The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION Senator Garcia, Chair Senator Sobel, Vice Chair

MEETING DATE: Thursday, November 3, 2011

TIME: 10:30 a.m.—12:15 p.m.

PLACE: Pat Thomas Committee Room, 412 Knott Building

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Diaz de la Portilla, Fasano, Gaetz,

Jones, and Norman

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	SB 80 Joyner	Human Trafficking; Requiring operators of massage establishments to maintain valid work authorization documents on the premises for each employee who is not a United States citizen; requiring presentation of such documents upon request of a law enforcement officer; prohibiting the use of a massage establishment license for the purpose of lewdness, assignation, or prostitution; providing criminal penalties, etc. HR 11/03/2011 Favorable CJ BC	Favorable Yeas 5 Nays 0
2	SB 208 Joyner	Health Care Fraud; Revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; requiring a delinquent licensee whose license becomes delinquent before the final resolution of a case regarding Medicaid fraud to affirmatively apply by submitting a complete application for active or inactive status during the licensure cycle in which the case achieves final resolution by order of the court; providing that failure by a delinquent licensee to apply for an active or inactive license before the expiration of that licensure cycle renders the license null, etc. HR 11/03/2011 Fav/CS BC	Fav/CS Yeas 5 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Health Regulation
Thursday, November 3, 2011, 10:30 a.m.—12:15 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	SB 364 Gaetz (Identical H 475)	Blood Establishments; Prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; exempting certain blood establishments from the requirements to be permitted as a prescription drug manufacturer and register products; authorizing the Department of Health to adopt rules regarding the distribution of prescription drugs by blood establishments, etc. HR 11/03/2011 Fav/CS	Fav/CS Yeas 5 Nays 0
4	Consideration of proposed committee OGSRs, s. 458.3193 and 459.0083	ee bill: (Mandatory Review 2012-309 and 2012-310), , F.S.	
	SPB 7010	OGSR/Physician Workforce Surveys/Department of Health; Amending provisions relating to exemptions from public records requirements provided for personal identifying information contained in physician workforce surveys submitted to the Department of Health by physicians and osteopathic physicians; saving the exemptions from repeal under the Open Government Sunset Review Act; removing the scheduled repeal of each exemption, etc.	Submitted as Committee Bill
5	Presentation on HIV/AIDS: Prevaled White Program.	nce and Incidence Rates in Florida and the Florida Ryan	Presented
6	Other related meeting documents.		

S-036 (10/2008) Page 2 of 2

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepare	d By: The	Professional Sta	aff of the Health Re	gulation Commi	ttee
BILL:	SB 80					
INTRODUCER: Senator Joyner						
SUBJECT:	Human Traf	ficking				
DATE:	November 1	, 2011	REVISED:			
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION
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I. Summary:

This bill requires operators of massage establishments to maintain valid work authorization documents on the premises for employees who are not U.S. citizens and present these documents to a law enforcement officer upon request. The bill makes it unlawful for a massage establishment operator to knowingly use a massage establishment for the purpose of lewdness, assignation, or prostitution. Criminal penalties are established for a violation of any of the provisions set forth in the bill.

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

This bill creates s. 480.0535, F.S.

II. Present Situation:

Human Trafficking

Human trafficking is a form of modern-day slavery. Victims of human trafficking are young children, teenagers, men, and women. Victims are subjected to force, fraud, or coercion for the purpose of sexual exploitation or forced labor.¹

The International Labor Organization (ILO), the United Nations agency charged with addressing labor standards, employment, and social protection issues, estimates that there are at least

¹ U.S. Department of Health and Human Services, Administration for Children & Families, *About Human Trafficking*, available at http://www.acf.hhs.gov/trafficking/about/index.html# (Last visited on September 22, 2011).

12.3 million adults and children in forced labor, bonded labor, and commercial sexual servitude at any given time.² The federal government has estimated that the number of persons trafficked into the United States each year ranges from 14,500-17,500.³ Additionally, an estimated 200,000 American children are at risk for trafficking into the sex industry each year, according to the U.S. Department of Justice.⁴

After drug dealing, trafficking of humans is tied with arms dealing as the second largest criminal industry in the world and is also the fastest growing. Many victims of human trafficking are forced to work in prostitution or the sex entertainment industry. However, trafficking also occurs in forms of labor exploitation, such as domestic servitude, restaurant work, janitorial work, sweatshop factory work, and migrant agricultural work.⁵

Traffickers use various techniques to instill fear in victims and to keep them enslaved. Some traffickers keep their victims under lock and key. However, the more frequent practice is to use less obvious techniques including:

- Debt bondage financial obligations, honor-bound to satisfy debt.
- Isolation from the public limiting contact with outsiders and making sure that any contact is monitored or superficial in nature.
- Isolation from family members and members of victims' ethnic or religious community.
- Confiscation of passports, visas, or identification documents.
- Use or threat of violence toward victims or families of victims.
- The threat of shaming victims by exposing circumstances to family.
- Telling victims they will be imprisoned or deported for immigration violations if they contact authorities.
- Control of the victims' money and holding their money for "safe-keeping."

Federal Trafficking Law

In 2000, Congress enacted the Trafficking Victims Protection Act (TVPA) to "combat trafficking in persons, a contemporary manifestation of slavery whose victims are predominantly women and children, to ensure just and effective punishment of traffickers, and to protect their victims." The TVPA not only criminalizes human trafficking, but it also requires that victims, who might otherwise be treated as criminals (e.g. engagement in prostitution), be treated as victims of crime and be provided with health and human services if they cooperate with prosecutions.

The Trafficking Victims Protection Reauthorization Act of 2003 (TVPRA 2003), Pub. L. 108-193, reauthorized the TVPA and added responsibilities to the U.S. Government's anti-

² See U.S. Department of State, *The 2009 Trafficking in Persons (TIP) Report*, June 2009, available at http://www.state.gov/g/tip/rls/tiprpt/2009/ (Last visited on September 22, 2011).

³ Sonide Simon, *Human Trafficking and Florida Law Enforcement*, Florida Criminal Justice Executive Institute, pg. 2, March 2008, available at http://www.fdle.state.fl.us/Content/getdoc/e77c75b7-e66b-40cd-ad6e-c7f21953b67a/Human-Trafficking.aspx (Last visited on September 22, 2011).

⁴ *Id*. at 3.

⁵ Supra fn. 1.

⁶ *Id*.

⁷Trafficking Victims Protection Act of 2000, Pub. L. No. 106-386, (2000).

trafficking portfolio. In particular, the TVPRA 2003 mandated new information campaigns to combat sex tourism, added refinements to the federal criminal law provisions, and created a new civil action that allows victims to sue their traffickers in federal district court. In addition, the TVPRA 2003 required an annual report from the Attorney General to Congress.⁸

The Trafficking Victims Protection Reauthorization Act of 2005 (TVPRA 2005), Pub. L. 109-164, reauthorized the TVPA and authorized new anti-trafficking resources, including grant programs to assist state and local law enforcement efforts and expand victim assistance programs to U.S. citizens or resident aliens subjected to trafficking; authorized pilot programs to establish residential rehabilitative facilities for trafficking victims, including one program aimed at juveniles; and provided extraterritorial jurisdiction over trafficking offenses committed overseas by persons employed by or accompanying the federal government.⁹

The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA 2008), Pub. L. 110-457, reauthorized the TVPA for 4 years and authorized new measures to combat human trafficking. The TVPRA 2008:

- Created new crimes imposing severe penalties on those who obstruct or attempt to obstruct the investigations and prosecutions of trafficking crimes;
- Changed the standard of proof for the crime of sex trafficking by force, fraud, or coercion by requiring that the government merely prove that the defendant acted in reckless disregard of the fact that such means would be used;
- Broadened the reach of the crime of sex trafficking of minors by eliminating the requirement to show that the defendant knew that the person engaged in commercial sex was a minor in cases where the defendant had a reasonable opportunity to observe the minor;
- Expanded the crime of forced labor by providing that "force" is a means of violating the law; imposed criminal liability on those who, knowingly and with intent to defraud, recruit workers from outside the U.S. for employment within the U.S. by making materially false or fraudulent representations;
- Enhanced the penalty for conspiring to commit trafficking-related crimes; and
- Penalized those who knowingly benefit financially from participating in a venture that engaged in trafficking crimes. ¹⁰

Between Fiscal Years 2001-2009, the FBI's Civil Rights Division and U.S. Attorneys' Offices, under authority of the TVPA, prosecuted 645 defendants, secured 466 convictions and guilty pleas, and opened 1,187 new investigations.¹¹

Florida Statewide Task Force on Human Trafficking

The Florida Statewide Task Force on Human Trafficking was created in 2009¹² with the express purpose of examining the problem of human trafficking and recommending strategies and

⁸ Attorney General's Annual Report to Congress and Assessment of U.S. Government Activities to Combat Trafficking in Persons, pg. 2 (July 2010), available at http://www.justice.gov/ag/annualreports/tr2009/agreporthumantrafficking2009.pdf (Last visited on September 22, 2011).

⁹ *Id.* at 3

¹⁰ *Id*.

¹¹ *Id.* at 48.

¹² See ch. 2009-95, Laws of Florida.

actions for reducing or eliminating the unlawful trafficking of men, women, and children into Florida. The Florida State University Center for the Advancement of Human Rights (CAHR) was directed to submit a statewide strategic plan to the task force by November 1, 2009. The strategic plan was required to address the following five subjects:

- A description of available data on human trafficking in Florida;
- Identification of available victim programs and services;
- Evaluation of public awareness strategies;
- Assessment of current laws; and
- A list of recommendations produced in consultation with governmental and non-governmental organizations. ¹⁴

The CAHR's strategic plan is broken up into five goals or objectives to meet the five subjects required to be addressed by the CAHR under ch. 2009-95, Laws of Florida. In summary, the strategic plan provided the following:

- Labor trafficking is the most prevalent type of human trafficking in Florida, while domestic minor sex trafficking is also prevalent and is the most under-reported and under-prosecuted human trafficking offense in Florida.
- There is a need to have and maintain an up-to-date resource directory of all persons and organizations that assist victims of trafficking in Florida.
- Public awareness is at the heart of Florida being able to successfully assist victims of human trafficking statewide. Public awareness campaigns must have broad support, involve diverse activities, and have an accurate and concise message, while also being culturally sensitive.
- Although Florida has made progress in its human trafficking laws, more training is needed to carry out enforcement of such laws, and further reforms should be considered.
- There is a need for state government training and awareness of human trafficking so that government employees and contractors may learn how they might encounter human trafficking and how they should respond; Florida needs to provide effective and safe services for victims; and law enforcement needs more training for more effective responses and needs to develop and sustain partnerships within communities.¹⁵

The task force was required to propose a plan of implementation of the strategic plan by October 1, 2010. Published in July 2011, the Statewide Human Trafficking Task Force Implementation Report details the state's progress towards addressing each of the five goals addressed in the strategic plan. ¹⁶

• Goal one: Collect comprehensive data on victims and prosecutions of human trafficking. The report consolidates available data from the numerous federal and state entities which deal with such victims, including from medical screenings, the Florida Abuse Hotline, the Department of Health, and the National Human Trafficking Resource Center. Further efforts

¹⁵ *Id*.

