in areas of critical need may use the certificate license to
464 work for any approved entity employer in any area of critical
465 need or as authorized by the State Surgeon General approved by
466 the board.

467 2.(b) The recipient of a temporary certificate for

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468 practice in areas of critical need shall, within 30 days after
469 accepting employment, notify the board of all approved
470 institutions in which the licensee practices and of all approved
471 institutions where practice privileges have been denied.

472 (b)(2) The board may administer an abbreviated oral
473 examination to determine the physician's competency, but ~~a~~ a
474 written regular examination is not required ~~necessary~~. Within 60
475 days after receipt of an application for a temporary
476 certificate, the board shall review the application and issue
477 the temporary certificate, ~~or~~ or notify the applicant of denial, or
478 notify the applicant that the board recommends additional
479 assessment, training, education, or other requirements as a
480 condition of certification. If the applicant has not actively
481 practiced during the prior 3 years and the board determines that
482 the applicant may lack clinical competency, possess diminished
483 or inadequate skills, lack necessary medical knowledge, or
484 exhibit patterns of deficits in clinical decisionmaking, the
485 board may:

486 1. Deny the application;

487 2. Issue a temporary certificate having reasonable
488 restrictions that may include, but are not limited to, a
489 requirement for the applicant to practice under the supervision
490 of a physician approved by the board; or

491 3. Issue a temporary certificate upon receipt of
492 documentation confirming that the applicant has met any
493 reasonable conditions of the board which may include, but are
494 not limited to, completing continuing education or undergoing an
495 assessment of skills and training.

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496 ~~(c)(3)~~ Any certificate issued under this section ~~is shall~~
497 be valid only so long as the State Surgeon General determines
498 that the reason area for which it was is issued remains a an
499 area of critical need to the state. The Board of Medicine shall
500 review each temporary certificateholder not the service within
501 said area not less than annually to ascertain that the minimum
502 requirements of the Medical Practice Act and its adopted the
503 rules and regulations promulgated thereunder are being complied
504 with. If it is determined that such minimum requirements are not
505 being met, the board shall ~~forthwith~~ revoke such certificate or
506 shall impose restrictions or conditions, or both, as a condition
507 of continued practice under the certificate.

508 ~~(d)(4)~~ The board may shall not issue a temporary
509 certificate for practice in an area of critical need to any
510 physician who is under investigation in any jurisdiction in the
511 United States another state for an act that which would
512 constitute a violation of this chapter until such time as the
513 investigation is complete, at which time the provisions of s.
514 458.331 ~~shall~~ apply.

515 ~~(4)(5)~~ The application fee and all licensure fees,
516 including neurological injury compensation assessments, shall be
517 waived for those persons obtaining a temporary certificate to
518 practice in areas of critical need for the purpose of providing
519 volunteer, uncompensated care for low-income residents
520 Floridians. The applicant must submit an affidavit from the
521 employing agency or institution stating that the physician will
522 not receive any compensation for any service involving the
523 practice of medicine.

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524 Section 26. Section 459.0076, Florida Statutes, is created
525 to read:

526 459.0076 Temporary certificate for practice in areas of
527 critical need.—

528 (1) Any physician who:

529 (a) Is licensed to practice in any jurisdiction in the
530 United States and whose license is currently valid; or

531 (b) Has served as a physician in the United States Armed
532 Forces for at least 10 years and received an honorable discharge
533 from the military;

534
535 and who pays an application fee of \$300 may be issued a
536 temporary certificate for practice in areas of critical need.

537 (2) A certificate may be issued to a physician who:

538 (a) Will practice in an area of critical need;

539 (b) Will be employed by or practice in a county health
540 department, correctional facility, Department of Veterans'
541 Affairs clinic, community health center funded by s. 329, s.
542 330, or s. 340 of the United States Public Health Services Act,
543 or other agency or institution that is approved by the State
544 Surgeon General and provides health care to meet the needs of
545 underserved populations in this state; or

546 (c) Will practice for a limited time to address critical
547 physician-specialty, demographic, or geographic needs for this
548 state's physician workforce as determined by the State Surgeon
549 General.

550 (3) The Board of Osteopathic Medicine may issue this
551 temporary certificate with the following restrictions:

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552 (a) The State Surgeon General shall determine the areas of
553 critical need. Such areas include, but are not limited to,
554 health professional shortage areas designated by the United
555 States Department of Health and Human Services.

556 1. A recipient of a temporary certificate for practice in
557 areas of critical need may use the certificate to work for any
558 approved entity in any area of critical need or as authorized by
559 the State Surgeon General.

560 2. The recipient of a temporary certificate for practice in
561 areas of critical need shall, within 30 days after accepting
562 employment, notify the board of all approved institutions in
563 which the licensee practices and of all approved institutions
564 where practice privileges have been denied.