¹³ Florida State University, Center for the Advancement of Human Rights, *Florida Strategic Plan on Human Trafficking*, available at http://www.dcf.state.fl.us/initiatives/humantrafficking/docs/FSUStrategicPlan2010.pdf (Last visited on September 22, 2011).

¹⁴ *Id*.

¹⁶ Florida Department of Children and Families, *Statewide Human Trafficking Task Force Implementation Report*, available at http://www.dcf.state.fl.us/initiatives/humantrafficking/docs/2011ImplementationPlan.pdf (Last visited on September 22, 2011).

are being made to amend federal and state crime reporting systems to capture trafficking cases.

- Goal two: Create and maintain a state resource guide of services to victims of trafficking. That guide has been developed and is available online.¹⁷
- Goal three: Develop strategies for public awareness and collaboration between entities active in combating human trafficking. The report reviews efforts that have been made to use existing materials available through the United States Department of Health and Human Services (HHS) awareness campaign and inter-agency efforts at the state and local level.
- Goal four: Enact changes to substantive law and provide sufficient funding to address trafficking in Florida. The Implementation Report identifies the number of laws that have already been enacted to combat trafficking and new provisions proposed during the 2011 Legislative Session.
- Goal five: Establish strong and effective social services, criminal justice systems and community responses. The report highlights agency activities and plans to implement goals related to training, awareness, collaboration, and services.

Human Trafficking in Florida

The exact number of persons trafficked in Florida is difficult to determine. Little data is available due to the reluctance of victims to report trafficking, the ease with which traffickers can move and operate, and until recently, little historical experience by law enforcement and prosecutors in cases of human trafficking. However, Florida is the third most popular American destination for human traffickers, with immigrants and non-English speaking persons especially vulnerable as victims. ^{18,19}

The CAHR has found that Asian massage parlors are often used to disguise sex trafficking. Women are trafficked in from Korea, Vietnam, Thailand or China using tourist visas. The women are then forced to work off their debt of being smuggled in, which is typically \$50,000 to \$100,000. Officials in Florida have discovered a very pronounced pattern of "moving targets" with some massage establishments operating a "taxi service," transporting women to other massage establishments throughout the country as often as every 7 to 14 days. Massage establishments engaged in trafficking will also often close and re-open frequently to avoid having to hold trafficked women in a single location.

Currently in Florida, all law enforcement recruits receive mandatory training in recognizing and investigating human trafficking cases. Also, the U.S. Justice Department currently operates

¹⁷ Florida State University, Center for the Advancement of Human Rights, *Resource Directory of Florida Organizations that Assist Human Trafficking Survivors*, available at http://www.cahr.fsu.edu/sub_category/resourcedirectory.pdf (Last visited on September 22, 2011).

¹⁸ Terry S. Coonan, *Human Rights in the Sunshine State: A proposed Florida Law on Human Trafficking*, 31 FLA. St. U. L. REV. 289 (Winter 2004).

¹⁹ *Supra* fn. 16.

²⁰ Email received from Terry Coonan, Executive Director of the FSU Center for the Advancement of Human Rights (CAHR), on February 1, 2011. A copy of the email is on file with the Senate Health Regulation Committee.

²¹ Terry Coonan, CAHR, *Rationale for the Proposed Revisions*. Document on file with the Senate Health Regulation Committee.

²² Supra fn. 20.

human trafficking task forces in Miami, Homestead, Naples, Fort Myers, and Tampa-Clearwater. ²³

Florida Laws on Human Trafficking, Sex Trafficking, and Prostitution

"Human trafficking" is defined under s. 787.06(2)(c), F.S., to mean transporting, soliciting, recruiting, harboring, providing, or obtaining another person for transport.

Section 787.06(3), F.S., provides that it is a second-degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S., (maximum imprisonment of 15 years, maximum fine of \$10,000, or penalties applicable for a habitual offender) for any person to knowingly:

- Engage, or attempt to engage, in human trafficking with the intent or knowledge that the trafficked person will be subjected to forced labor or services; or
- Benefit financially by receiving anything of value from participation in a venture that has subjected a person to forced labor or services.

"Sex trafficking" is regulated under ch. 796, F.S., relating to prostitution. Section 796.045, F.S., provides that any person who knowingly recruits, entices, harbors, transports, provides, or obtains by any means a person, knowing that force, fraud, or coercion will be used to cause that person to engage in prostitution, commits the offense of sex trafficking, a second-degree felony. A person commits a first-degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S., (maximum imprisonment of 30 years, maximum fine of \$10,000, or penalties applicable for a habitual offender) if the offense of sex trafficking is committed against a person who is under the age of 14 or if such offense results in death.

Section 796.07, F.S., makes it unlawful to, among other things, own, establish, maintain, or operate any place, structure, building, or conveyance for the purpose of lewdness, assignation, or prostitution. A person who commits this offense is guilty of:

- A misdemeanor of the second-degree for the first violation, punishable as provided in s. 775.082, F.S., or s. 775.083, F.S., (maximum imprisonment of 60 days or maximum fine of \$500);
- A misdemeanor of the first-degree for the second violation, punishable as provided in s. 775.082, F.S., or s. 775.083, F.S., (maximum imprisonment of 1 year or maximum fine of \$1,000); or
- A felony of the third degree for the third or subsequent violation, punishable as provided in s. 775.082, F.S., s. 775.083, F.S., or s. 775.084, F.S., (maximum imprisonment of 5 years, maximum fine of \$5,000, or penalties applicable for a habitual offender).

"Prostitution" is defined under s. 796.07, F.S., to mean the giving or receiving of the body for sexual activity for hire but excludes sexual activity between spouses. "Lewdness" means any indecent or obscene act, and "assignation" means the making of any appointment or engagement for prostitution or lewdness or any act in furtherance of such appointment or engagement.

²³ United States Department of Justice, *BJA/OVC Human Trafficking Task Forces*, available at http://www.ojp.usdoj.gov/BJA/grant/40HTTF.pdf (Last visited on October 25, 2011).

Florida Regulation of Massage Therapists and Massage Establishments

Massage therapists and massage establishments in Florida are regulated by the Board of Massage Therapy (the board) in the DOH under the Massage Practice Act, ch. 480, F.S., and Chapter 64B7, F.A.C. A person must be licensed as a massage therapist to practice massage for compensation, unless otherwise specifically exempted under the Massage Practice Act.²⁴ In order to be licensed as a massage therapist, an applicant must:

- Be at least 18 years old or have received a high school diploma or graduate equivalency diploma;
- Complete a course of study at a board-approved massage school or apprenticeship program; and
- Pass an examination, ²⁵ which is currently offered in English and in Spanish. ²⁶

Licensed massage therapists may practice in a licensed massage establishment, at a client's residence or office, or at a sports event, convention or trade show.²⁷ Sexual misconduct in the practice of massage therapy is defined as violation of the massage therapist-patient relationship through which the massage therapist attempts to seduce the patient or engage him or her in sexual activity outside the scope of generally accepted examination or treatment. Any sexual misconduct is strictly prohibited.²⁸

A person may be approved by the board to become an apprentice to study massage under the instruction of a licensed massage therapist if the person meets the qualifications stated in Rule 64B7-29.002, F.A.C. To qualify for an apprenticeship, the applicant must be sponsored by a licensed massage therapist, complete a DOH application, pay a \$100 fee, and must not be enrolled simultaneously as a student in a board-approved massage school.²⁹

Section 480.43, F.S., provides that a massage establishment license is required at any facility where massage therapy services are offered by a licensed massage therapist and directs the board to adopt application criteria. It also provides that massage establishment licenses may not be transferred to a new owner, but they may be transferred to a new location if the new location is inspected and approved by the board and an application and inspection fee is paid. A license may be transferred from one business name to another if approved by the board and if an application fee has been paid.

The board's rules include requirements concerning insurance, compliance with building codes, safety and sanitation, and the on-site presence of a licensed massage therapist any time a client is receiving massage services.³⁰ Upon receiving an application, the DOH inspects the establishment

²⁴ Section 480.047(1)(a), F.S. See also s. 480.033(4), F.S.

²⁵ Section 480.042, F.S.

²⁶ Rule 64B7-25.001(3), F.A.C.

²⁷ Section 480.046(1)(n), F.S.

²⁸ Section 480.0485, F.S. See also Rule 64B7-26.010, F.A.C.

²⁹ See rule 64B7-27.005, for the apprentice fee amount.

³⁰ Rule 64B7-26.003, F.A.C.

to ensure it meets the licensure requirements.³¹ Once licensed, the DOH inspects the establishment at least annually.³²

An application for a massage establishment license may be denied if an applicant has been convicted of crimes related to the practice of massage. Applications must be denied for convictions of enumerated crimes within 15 years of application³³ and for past sexual misconduct.³⁴

It is a misdemeanor of the first degree to operate an unlicensed massage establishment. Currently, upon receiving a complaint that unlicensed activity is occurring, the DOH's Medical Quality Assurance inspectors coordinate with local law enforcement. Unlicensed practice of massage therapy is punishable as a third-degree felony. The DOH may issue cease and desist notices, enforceable by filing for an injunction or writ of mandamus, and seek civil penalties against the unlicensed party in circuit court. The DOH may also impose, by citation, an administrative penalty up to \$5,000. While the DOH has investigative authority, it does not have arrest authority or sworn law enforcement personnel.

I-551 Permanent Residence Card, Employment Authorization Document

The U.S. Citizen and Immigration Service (USCIS) within the Department of Homeland Security (DHS) is the federal department responsible for granting lawful permanent residence.³⁸ A permanent resident is someone who has been granted authorization to live and work in the U.S. on a permanent basis. As proof of that status, a person is granted a Permanent Resident Card or Alien Registration Receipt Card. A Permanent Resident Card is officially called "Form I-551" and commonly called a "green card."³⁹

Individuals who are temporarily in the U.S. and eligible⁴⁰ for employment authorization may file a Form I-765, Application for Employment Authorization, to request an Employment Authorization Document (EAD).⁴¹ An EAD card, commonly called a "work permit," provides its holder the legal right to work in the U.S.

³¹ Rule 64B7-26.004, F.A.C.

³² Rule 64B7-26.005, F.A.C.

³³ Section 456.0635, F.S.

³⁴ Section 456.063, F.S.

³⁵ Section 480.047, F.S.

³⁶ Section 456.065, F.S.

³⁷ Id.

³⁸ U.S. Immigration Support, *USCIS*, available at http://www.usimmigrationsupport.org/uscis.html (Last visited on September 22, 2011).

³⁹ U.S. Immigration Support, *Form I-551 (Green Card)*, available at

http://www.usimmigrationsupport.org/form-i-551-greencard.html (Last visited on September 22, 2011).

Employment authorization eligibility is codified in Federal Regulations at 8 C.F.R. §274a.12, available at http://law.justia.com/us/cfr/title08/8-1.0.1.2.54.2.1.1.html (Last visited on September 22, 2011).

⁴¹ Ü.S. Citizen and Immigration Service, *I-765, Application for Employment Authorization*, available at http://www.uscis.gov/portal/site/uscis/menuitem.5af9bb95919f35e66f614176543f6d1a/?vgnextoid=73ddd59cb7a5d010Vgn VCM10000048f3d6a1RCRD&vgnextchannel=db029c7755cb9010VgnVCM10000045f3d6a1RCRD (Last visited on September 22, 2011).

III. Effect of Proposed Changes:

Section 1 creates s. 480.0535, F.S., to require a person who operates a massage establishment pursuant to s. 480.043, F.S., to maintain valid work authorization documents on the premises for *each* employee who is not a U.S. citizen and to present to a law enforcement officer, upon request, the work authorization documents for each employee who is not a U.S. citizen. Valid work authorization documents include:

- A valid I-551 permanent residence card; or
- A valid government-issued employment authorization document.

The bill prohibits a person operating a massage establishment from knowingly using a massage establishment licensed pursuant to s. 480.043, F.S., including any location, structure, trailer, conveyance or any other part thereof, for the purpose of lewdness, assignation, or prostitution.

The bill provides a cross-reference to s. 796.07, F.S., to define the terms lewdness, assignation, and prostitution.

A person who violates any provisions of the bill commits:

- A misdemeanor of the second degree for the first violation, punishable as provided in s. 775.082, F.S., or s. 775.083, F.S., (maximum imprisonment of 60 days or maximum fine of \$500);
- A misdemeanor of the first-degree for the second violation, punishable as provided in s. 775.082, F.S., or s. 775.083, F.S., (maximum imprisonment of 1 year or maximum fine of \$1,000); or
- A felony of the third-degree for the third or subsequent violation, punishable as provided in s. 775.082, F.S., s. 775.083, F.S., or s. 775.084, F.S., (maximum imprisonment of 5 years, maximum fine of \$5,000, or penalties applicable for a habitual offender).

Section 2 provides an effective date of October 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Operators or owners of massage establishments may incur nominal administrative costs to comply with the requirements set forth in the bill. The provisions of the bill might prevent or deter human trafficking in massage establishments.

C. Government Sector Impact:

Although the Criminal Justice Impact Conference has yet to consider this bill, during the 2011 session a similar bill (SB 246) was found to have an insignificant fiscal impact and an insignificant effect on the prison population.⁴² An updated report for this session has been requested.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill designates a new felony of the third degree for individuals who thrice violate the bill's prohibition on using a licensed massage establishment for purposes of lewdness, assignation, or prostitution. The bill does not list this new offense in the Offense Severity Ranking Chart under s. 921.0022, F.S.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

⁴² Office of Economic and Demographic Research, Criminal Justice Impact Conference report for the 2011 Legislative Session, available at http://edr.state.fl.us/content/conferences/criminaljusticeimpact/CJIC_11.xls (Last visited on September 22, 2011).

Florida Senate - 2012 SB 80

201280

By Senator Joyner

18-00037-12

A bill to be entitled An act relating to human trafficking; creating s. 480.0535, F.S.; requiring operators of massage establishments to maintain valid work authorization documents on the premises for each employee who is not a United States citizen; requiring presentation of such documents upon request of a law enforcement officer; prohibiting the use of a massage establishment license for the purpose of lewdness, 10 assignation, or prostitution; providing criminal 11 penalties; providing an effective date. 12 13 Be It Enacted by the Legislature of the State of Florida: 14 15 Section 1. Section 480.0535, Florida Statutes, is created 16 17 480.0535 Documents required while offering or providing 18 massage services.-19 (1) In order to provide law enforcement agencies the means 20 to more effectively identify, investigate, and arrest persons 21 engaging in human trafficking as defined in s. 787.06: 22 (a) A person operating a massage establishment pursuant to 23 s. 480.043 shall maintain, and it is unlawful to operate a 24 massage establishment without, a valid work authorization 25 document on the premises for each employee who is not a United 26 States citizen. Valid work authorization documents for an 27 employee who is not a United States citizen include: 28 1. A valid I-551 permanent resident card; or 29 2. A valid government-issued employment authorization

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 ${\tt CODING:}$ Words ${\tt stricken}$ are deletions; words ${\tt \underline{underlined}}$ are additions.

Florida Senate - 2012 SB 80

201280

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	10-00037-12
30	document.
31	(b) Upon request by a law enforcement officer, any person
32	operating a massage establishment must present one of the
33	documents specified in paragraph (a) for each employee who is
34	not a United States citizen.
35	(2) A person operating a massage establishment may not
36	knowingly use a license for operation of a massage establishment
37	issued under s. 480.043 for the purpose of lewdness,
38	assignation, or prostitution, as these terms are defined in s.
39	796.07, at any massage establishment location or structure, or
40	any part thereof, including any trailer or other conveyance.
41	(3) A person who violates any provision of this section
42	<pre>commits:</pre>
43	(a) A misdemeanor of the second degree for a first
44	violation, punishable as provided in s. 775.082 or s. 775.083.
45	(b) A misdemeanor of the first degree for a second
46	violation, punishable as provided in s. 775.082 or s. 775.083.
47	(c) A felony of the third degree for a third or subsequent
48	violation, punishable as provided in s. 775.082, s. 775.083, or
49	<u>s. 775.084.</u>
50	Section 2. This act shall take effect October 1, 2012.

Page 2 of 2

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



SENATOR ARTHENIA L. JOYNER

Democratic Leader Pro Tempore 18th District

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:Budget - Subcommittee on Criminal and Civil Justice Appropriations, Vice Chair Judiciary, Vice Chair Budget

Budget - Subcommittee on Higher Education Appropriations
Communications, Energy, and Public Utilities
Rules - Subcommittee on Ethics and Elections

Reapportionment Transportation

SELECT COMMITTEE:

Protecting Florida's Children, Vice Chair

JOINT COMMITTEE:

Legislative Auditing Committee

September 21, 2011

Senator Rene Garcia, Chairman Senate Committee on Health Regulation 530 Knott Building 404 S. Monroe Street Tallahassee, FL 32399-1100

Dear Mr. Chairman:

This is to request that Senate Bill 80, Human Trafficking, be placed on the agenda for the Committee on Health Regulation. Your consideration of this request is greatly appreciated.

Sincerely,

Arthenia L. Joyner

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State Senator, District 18

ALJ/rr



REPLY TO:

☐ 508 W Dr. Martin Luther King Jr. Blvd, Suite C, Tampa, Florida 33603-3415 (813) 233-4277

□ 202 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5059

Senate's Website: www.flsenate.gov

THE FLORIDA SENATE

APPEARANCE RECORD

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M	leeting D	ate (

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Topic Name ANCT MABRY Job Title	Bill Number (if applicable) Amendment Barcode (if applicable)
Address 2866 Bay Heather Circle Street Breeze F1 32563 City State Zip	Phone 850-501-2502 E-mail
Speaking: For Against Information Representing Florida STATE Mass	ase Assoc
Appearing at request of Chair: Yes No Lobbyist	t registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 11/3/2011 Meeting Date Bill Number (if applicable) Trafficking Topic Amendment Barcode (if applicable) **TRUSTEE BRIAN PITTS** Job Title Name 727-897-9291 1119 NEWTON AVENUE SOUTH Phone Address Street E-mail JUSTICE2JESUS@YAHOO.COM 33705 SAINT PETERSBURG FLORIDA ZipCity State Information Speaking: Against JUSTICE-2-JESUS Representing Appearing at request of Chair: No Yes For officially noticed committee meetings, pursuant to s. 11.061, Florida Statutes, state, state university, or community college employees are required to file the first copy of this form with the Lobbyist registered with Legislature: Committee, unless appearance has been requested by the Chair as a witness or for informational purposes. While it is a Senate tradition to encourage public testimony, time may not permit all If designated employee: persons wishing to speak to be heard at this meeting. Those who do speak may be Time: from asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (08/24/11)

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepare	ed By: The	Professional St	aff of the Health Re	gulation Comm	ittee	
BILL:	CS/SB 208						
INTRODUCER:	Health Regu	ılation Co	mmittee and S	Senator Joyner			
SUBJECT:	Health Care	e Fraud					
DATE:	November '	7, 2011	REVISED:				
ANAL Davlantes 2. 3. 4. 5.	LYST	Stovall	DIRECTOR	REFERENCE HR BC	Fav/CS	ACTION	
	Please A. COMMITTE B. AMENDMEN	E SUBSTI	TUTE X	for Addition Statement of Subs Technical amenda Amendments were Significant amend	stantial Chango nents were rec e recommende	es commended ed	

I. Summary:

The Committee Substitute (CS) amends current law relating to the licensure responsibility and authority of the Department of Health (DOH) over health professions and occupations. The CS also amends current law relating to the grounds for a board, or the DOH if there is no applicable board, to refuse to admit certain candidates seeking licensure to any examination and refuse to issue or renew a license, certificate, or registration to certain applicants.

The CS will result in a recurring increase in workload to the DOH to implement and in non-recurring costs for rulemaking. The CS will also result in a recurring increase in workload and costs to the Agency for Health Care Administration (AHCA) concerning data sharing infrastructure with the DOH. Costs are indeterminate.

This CS substantially amends ss. 456.036 and 456.0635, F.S.