565 (b) The board may administer an abbreviated oral
566 examination to determine the physician's competency, but a
567 written regular examination is not required. Within 60 days
568 after receipt of an application for a temporary certificate, the
569 board shall review the application and issue the temporary
570 certificate, notify the applicant of denial, or notify the
571 applicant that the board recommends additional assessment,
572 training, education, or other requirements as a condition of
573 certification. If the applicant has not actively practiced
574 during the prior 3 years and the board determines that the
575 applicant may lack clinical competency, possess diminished or
576 inadequate skills, lack necessary medical knowledge, or exhibit
577 patterns of deficits in clinical decisionmaking, the board may:

578 1. Deny the application;

579 2. Issue a temporary certificate having reasonable

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580 restrictions that may include, but are not limited to, a
581 requirement for the applicant to practice under the supervision
582 of a physician approved by the board; or

583 3. Issue a temporary certificate upon receipt of
584 documentation confirming that the applicant has met any
585 reasonable conditions of the board which may include, but are
586 not limited to, completing continuing education or undergoing an
587 assessment of skills and training.

588 (c) Any certificate issued under this section is valid only
589 so long as the State Surgeon General determines that the reason
590 for which it was issued remains a critical need to the state.
591 The Board of Osteopathic Medicine shall review each temporary
592 certificateholder not less than annually to ascertain that the
593 minimum requirements of the Osteopathic Medical Practice Act and
594 its adopted rules are being complied with. If it is determined
595 that such minimum requirements are not being met, the board
596 shall revoke such certificate or shall impose restrictions or
597 conditions, or both, as a condition of continued practice under
598 the certificate.

599 (d) The board may not issue a temporary certificate for
600 practice in an area of critical need to any physician who is
601 under investigation in any jurisdiction in the United States for
602 an act that would constitute a violation of this chapter until
603 such time as the investigation is complete, at which time the
604 provisions of s. 459.015 apply.

605 (4) The application fee and all licensure fees, including
606 neurological injury compensation assessments, shall be waived
607 for those persons obtaining a temporary certificate to practice

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608 in areas of critical need for the purpose of providing
609 volunteer, uncompensated care for low-income residents. The
610 applicant must submit an affidavit from the employing agency or
611 institution stating that the physician will not receive any
612 compensation for any service involving the practice of medicine.
613
614

615 -----
616 **T I T L E A M E N D M E N T**

617 Remove line 109 and insert:

618 Association and appointed by the Governor; repealing s.
619 381.0403(4) and (9), F.S., relating to the program for graduate
620 medical education innovations and the graduate medical education
621 committee and report; amending s. 381.4018, F.S.; providing
622 definitions; requiring the Department of Health to coordinate
623 and enhance activities regarding the reentry of retired military
624 and other physicians into the physician workforce; revising the
625 list of governmental stakeholders that the Department of Health
626 is required to work with regarding the state strategic plan and
627 in assessing the state's physician workforce; creating the
628 Physician Workforce Advisory Council; providing membership of
629 the council; providing for appointments to the council;
630 providing terms of membership; providing for removal of a
631 council member; providing for the chair and vice chair of the
632 council; providing that council members are not entitled to
633 receive compensation or reimbursement for per diem or travel
634 expenses; providing the duties of the council; establishing the
635 physician workforce graduate medical education innovation pilot

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636 projects under the department; providing the purposes of the
637 pilot projects; providing for the appropriation of state funds
638 for the pilot projects; requiring the pilot projects to meet
639 certain policy needs of the physician workforce in this state;
640 providing criteria for prioritizing proposals for pilot
641 projects; requiring the department to adopt by rule appropriate
642 performance measures; requiring participating pilot projects to
643 submit an annual report to the department; requiring state funds
644 to be used to supplement funds from other sources; requiring the
645 department to adopt rules; amending ss. 458.3192 and 459.0082,
646 F.S.; requiring the department to determine by geographic area
647 and specialty the number of physicians and osteopathic
648 physicians who plan to relocate outside the state, practice
649 medicine in this state, and reduce or modify the scope of their
650 practice; authorizing the department to report additional
651 information in its findings to the Governor and the Legislature;
652 amending s. 458.315, F.S.; revising the standards for the Board
653 of Medicine to issue a temporary certificate to a certain
654 physicians to practice medicine in areas of critical need;
655 authorizing the State Surgeon General to designate areas of
656 critical need; creating s. 459.0076, F.S.; authorizing the Board
657 of Osteopathic Medicine to issue temporary certificates to
658 osteopathic physicians who meet certain requirements to practice
659 osteopathic medicine in areas of critical need; providing
660 restrictions for issuance of a temporary certificate;
661 authorizing the State Surgeon General to designate areas of
662 critical need; authorizing the Board of Osteopathic Medicine to

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663 | waive the application fee and licensure fees for obtaining
664 | temporary certificates for certain purposes; providing an