II. Present Situation:

The Legislature created s. 456.0635, F.S., in 2009 with the enactment of CS/CS/CS/SB 1986, a comprehensive bill designed to address systemic health care fraud in Florida. That bill increased

the Medicaid program's authority to address fraud, particularly as it relates to home health services; increased health care facility and health care practitioner licensing standards to keep fraudulent actors from obtaining a health care license in Florida; and created disincentives to commit Medicaid fraud by increasing the administrative penalties for committing such fraud, posting sanctioned and terminated Medicaid providers on the AHCA website, and creating additional criminal felonies for committing health care fraud; among other anti-fraud provisions. ¹

Health Care Practitioner Licensure Authority of the Department of Health

The DOH is responsible for the licensure of most health care practitioners in the state. Chapter 456, F.S., provides general provisions for the regulation of health care professions in addition to the regulatory authority in specific practice acts for each profession or occupation. Section 456.001, F.S., defines "health care practitioner" as any person licensed under:

- Chapter 457 (acupuncture)
- Chapter 458 (medical practice)
- Chapter 459 (osteopathic medicine)
- Chapter 460 (chiropractic medicine)
- Chapter 461 (podiatric medicine)
- Chapter 462 (naturopathy)
- Chapter 463 (optometry)
- Chapter 464 (nursing)
- Chapter 465 (pharmacy)
- Chapter 466 (dentistry)
- Chapter 467 (midwifery)
- Part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468 (speech-language pathology and audiology; nursing home administration; occupational therapy; respiratory therapy; dietetics and nutrition practice; athletic trainers; and orthotics, prosthetics, and pedorthics)
- Chapter 478 (electrolysis)
- Chapter 480 (massage practice)
- Part III or part IV of chapter 483 (clinical laboratory personnel and medical physicists)
- Chapter 484 (dispensing of optical devices and hearing aids)
- Chapter 486 (physical therapy practice)
- Chapter 490 (psychological services)
- Chapter 491 (clinical, counseling, and psychotherapy services)

Current law² prohibits the DOH and the medical boards within the DOH from allowing any person to sit for an examination who has been:

• Convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under ch. 409, F.S., ch. 817, F.S., ch. 893, F.S., 21 U.S.C. ss. 801-970, or

³ ch. 409, F.S., "Social and Economic Assistance," is in Title XXX, "Social Welfare," and includes the Florida Medicaid and Kidcare programs, among other programs.

¹ See ch. 2009-223, Laws of Florida.

² See s. 456.0635, F.S.

⁴ ch. 817, F.S., "Fraudulent Practices," is in Title XLVI, "Crimes."

⁵ ch. 893, F.S., "Drug Abuse Prevention and Control," is in Title XLVI, "Crimes."

- 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or pleas ended more than 15 years prior to the date of the application;
- Terminated for cause from the Florida Medicaid program, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years; or
- Terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years prior to the date of application.

The DOH and the medical boards must refuse to issue or renew a license, certificate, or registration if an applicant or person affiliated with that applicant has violated any of the provisions listed above.

Implementation of Current Law by the Department of Health

Neither the DOH nor the boards deny licensure based on an applicant's termination for cause from the federal Medicare program because federal law does not implement such terminations "for cause." The DOH does not deny licensure renewal based on an applicant's termination for cause from the federal Medicare program for the same reason.

The DOH applies the denial of renewals to offenses occurring after July 1, 2009, when s. 456.0635, F.S., took effect.

III. Effect of Proposed Changes:

Section 1 amends s. 456.0635, F.S. The catch line is changed from "Medicaid fraud; disqualification for license, certificate, or registration," to "Health care fraud; disqualification for license, certificate, or registration." Other references in the statute to the general subject of "Medicaid fraud" are changed to "health care fraud." References to "candidate" vs. "candidate or applicant" are also standardized throughout the CS.

The CS separates the disqualifications for licensure, certification, or registration from those relating to licensure renewal into two different statutory subsections.

The CS requires a board or the DOH to refuse to admit a candidate to any examination and to refuse to issue a license to any applicant who has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under ch. 409, F.S., ch. 817, F.S., ch. 893, F.S., or similar felony offenses committed in another state or jurisdiction. The CS deletes the provision in current law that nullifies the prohibition if the sentence and probation period ended more than 15 years prior to the date of application, and replaces it with the following provisions:

• For felonies of the first or second degree, the prohibition expires when the sentence and probation period have ended more than 15 years before the date of application.

⁶ 21 U.S.C. ss. 801-970 create the Controlled Substances Act, which regulates the registration of manufacturers, distributors, and dispensers of controlled substances at the federal level.

⁷ 42 U.S.C. ss. 1395-1396 create the federal Medicare, Medicaid, and Children's Health Insurance programs.

• For felonies of the third degree, the prohibition expires when the sentence and probation period have ended more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a), F.S.⁸

• For felonies of the third degree under s. 893.13(6)(a), F.S., the prohibition expires when the sentence and probation period have ended more than 5 years before the date of application.

An applicant or candidate who has been convicted of or pled guilty or nolo contendere to any state felony listed above is eligible for initial licensure without any prohibition if he or she successfully completes a pretrial intervention or drug diversion program for that felony.

The CS moves into a new paragraph the requirement for a board or the DOH to refuse to admit a candidate to any examination and to refuse to issue a license to any applicant who has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396, unless the sentence and any probation period for such conviction or plea ended more than 15 years before the date of the application.

The CS deletes reference to "terminated for cause" from the federal Medicare program as grounds for which a board or the DOH is required to deny a license and creates a new standard to exclude applicants currently listed on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

The CS specifies that the prohibitions above relating to examination, licensure, certification, or registration do not apply to applicants for initial licensure or certification who were enrolled in a DOH- or board-recognized educational or training program on or before July 1, 2009, and who applied for licensure after July 1, 2012.

The CS creates a new statutory subsection relating to license *renewal* that requires a board or the DOH to deny renewal to applicants who, after July 1, 2009, have been convicted of or pled guilty or nolo contendere to the same felony offenses listed under the subsection on initial licensure. The same 5, 10, and 15-year prohibition periods apply concerning eligibility for relicensure after a felony as for initial licensure after a felony. Applicants who have been convicted of or pled guilty or nolo contendere to specified state felonies are eligible for license renewal without any prohibition period if they are currently enrolled in or have successfully completed a pretrial intervention or drug diversion program for that felony.

The CS also includes the same provisions for denying licensure renewal as those described above for initial examination, licensure, certification, and registration, relative to exclusion from the Medicare program and termination from Medicaid programs in Florida or in other states.

Section 2 amends s. 456.036, F.S. Any person who has been denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., may only regain licensure, certification, or registration by undergoing the procedure for initial licensure as defined by a

⁸ Section 893.13(6)(a), F.S. makes it unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice, or to be in actual or constructive possession of a controlled substance except as otherwise authorized by ch. 893, F.S.

board or the department. However, a person who was denied renewal between July 1, 2009 and June 30, 2012 is not required to retake any examinations which would otherwise be necessary for initial licensure.

Section 3 provides that the effective date of the bill is July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this CS have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the CS have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this CS have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill will affect the ability of certain applicants to become licensed or to renew a license and thereby affect their ability to qualify or remain qualified for gainful employment within certain occupations regulated by the DOH. The bill will apply the statutory licensure prohibitions to persons with felony convictions or pleas effective in other states the same as they are applied to persons with felony convictions or pleas effective in Florida. This will create more equity in the application of the law and should result in more mandatory denials among persons within that demographic. However, the bill also relaxes the standards in other ways, such as the "sliding scale" for the prohibition's duration based on the type of felony, which should result in fewer mandatory denials under those circumstances.

C. Government Sector Impact:

The DOH will experience a recurring increase in workload to implement the bill and non-recurring costs for rulemaking, the costs of which are indeterminate. Increased workload

will derive from the additional screening procedures that the DOH will conduct on applicants and re-applicants, including:

- Analyzing the laws of other states to determine which are similar to chs. 409, 817, or 893, F.S., and which applicants have violated such laws.
- Verifying that the applicants have not committed Medicaid fraud in other states or federal health care fraud.
- Determining whether enough time has passed between applicants' criminal convictions under chs. 409, 817, or 893, F.S., and their requests for licensure.

The AHCA will also experience a recurring increase in workload and costs to build and maintain an information sharing infrastructure with the department for the additional data which will be collected by the DOH under this bill. The exact fiscal impact is indeterminate.¹⁰

VI. Technical Deficiencies:

None.

VII. Related Issues:

Since s. 456.0635, F.S., was enacted, 21 U.S.C. Subchapter 13, the Controlled Substances Act, has been amended to include a s. 971, regarding notification, suspension of shipment, and penalties with respect to importation and exportation of certain chemicals. CS/SB 208 as currently written does not authorize initial or renewal license disqualification of health care professionals for violations of this section; only felonies under 21 U.S.C. ss. 801-970 may result in denial of licensure.

The CS contains no guidance or standards for determining what constitutes a "similar felony offense committed in another state or jurisdiction." Criminal statutes are different in every state. When licensure or renewal is denied based on a "similar" felony committed in another state or jurisdiction, the applicant may be encouraged to challenge the denial and argue that without specific standards within Florida law, the characteristics of the out-of-state felony cannot be justified by the DOH in keeping with legislative intent as being adequately "similar" to any certain offense within chs. 409, 817, or 893, F.S. However, a counterargument is that there are numerous statutes which require a determination whether an offense in another jurisdiction is similar to a Florida offense and which do not provide any guidance or standards for making that determination.¹¹

⁹ Department of Health, 2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 208. A copy of this analysis is on file with the Senate Health Regulation Committee.

¹⁰ Agency for Health Care Administration, 2012 Bill Analysis and Economic Impact Statement for SB 208. A copy of this analysis is on file with the Senate Health Regulation Committee.

¹¹ See e.g., ss. 39.0139, 311.12, 322.03, 373.6055, 393.0655, 408.809, 430.0402, 435.03, 435.04, 464.018, 468.3101, 744.474, 775.21, 943.0435, 948.30, 985.644, and 1012.467, F.S.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on November 3, 2011:

The CS clarifies that persons who have been convicted of or pled guilty or nolo contendere to certain state felonies are eligible for initial licensure, certification, or registration without a prohibition period if they successfully complete a pretrial intervention or drug diversion program for that felony. A similar provision concerning pretrial intervention or drug diversion programs has been clarified in the subsection of the CS concerning license renewals.

The CS alters the time frame for an exemption to the above provisions for students. Students who were enrolled in a department-approved training program before July 1, 2009 and who applied for initial licensure after July 1, 2012 are eligible regardless of the presence or timing of past state or federal felonies. Both of these dates were July 1, 2011 in SB 208.

The CS amends the effective dates relating to license renewals for applicants with felony convictions or plea of guilty or nolo contendere (both effective dates are changed to July 1, 2009). It also applies the tiered waiting periods described under the initial licensure provisions to renewals as well.

The CS replaces section 2 of SB 208 with a provision that any person who was denied license renewal under s.456.0635(3), F.S., may only regain his or her license by undergoing the initial licensure procedures defined by the relevant board or the department. The CS provides an exception for persons who were denied renewal between July 1, 2009 and June 30, 2012; these applicants are not required to retake any examinations normally needed for initial licensure.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.



LEGISLATIVE ACTION

Senate House

Comm: RCS 11/03/2011

The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 456.0635, Florida Statutes, is amended to read:

456.0635 Medicaid Health care fraud; disqualification for license, certificate, or registration.-

- (1) Medicaid Health care fraud in the practice of a health care profession is prohibited.
- (2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a

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candidate to any examination and refuse to issue or renew a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant, has been:

- (a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a pretrial intervention or drug diversion program for that felony. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or pleas plea ended more than 15 years prior to the date of the application;:
- 1. For felonies of the first or second degree, more than 15 years before the date of application.
- 2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).
- 3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.
- (b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of



the application;

(b)(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(c) (d) Has been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the candidate or applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years prior to before the date of the application-; or

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individual and Entities.

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> This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

- (3) The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:
- (a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under

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chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction since July 1, 2009, unless the applicant is currently enrolled in or has successfully completed a pretrial intervention or drug diversion program for that felony. Any such conviction or plea shall exclude the applicant from renewal of licensure, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

- 1. For felonies of the first or second degree, more than 15 years before the date of application.
- 2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).
- 3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.
- (b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.
- (c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.
- (d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5 years and

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the termination occurred at least 20 years before the date of the application.

- (e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.
- (3)(4) Licensed health care practitioners shall report allegations of Medicaid health care fraud to the department, regardless of the practice setting in which the alleged Medicaid health care fraud occurred.
- $\frac{(4)}{(5)}$ The acceptance by a licensing authority of a candidate's licensee's relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging Medicaid health care fraud or similar charges constitutes the permanent revocation of the license.
- Section 2. Subsections (14) and (15) of section 456.036, Florida Statutes, are renumbered as subsections (15) and (16), respectively, and subsection (14) is added to that section, to read:
 - 456.036 Licenses; active and inactive status; delinquency.-
- (14) A person who has been denied renewal of licensure, certification, or registration under s. 456.0635(3) may only regain licensure, certification, or registration by meeting the qualifications and completing the application process for initial licensure as defined by the board, or the department if there is no board. However, a person who was denied renewal of licensure, certification, or registration under s. 24 of ch. 2009-223, Laws of Florida, between July 1, 2009 and June 30, 2012, is not required to retake and pass examinations applicable



for initial licensure, certification, or registration. Section 3. This act shall take effect July 1, 2012.

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======= T I T L E A M E N D M E N T ========= And the title is amended as follows:

A bill to be entitled

Delete everything before the enacting clause and insert:

> An act relating to health care fraud; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care

practitioner; providing an exception; amending s. 456.036, F.S.; providing that all persons who were denied renewal of licensure, certification, or registration under s. 456.0635(3) may only regain licensure, certification, or registration by

completing the application process for initial licensure; providing an exception; providing an

150 effective date. Florida Senate - 2012 SB 208

By Senator Joyner

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18-00036B-12 2012208

A bill to be entitled An act relating to health care fraud; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and refuse to issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; amending s. 456.036, F.S.; requiring a delinguent licensee whose license becomes delinquent before the final resolution of a case regarding Medicaid fraud to affirmatively apply by submitting a complete application for active or inactive status during the licensure cycle in which the case achieves final resolution by order of the court; providing that failure by a delinguent licensee to apply for an active or inactive license before the expiration of that licensure cycle renders the license null; requiring that any subsequent licensure be as a result of applying for and meeting all requirements imposed on an applicant for new licensure; providing an effective date.

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

Section 1. Section 456.0635, Florida Statutes, is amended to read:

456.0635 Health care Medicaid fraud; disqualification for license, certificate, or registration .-

(1) Medicaid Fraud in the practice of a health care

Page 1 of 6

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

Florida Senate - 2012 SB 208

18-00036B-12 2012208 profession is prohibited. 31 (2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a 32 candidate to any examination and refuse to issue or renew a license, certificate, or registration to any applicant if the 34 35 candidate or applicant or any principal, officer, agent, 36 managing employee, or affiliated person of the applicant, has 37 been: 38 (a) Has been convicted of, or entered a plea of guilty or 39 nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony 41 offense committed in another state or jurisdiction 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any 42 43 subsequent period of probation for such conviction or plea pleas ended: more than 15 years prior to the date of the application; 45 1. For a felony of the first or second degree, more than 15 46 years before the date of application. 2. For a felony of the third degree, more than 10 years before the date of application, except for a felony of the third 48 49 degree under s. 893.13(6)(a). 50 3. For a felony of the third degree under s. 893.13(6)(a), more than 5 years before the date of application. 52 53 Notwithstanding s. 120.60, for a felony in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the board, or the department if there is no board, may 56 57 not approve or deny the application for a license, certificate,

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Page 2 of 6

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

or registration until the final resolution of the case;

Florida Senate - 2012 SB 208

18-00036B-12 2012208

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

 $\underline{\text{(c)}}$ Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(d) (e) Has been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years before prior to the date of the application; or-

 $\underline{\text{(e) Is currently listed on the United States Department of}}\\ \underline{\text{Health and Human Services Office of Inspector General's List of}}\\ \underline{\text{Excluded Individuals and Entities.}}$

This subsection does not apply to an applicant for initial licensure or certification who was enrolled in an educational or training program on or before July 1, 2011, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2011.

(3) The department shall refuse to renew a license, certificate, or registration of any applicant if the candidate or applicant or any principal, officer, agent, managing

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 ${\tt CODING:}$ Words ${\tt stricken}$ are deletions; words ${\tt \underline{underlined}}$ are additions.

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88	employee, or affiliated person of the applicant:
89	(a) Has been convicted of, or entered a plea of guilty or
90	nolo contendere to, regardless of adjudication, a felony under
91	chapter 409, chapter 817, or chapter 893, or a similar felony
92	offense committed in another state or jurisdiction since July 1,
93	<u>2010.</u>
94	(b) Has been convicted of, or entered a plea of guilty or
95	nolo contendere to, regardless of adjudication, a felony under
96	21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, since July 1,
97	<u>2011.</u>
98	(c) Has been terminated for cause from the Florida Medicaid
99	program pursuant to s. 409.913, unless the applicant has been in
L00	good standing with the Florida Medicaid program for the most
101	<pre>recent 5 years.</pre>
102	(d) Has been terminated for cause, pursuant to the appeals
103	procedures established by the state, from any other state
L04	$\underline{\text{Medicaid program, unless the applicant has been in good standing}}$
L05	with a state Medicaid program for the most recent 5 years and
106	the termination occurred at least 20 years before the date of
L07	the application.
L08	(e) Is currently listed on the United States Department of
L09	Health and Human Services Office of Inspector General's List of
L10	Excluded Individuals and Entities.
111	
112	For a felony in which the defendant entered a plea of guilty or
113	nolo contendere in an agreement with the court to enter a
114	pretrial intervention or drug diversion program, the department
115	may not approve or deny the application for a renewal of a
116	license, certificate, or registration until the final resolution

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of the case.

 $\underline{\text{(4)}}$ Licensed health care practitioners shall report allegations of <u>health care</u> <u>Medicaid</u> fraud to the department, regardless of the practice setting in which the alleged Medicaid fraud occurred.

(5)(4) The acceptance by a licensing authority of a candidate's relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care Medicaid fraud or similar charges constitutes the permanent revocation of the license.

Section 2. Subsection (6) of section 456.036, Florida Statutes, is amended to read:

456.036 Licenses; active and inactive status; delinquency.-

(6) (a) Except as provided in paragraph (b), a delinquent licensee must affirmatively apply with a complete application, as defined by rule of the board, or the department if there is no board, for active or inactive status during the licensure cycle in which a licensee becomes delinquent. Failure by a delinquent licensee to become active or inactive before the expiration of the current licensure cycle renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on an applicant for new licensure.

(b) A delinquent licensee whose license becomes delinquent before the final resolution of a case under s. 456.0635(3) must affirmatively apply by submitting a complete application, as defined by rule of the board, or the department if there is no board, for active or inactive status during the licensure cycle

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146	in which the case achieves final resolution by order of the
147	court. Failure by a delinquent licensee to apply for an active
148	or inactive license before the expiration of that licensure
149	cycle renders the license null without any further action by the
150	board or the department. Any subsequent licensure shall be as a
151	result of applying for and meeting all requirements imposed on
152	an applicant for new licensure.
153	Section 3. This act shall take effect July 1, 2012.

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SENATOR ARTHENIA L. JOYNER

Democratic Leader Pro Tempore 18th District

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES: Budget - Subcommittee on Criminal and Civil Justice Appropriations, Vice Chair Judiciary, Vice Chair Budget Budget - Subcommittee on Higher Education

Appropriations
Communications, Energy, and Public Utilities
Rules - Subcommittee on Ethics and Elections Reapportionment Transportation

SELECT COMMITTEE: Protecting Florida's Children, Vice Chair

JOINT COMMITTEE: Legislative Auditing Committee

September 21, 2011

Senator Rene Garcia, Chairman Senate Committee on Health Regulation 530 Knott Building 404 S. Monroe Street Tallahassee, FL 32399-1100

Dear Mr. Chairman:

This is to request that Senate Bill 208, Health Care Fraud, be placed on the agenda for the Committee on Health Regulation. Your consideration of this request is greatly appreciated.

Sincerely,

Arthenia L. Joyner

arthenia Lyon

State Senator, District 18

ALJ/rr



REPLY TO:

☐ 508 W Dr. Martin Luther King Jr. Blvd, Suite C, Tampa, Florida 33603-3415 (813) 233-4277

□ 202 Senate Office Building, 404 South Monroe Street, Tallahassee, Flonda 32399-1100 (850) 487-5059

Senate's Website: www.flsenate.gov

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

			208 Bill Number (if applicab	le)
Topic health care			Amendment Barcode (if applie	 cable)
Name BRIAN PITTS			Job TitleTRUSTEE	»«
Address1119 NEWTON AVENUE S	OUTH		Phone 727-897-9291	
Street SAINT PETERSBURG City	FLORIDA State	33705 Zip	E-mail_JUSTICE2JESUS@YAHOO.Co	<u> </u>
Speaking: For Against RepresentingJUSTICE-2-JES	✓ Information			
Appearing at request of Chair: Lobbyist registered with Legislature: While it is a Senate tradition to encourage public testimo persons wishing to speak to be heard at this meeting. The asked to limit their remarks so that as many persons as in	nose who do speak may be	Florida State employees Committee, as a witness If designat	y noticed committee meetings, pursuant to s. 11.0 tutes, state, state university, or community college are required to file the first copy of this form with to, unless appearance has been requested by the Cas or for informational purposes. ted employee: to	the
This form is part of the public record for this meeting.			S-001 (08/	 '24/11)

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepar	ed By: The	Professional Sta	aff of the Health Re	gulation Comm	nittee	
BILL:	CS/SB 364						
INTRODUCER:	Health Reg	ulation Co	ommittee and	Senator Gaetz			
SUBJECT:	Blood Esta	blishment	s				
DATE:	November	7, 2011	REVISED:				
ANAL . Steele	_YST	STAFF Stovall	DIRECTOR	REFERENCE HR	Fav/CS	ACTION	
·							
·							
	Please	see Se	ction VIII.	for Addition	al Informa	ation:	
	B. AMENDMENTS		Statement of Subs Technical amenda Amendments were Significant amend	nents were red e recommende	commended ed		

I. Summary:

This bill requires blood establishments to comply with certain business practices and disclose specified information on the Internet, exempts blood establishments from obtaining a manufacturing permit, and establishes a permit and process for blood establishments to distribute certain prescription drugs to facilitate the delivery of medical care involving blood and blood components.

There is a positive fiscal impact to community blood centers intending to engage in the wholesale distribution of certain prescription drugs in order to provide health care services typically provided by blood establishments. There is a minimal fiscal impact to the state of Florida from the proposed legislative changes. The proposed permitting cost is \$600 biennially, compared to the current annual cost of \$800.

This bill substantially amends the following sections of the Florida Statutes: 381.06014, 499.003, 499.005, and 499.01.

BILL: CS/SB 364 Page 2

II. Present Situation:

Regulatory Background

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 law requires a blood establishment operating within the state 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: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 derivatives,³ routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by the AHCA, unless otherwise exempt. As a part of this license, the facility is inspected at least every 2 years. The AHCA may accept surveys or inspections conducted by private accrediting organizations in lieu of conducting an inspection. The clinical laboratory personnel are required to maintain professional licensure by the Department of Health (DOH). Community blood centers must also

¹ Section 381.06014, F.S.

² A description of these classifications may be found at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm (Last visited on October 25, 2011).

³ Blood derivatives are classified as prescription drugs. *See* s. 499.003(43), F.S. and s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

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

⁵ Section 483.061(1), F.S.

⁶ Section 483.061(4), F.S.

have appropriate licenses issued by the DOH and comply with laws related to biomedical waste⁷ and radiation services.⁸

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). RBCs are prepared from whole blood by removing the plasma. They are given to surgery and trauma patients, and 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 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 apheresis ¹⁰ 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 7 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 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 5 days.

Community Blood Centers

Currently, there are four not-for-profit corporations¹¹ and one for-profit corporation¹² that operate community blood centers in Florida.¹³ Several hospital-owned blood centers operate in

⁷ See ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.

⁸ See ch. 64E-5, F.A.C., Control of Radiation Hazards. If a blood center irradiates blood products using radioactive materials, the location in which this occurs must be licensed. If a blood center irradiates blood products using a machine, then the community blood center must register the machine.

⁹ Blood component definitions from: AABB, *Whole Blood and Blood Components*, available at: http://www.aabb.org/resources/bct/bloodfacts/Pages/fabloodwhole.aspx (Last visited on October 25, 2011).

¹⁰ *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.

¹¹ The not-for-profit corporations include: LifeSouth Community Blood Centers, Suncoast Communities Blood Bank, The Blood Alliance and a new center with a name as of yet to be determined from the merger of Community Blood Centers of South Florida, Florida Blood Services, Florida's Blood Centers. A copy of the press release of the merger is available at http://www.tampabay.com/news/health/three-of-the-states-largest-blood-banks-vote-to-merge/1181899 (last visited on October 28, 2011).

Florida as well, primarily collecting blood or blood components to be used in each hospital's own facilities. At least one community blood center without a fixed location in Florida collects blood and blood components with a mobile blood-collection vehicle from volunteer donors, and distributes blood and blood components to health care providers in Florida.

The for-profit community blood center was notified of a policy that impairs its ability to engage in blood collection activities and compete with not-for-profit community blood centers. According to internal correspondence within the Miami Parking Authority dated October 13, 2009, "Meter rentals for blood mobile agencies will only be granted to non-profit companies conducting a blood drive ..."

14

Pricing

The cost of blood and blood components is primarily based on the cost of labor and required safety testing. In addition to screening, collecting, processing (separation), and testing, blood centers must 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.¹⁵

Generally, the median fees charged by community blood centers in Florida are at or near the lowest median fees nationally. As a part of The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, professional staff surveyed a small sample of for-profit and not-for-profit hospitals. Based on responses to the question of the average cost of a unit of specified blood components paid by the hospital over the last 12 months, it appeared that the for-profit hospitals and not-for-profit hospitals sampled were not paying an equivalent price for blood and blood components. 17

¹² The for-profit corporation is the United States Blood Bank (USBB).

¹³ However, on November 18, 2010, the Community Blood Centers of Florida, Florida's Blood Centers, and Florida Blood Services announced they had received approval from each of their Boards to pursue a merger. A copy of the press release and a video of the announcement are available at

 $http://www.floridasbloodcenters.org/news/news.stml?portalProcess_dd_0_1_1=showPublicPosting\&calendar_entry_id=744 \\ (Last visited on October 25, 2011).$

¹⁴ 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.

¹⁵ AABB, Blood FAQ: What fees are associated with blood?, available at

http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx#a11 (Last visited on October 25, 2011). *See also* 21 C.F.R. Part 606, available at

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=606&showFR=1&subpartNode=21:7.0.1. 1.3.6 (Last visited on October 25, 2011).

¹⁶ 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 October 25, 2011).

¹⁷ *Ibid*.

Licensure to Handle Prescription Drugs

Human blood and blood products are characterized as both "biologics," 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). Some community blood centers are licensed by the Department of Business and Professional Regulation (DBPR) 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.

The Florida Drug and Cosmetic Act (the Act), ²² as well as federal law, ²³ prohibits the sale, purchase, or trade (wholesale distribution) of a prescription drug that was purchased by a health care entity or donated or supplied at a reduced price to a charitable organization. A community blood center is a health care entity²⁴ and the not-for-profit community blood centers are charitable organizations. ²⁵ Some of the community blood centers in Florida, however, 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 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 these products. In the past, the DOH provided denial notices to blood establishments seeking a renewal of the prescription drug wholesaler permit. ²⁶ The Act

¹⁸ 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/usc_sec_42_00000262----000-.html (Last visited on October 25, 2011).

¹⁹ The FDA, Inspections, Compliance, Enforcement, and Criminal Investigations: CPG 230.120 – Human Blood and Blood Products as Drugs, available at:

http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm073863.htm (Last visited on October 25, 2011). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.

²⁰ Effective October 1, 2011, the regulatory authority over, ch. 499, F.S., The Florida Drug and Cosmetic Act was transferred to the DBPR from the DOH. *See* s. 27, ch. 2010-161, L.O.F.

²¹ Part I, ch. 499, F.S., related to Drugs, Devices, and Cosmetics.

²² Section 499.005(21), F.S.

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

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.

²⁵ See Internal Revenue Service, Exemption Requirements - Section 501(c)(3) Organizations, updated November 15, 2010, available at http://www.irs.gov/charities/charitable/article/0,,id=96099,00.html (Last visited on October 25, 2011).

²⁶ Information obtained by Florida Senate Health Regulation Committee staff via a telephone conference with representatives from the DOH on January 5, 2011.

and the licensure of community blood centers under the Act are at odds with providing critical health care services by community blood centers.²⁷

In November 2008, the FDA's rule to address this dilemma in federal law became effective. ²⁸ That rule provides for exceptions to authorize a registered blood establishment that qualifies as a health care entity to sell, purchase, or trade certain prescription drugs that would otherwise be prohibited. The DOH suggested to include in the Act the authorizations in the federal rule, but with more narrowly crafted language to limit the sale, purchase, or trade of these prescription drugs *to a health care entity* to avoid unintended consequences or the opportunity for community blood centers to compete in the marketplace as a prescription drug wholesaler.

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 (going forward from October 1, 2011, with the DBPR), notwithstanding the fact that blood establishments are considered manufacturers of prescription drugs under federal law. The distribution of prescription drugs manufactured by blood establishments is exempted from the definition of wholesale distribution under s. 499.003(54)(d), F.S. This situation applies to community blood centers, as well as other types of blood establishments (e.g. establishments collecting plasma from paid donors).

Restricted Prescription Drug Distributor Permit

The Act is found in part I of ch. 499, F.S. The DBPR is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics. ²⁹ The DBPR issues 20 types of permits to persons (defined to include business entities) who qualify to engage in activity regulated under the Act. A prescription drug must be held under a permit or license, until dispensed to a patient, at which point the practitioner's prescription represents the authority for the patient to possess the prescription drug. ³⁰

One of the permits issued by the DBPR under the Act is the Restricted Prescription Drug Distributor (RPDD) Permit.³¹ The biennial fee for the RPDD permit is \$600 and the permit is valid for 2 years, unless suspended or revoked.³²

A RPDD permit is required for any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution." The DBPR issues various RPDD

²⁷ 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.

²⁸ 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 October 25, 2011).

²⁹ Section 499.002, F.S.

³⁰Section 499.03(1), F.S.

³¹ Section 499.01(2)(g), F.S.

³² Chapter 64F-12.018, F.A.C., Fees.

³³ Under s. 499.003(54)(a), F.S., the sale, purchase, or trade of blood and blood components intended for transfusion are specifically excluded from the definition of wholesale distribution.

permits to eligible persons, including certain health care entities, for limited distributions of prescription drugs that are authorized under the Act.

Senate Interim Project Report 2010-119

During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation reviewed the regulation of blood banks (a.k.a. community blood centers). The following Legislative action was recommended: prohibit public agencies from restricting the access to, or use of, public facilities or infrastructure for the collection of blood and blood components based on the tax status of the community blood center; prohibit 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 at which it offers to sell or sells blood or blood components to the hospital or other health care facility; and address the statutory obstacle in Florida law concerning a community blood center distributing prescription drugs in a manner that is consistent with federally authorized distributions, with certain additional safeguards.

In the 2010 general legislative session, SB 1818 sought to implement the committee staff's recommendations as well as additional provisions to increase transparency in the activities of community blood centers and address other glitches in Florida law related to the permitting of blood establishments. The Florida Senate passed bills in the 2010 Legislative Session (SB 1818) and the 2011 Legislative Session (SB 94); however, neither bill passed the Legislature.

III. Effect of Proposed Changes:

Section 1 amends s. 381.06014, F.S., to redefine "blood establishment" to clarify that a person, entity, or organization that uses a mobile unit within the state and performs any of the activities under the definition of "blood establishment" is also a blood establishment. The term "volunteer donor" is created and defined as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under federal regulations.

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. Additionally, the bill prohibits a blood establishment from using as the sole factor whether a hospital or other health care entity is a for-profit or not-for-profit corporation when the blood establishment sets the service fee (price) at which it sells blood and blood components collected from voluntary donors to the hospital or other health care entity.

The bill requires a blood establishment that collects blood or blood components from volunteer donors to disclose information on its website concerning its activities. A hospital collecting blood or blood components from volunteer donors solely for use in its own licensed facilities is not required to disclose this information. The disclosures may be cumulative for all blood establishments (branches) within the business entity. The required disclosure includes:

 A description of the activities of the blood establishment related to collecting, processing, and distributing volunteer blood donations.

- The number of units that the blood establishment:
 - o Produced (such as units that passed quality control and are available for use),
 - Obtained from other sources,
 - Distributed to health care providers that are located outside the state. However, if the blood center collects donations in a county outside Florida and distributes to health care providers in that county, then the distributions made to that county must be excluded. This distribution information must be the aggregate of health care providers that are located within the United States and its territories or outside the United States and its territories, and
 - Distributed to entities that are not health care providers. This information must be the aggregate of purchasers that are located within the United States and its territories or outside the United States and its territories.

This information must be on the establishment's website by March 1 of each year reflecting data from the preceding calendar year;

- The blood establishment's policies pertaining to conflicts of interest, related-party transactions, whistle-blowers, and determining executive compensation. If any changes are made to any of these policies, the revised document must be on the blood establishment's website by the following March 1; and
- Either the most recent 3 years of a not-for-profit blood establishment's Form 990 that have been reported to the Internal Revenue Services, which must be posted within 60 calendar days after filing, or an audited or reviewed balance sheet, income statement, and statement of changes in cash flow, along with the expression of opinion on these statements from an independent certified public accountant, which must be posted within 120 days following the end of the fiscal year for a for-profit blood establishment and which must remain on the website for 36 months. However, hospitals that collect blood or blood components from volunteer donors are exempt from these financial disclosure requirements.

A blood establishment failing to make the required disclosures is liable for a civil penalty up to \$10,000 per year, which is to be enforced by the Department of Legal Affairs (Department). If multiple blood establishments, under the common control of one business entity, fail to meet the disclosure requirements, the civil penalty may only be assessed against one of the business entity's blood establishments. The Department may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. The Department is authorized to waive the civil penalty if the blood establishment shows good cause for the failure to disclose. All civil penalties collected must be deposited into the General Revenue Fund unallocated.

Section 2 amends s. 499.003, F.S., to revise the definition of a health care entity to authorize a blood establishment that collects blood or blood components from volunteer donors to be a health care entity and engage in the wholesale distribution of prescription drugs in accordance with the requirements contained in section 4 of the bill related to the restricted prescription drug distributor permit for a blood establishment.

Section 3 amends s. 499.005, F.S., to remove the prohibition against the wholesale distribution of prescription drugs by a blood establishment that collects blood or blood components from volunteer donors if the blood establishment is operating in compliance with the requirements contained in section 4 of the bill related to the restricted prescription drug distributor permit for a blood establishment.

This section comports with federal law. The federal regulation (21 C.F.R. § 203.20) uses the same language prohibiting sales by health care entities and charitable organizations as does section 3 of the bill (s. 499.005(21)). The federal regulation then provides exclusions in 21 C.F.R § 203.22, which includes an exclusion stating that the prohibition does not apply to registered blood establishments that qualify as a health care entity.

Section 4 amends s. 499.01, F.S., to exempt a blood establishment that only manufactures blood and blood components from the requirements to be permitted as a prescription drug manufacturer and register the products it manufactures.

The bill also requires certain blood establishments to obtain a permit as a restricted prescription drug distributor in order to lawfully sell and distribute prescription drugs to another health care entity. The bill provides for certain restrictions on this authorization, including:

- The permit may be issued only to a blood establishment that is located in Florida;
- The permit may be issued to a blood establishment that collects blood and blood components from volunteer donors only or pursuant to an authorized practitioner's order for medical treatment or therapy;
- The distributions may be made only to a health care entity that is licensed as a closed pharmacy or provides health care services at the location where the health care entity receives the prescription drugs;
- The prescription drugs that may be distributed pursuant to the restricted prescription drug distributor permit are limited to:
 - o 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;
 - A prescription drug that is essential to services performed or provided by blood establishments and is authorized for distribution by blood establishments under federal law if it is identified in rules adopted by the DBPR; or
 - To the extent it is permitted by federal law, a drug necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures; and to diagnose, treat, manage and prevent any reaction of either a volunteer blood donor or a patient undergoing therapeutic procedures; and
- The blood establishment may only provide health care services that:
 - o Are related to its activities as an FDA-registered blood establishment;
 - Consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells; or
 - Consist of performing diagnostic testing of specimens if these specimens are tested together with specimens undergoing routine donor testing.

In addition, the bill provides that a blood establishment permitted as a restricted prescription drug distributor must comply with all the storage, handling, and recordkeeping requirements with

which a prescription drug wholesale distributor must comply. This includes providing pedigree papers³⁴ upon the wholesale distribution of these prescription drugs.

The DBPR is authorized to adopt rules related to the distribution of prescription drugs by blood establishments.

Section 5 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

Instead of paying \$800 annually for a prescription drug wholesale distributor permit and a \$150 fee for certification of a designated representative, a community blood center that intends to engage in the wholesale distribution of certain prescription drugs in order to provide health care services typically provided by blood establishments will pay a \$600 fee biennially for a restricted prescription drug distributor permit.³⁵

B. Private Sector Impact:

Blood establishments that collect donations of blood and blood components from volunteer donors will need to ensure that pricing considerations for the sale of blood and blood components are not based solely on whether the customer is a for-profit corporation or not-for-profit corporation.

A blood establishment that collects donations of blood and blood components from volunteer donors, except certain hospitals, will be required to post certain information concerning its activities on its Internet website.

³⁴ A pedigree paper contains information required by s. 499.01212, F.S., regarding the sale and distribution of a prescription drug.

³⁵ See ch. <u>64F-12.018</u>, F.A.C., Fees.

A blood establishment that chooses to engage in the wholesale distribution of certain prescription drugs may lawfully do so if it is permitted as a restricted prescription drug distributor and complies with the requirements of that permit.

C. Government Sector Impact:

Governmental agencies may not limit the use of public infrastructure for the purpose of collecting voluntary donations of blood or blood components solely upon whether the corporation collecting the blood is for-profit or not-for-profit.

The DBPR will incur costs to adopt rules for the permitting of a blood establishment as a restricted prescription drug distributor and other activities of blood establishments that are regulated under the Act. Revenues may be reduced as a result of the reduced permitting fees, but the impact will be minimal.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation Committee on November 3, 2011:

The title was revised to substitute the Department of Business and Professional Regulation for the Department of Health to reflect the current department with regulatory responsibility for the Act.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.



LEGISLATIVE ACTION

Senate House

Comm: RCS 11/03/2011

The Committee on Health Regulation (Gaetz) recommended the following:

Senate Amendment

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In title, delete lines 39 - 40 and insert:

> distributor permit; authorizing the Department of Business and Professional Regulation to adopt rules regarding the distribution of

By Senator Gaetz

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4-00048-12 2012364

A bill to be entitled An act relating to blood establishments; amending s. 381.06014, F.S.; redefining the term "blood establishment" and defining the term "volunteer donor"; prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; authorizing the Department of Legal Affairs to assess a civil penalty against a blood establishment that fails to disclose specified information on the Internet; providing that the civil penalty accrues to the state and requiring that it be deposited as received into the General Revenue Fund; amending s. 499.003, F.S.; redefining the term "health care entity" to clarify that a blood establishment is a health care entity that may engage in certain activities; amending s. 499.005, F.S.; clarifying provisions that prohibit the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity or donated or supplied at a reduced price to a charitable

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Florida Senate - 2012 SB 364

	4-00048-12 2012364
30	organization, to conform to changes made by the act;
31	amending s. 499.01, F.S.; exempting certain blood
32	establishments from the requirements to be permitted
33	as a prescription drug manufacturer and register
34	products; requiring that certain blood establishments
35	obtain a restricted prescription drug distributor
36	permit under specified conditions; limiting the
37	prescription drugs that a blood establishment may
38	distribute under a restricted prescription drug
39	distributor permit; authorizing the Department of
40	Health to adopt rules regarding the distribution of
41	prescription drugs by blood establishments; providing
42	an effective date.
43	
44	Be It Enacted by the Legislature of the State of Florida:
45	
46	Section 1. Section 381.06014, Florida Statutes, is amended
47	to read:
48	381.06014 Blood establishments.—
49	(1) As used in this section, the term:
50	(a) "Blood establishment" means any person, entity, or
51	organization, operating within the state, which examines an
52	individual for the purpose of blood donation or which collects,
53	processes, stores, tests, or distributes blood or blood
54	components collected from the human body for the purpose of
55	transfusion, for any other medical purpose, or for the
56	production of any biological product. A person, entity, or
57	organization that uses a mobile unit to conduct such activities
58	within the state is also a blood establishment.

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(b) "Volunteer donor" means a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under 21 C.F.R. s. 606.121.

8.3

- (2) Any blood establishment operating in the state may not conduct any activity defined in paragraph (1)(a) subsection (1) unless that blood establishment is operated in a manner consistent with the provisions of $\overline{\text{Title}}$ 21 $\underline{\text{C.F.R.}}$ parts 211 and 600-640, Code of Federal Regulations.
- (3) Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of Title 21 C.F.R. parts 211 and $600\text{-}640_{7}$ Code of Federal Regulations, and in a manner that constitutes a danger to the health or well-being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection reports and the revocation of the blood establishment's license or registration is shall be in violation of this chapter and must shall immediately cease all operations in the state.
- (4) The operation of a blood establishment in a manner not consistent with the provisions of Title 21 C.F.R. parts 211 and 600-640, Code of Federal Regulations, and in a manner that constitutes a danger to the health or well-being of blood donors or recipients as evidenced by the federal Food and Drug Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the blood establishment.

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

- (6) In determining the service fee of blood or blood components received from volunteer donors and sold to hospitals or other health care providers, a blood establishment may not base the service fee of the blood or blood component solely on whether the purchasing entity is a for-profit organization or not-for-profit organization.
- (7) A blood establishment that collects blood or blood components from volunteer donors must disclose on the Internet the information required under this subsection to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components to be used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's business entity is exempt from the disclosure requirements in this subsection. The information required to be disclosed under this subsection may be cumulative for all blood establishments within a business entity. A blood establishment must disclose on its website all of the following information:
- (a) A description of the steps involved in collecting, processing, and distributing volunteer donations.
- (b) By March 1 of each year, the number of units of blood components which were:
- Produced by the blood establishment during the preceding calendar year;

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2. Obtained from other sources during the preceding calendar year;

- 3. Distributed during the preceding calendar year to health care providers located outside this state. However, if the blood establishment collects donations in a county outside this state, distributions to health care providers in that county shall be excluded. Such information shall be reported in the aggregate for health care providers located within the United States and its territories or outside the United States and its territories; and
- 4. Distributed during the preceding calendar year to entities that are not health care providers. Such information shall be reported in the aggregate for purchasers located within the United States and its territories or outside the United States and its territories.
- (c) The blood establishment's conflict-of-interest policy, policy concerning related-party transactions, whistleblower policy, and policy for determining executive compensation. If a change occurs to any of these documents, the revised document must be available on the blood establishment's website by the following March 1.
- (d) Except for a hospital that collects blood or blood components from volunteer donors:
- 1. The most recent 3 years of the Return of Organization Exempt from Income Tax, Internal Revenue Service Form 990, if the business entity for the blood establishment is eligible to file such return. The Form 990 must be available on the blood establishment's website within 60 calendar days after it is filed with the Internal Revenue Service; or

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146	2. If the business entity for the blood establishment is
147	not eligible to file the Form 990 return, a balance sheet,
148	income statement, and statement of changes in cash flow, along
149	with the expression of an opinion thereon by an independent
150	certified public accountant who audited or reviewed such
151	financial statements. Such documents must be available on the
152	blood establishment's website within 120 days after the end of
153	the blood establishment's fiscal year and must remain on the
154	blood establishment's website for at least 36 months.
155	(8) A blood establishment is liable for a civil penalty for
156	failing to make the disclosures required under subsection (7).
157	The Department of Legal Affairs may assess the civil penalty
158	against the blood establishment for each day that it fails to
159	make such required disclosures, but the penalty may not exceed
160	\$10,000 per year. If multiple blood establishments operated by a
161	single business entity fail to meet such disclosure
162	requirements, the civil penalty may be assessed against only one
163	of the business entity's blood establishments. The Department of
164	Legal Affairs may terminate an action if the blood establishment
165	agrees to pay a stipulated civil penalty. A civil penalty so
166	collected accrues to the state and shall be deposited as
167	received into the General Revenue Fund unallocated. The
168	Department of Legal Affairs may terminate the action and waive
169	the civil penalty upon a showing of good cause by the blood
170	establishment as to why the required disclosures were not made.
171	Section 2. Subsection (23) of section 499.003, Florida
172	Statutes, is amended to read:
173	499.003 Definitions of terms used in this part.—As used in
174	this part, the term:

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(23) "Health care entity" means 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. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 3. Subsection (21) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

- (21) The wholesale distribution of any prescription drug that was:
- (a) Purchased by a public or private hospital or other health care entity; or
- (b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

Section 4. Paragraphs (a) and (g) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.-

- (2) The following permits are established:
- (a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a

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Florida Senate - 2012 SB 364

4-00048-12 $$2012364_$$ manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

2.07

- 1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which that apply to a wholesale distributor.
- 2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.
- 3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.
 - (g) Restricted prescription drug distributor permit.-
- $\underline{\textbf{1.}}$ A restricted prescription drug distributor permit is required for:
- <u>a.</u> Any person <u>located in this state who</u> that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

<u>b.1-</u> Any A person <u>located in this state</u> who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction $\frac{must}{must}$ obtain a permit as a restricted prescription drug distributor if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating

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233	the return, or the manufacturer of the drug.
234	c. A blood establishment located in this state which
235	collects blood and blood components only from volunteer donors
236	as defined in s. 381.06014 or pursuant to an authorized
237	practitioner's order for medical treatment or therapy and
238	engages in the wholesale distribution of a prescription drug not
239	described in s. 499.003(54)(d) to a health care entity. The
240	health care entity receiving a prescription drug distributed
241	under this sub-subparagraph must be licensed as a closed
242	pharmacy or provide health care services at that establishment.
243	The blood establishment must operate in accordance with s.
244	381.06014 and may distribute only:
245	(I) Prescription drugs indicated for a bleeding or clotting
246	disorder or anemia;
247	(II) Blood-collection containers approved under s. 505 of
248	the federal act;
249	(III) Drugs that are blood derivatives, or a recombinant or
250	synthetic form of a blood derivative;
251	(IV) Prescription drugs that are identified in rules
252	adopted by the department and that are essential to services
253	performed or provided by blood establishments and authorized for
254	distribution by blood establishments under federal law; or
255	(V) To the extent authorized by federal law, drugs
256	necessary to collect blood or blood components from volunteer
257	blood donors; for blood establishment personnel to perform
258	therapeutic procedures under the direction and supervision of a
259	licensed physician; and to diagnose, treat, manage, and prevent
260	any reaction of a volunteer blood donor or a patient undergoing
261	a therapeutic procedure performed under the direction and

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262	supervision of a licensed physician,
263	
264	as long as all of the health care services provided by the blood
265	establishment are related to its activities as a registered
266	blood establishment or the health care services consist of
267	collecting, processing, storing, or administering human
268	hematopoietic stem cells or progenitor cells or performing
269	diagnostic testing of specimens if such specimens are tested
270	together with specimens undergoing routine donor testing.
271	2. Storage, handling, and recordkeeping of these
272	distributions by a person required to be permitted as a
273	$\underline{\text{restricted prescription drug distributor}} \ \text{must} \ \underline{\text{be in accordance}}$
274	$\ensuremath{\operatorname{\textsc{comply}}}$ with the requirements for wholesale distributors under s.
275	499.0121, but not those set forth in s. 499.01212 $\underline{\text{if the}}$
276	distribution occurs pursuant to sub-subparagraph 1.a. or sub-
277	subparagraph 1.b.
278	3. A person who applies for a permit as a restricted
279	prescription drug distributor, or for the renewal of such a
280	permit, must provide to the department the information required
281	under s. 499.012.
282	4. The department may adopt rules regarding the
283	distribution of prescription drugs by hospitals, health care
284	entities, charitable organizations, or other persons not
285	involved in wholesale distribution, and blood establishments,
286	which rules are necessary for the protection of the public
287	health, safety, and welfare.
288	Section 5. This act shall take effect July 1, 2012.

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Tallahassee, Florida 32399-1100

COMMITTEES:
Reapportionment, Chair
Banking and Insurance
Budget
Budget - Subcommittee on Health and Human Services

Appropriations
Budget - Subcommittee on Transportation, Tourism, and Economic Development Appropriations

Health Regulation

Rules - Subcommittee on Ethics and Elections

JOINT COMMITTEE: Legislative Budget Commission

October 19, 2011

The Honorable Rene Garcia, Chair Committee on Health Regulation 310 Senate Office Building 404 South Monroe Street Tallahassee, Fl 34450

Dear Senator Garcia;

SENATOR DON GAETZ

4th District

I respectfully request that you place Senate Bill 364, relating to Blood Establishments, on your Health Regulation committee agenda as soon as conveniently possible.

Please do not hesitate to contact me if you have any questions.

Respectfully,

Senator Don Gaetz District 4 JEHETNE &

CC: Sandra R. Stovall, Staff Director Celia Georgiades,

REPLY TO:

☐ 4300 Legendary Drive, Suite 230, Destin, Florida 32541 (850) 897-5747

☐ 420 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5009

Senate's Website: www.flsenate.gov

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date				Bill Number (if applicable)
Topic <u>Blood</u>		, M., J., J		Amendment Barcode (if applicable)
NameBRIAN PITTS			Job Title_	TRUSTEE
Address1119 NEWTON AVENUE S	OUTH		Phone	727-897-9291
Street SAINT PETERSBURG City Speaking: For Against Representing JUSTICE-2-JES	FLORIDA State Information US	33705 Zip	E-mail_ <u>JU</u>	STICE2JESUS@YAHOO.COM
Appearing at request of Chair: Lobbyist registered with Legislature: While it is a Senate tradition to encourage public testimo persons wishing to speak to be heard at this meeting. To asked to limit their remarks so that as many persons as	hose who do speak may be	Florida Statu employees a Committee, u as a witness	tes, state, state ι re required to file	ee meetings, pursuant to s. 11.061, university, or community college the first copy of this form with the ce has been requested by the Chair nal purposes.

This form is part of the public record for this meeting.

S-001 (08/24/11)

Committee on Health Regulation

OPEN GOVERNMENT SUNSET REVIEW OF SECTION 458.3193, F.S., PHYSICIAN **WORKFORCE SURVEYS**

Issue Description

Each Florida-licensed allopathic physician is required to furnish specified information to the Department of Health (DOH) in a physician workforce survey in conjunction with the renewal of his or her medical license. Section 458.3193, F.S., creates an exemption from the requirements of the Public Records Law to make all personal identifying information contained in records provided by physicians in response to the physician workforce survey that is held by the DOH confidential and exempt from s. 119.07(1), F.S., and Article I, s. 24 of the State Constitution. This exemption will be repealed on October 2, 2012, unless it is reviewed under the Open Government Sunset Review Act and saved from repeal through reenactment by the Legislature.

Background

Public Records and Meetings

The State of Florida has a long history of providing public access to governmental records. The Florida Legislature enacted the first public records law in 1892. One hundred years later, Floridians adopted an amendment to the State Constitution that raised the statutory right of access to public records to a constitutional level.² Article I, s. 24 of the State Constitution, provides that:

(a) Every person has the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

In addition to the State Constitution, the Public Records Act,³ which pre-dates the current State Constitution, specifies conditions under which public access must be provided to records of the executive branch and other agencies. Section 119.07(1)(a), F.S., states:

Every person who has custody of a public record shall permit the record to be inspected and copied by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records.

Unless specifically exempted, all agency⁴ records are available for public inspection. The term "public record" is broadly defined to mean:

Section 1390, 1391 Florida Statutes. (Rev. 1892).

² Article I, s. 24 of the State Constitution.

³ Chapter 119, F.S.

⁴ The word "agency" is defined in s. 119.011(2), F.S., to mean "... any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."

. . .all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.⁵

The Florida Supreme Court has interpreted this definition to encompass all materials made or received by an agency in connection with official business, which are used to perpetuate, communicate, or formalize knowledge. All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.

Article I, s. 24 of the State Constitution also provides that all meetings of any collegial public body of the executive branch of state government or of any collegial public body of a county, municipality, school district, or special district, at which official acts are to be taken or at which public business of such body is to be transacted or discussed, shall be open and noticed to the public and meetings of the Legislature shall be open and noticed as provided in Article III, Section 4(e), except with respect to meetings exempted pursuant to this section or specifically closed by this Constitution. In addition, the Sunshine Law, s. 286.011, F.S., provides that all meetings of any board or commission of any state agency or authority or of any agency or authority of any county, municipal corporation, or political subdivision, except as otherwise provided in the Constitution, at which official acts are to be taken are declared to be public meetings open to the public at all times, and no resolution, rule, or formal action shall be considered binding except as taken or made at such meeting.

Only the Legislature is authorized to create exemptions to open government requirements. An exemption must be created in general law, must state the public necessity justifying it, and must not be broader than necessary to meet that public necessity. A bill enacting an exemption any not contain other substantive provisions, although it may contain multiple exemptions that relate to one subject. 11

There is a difference between records that the Legislature has made exempt from public inspection and those that are *confidential* and exempt. If the Legislature makes a record confidential and exempt, such information may not be released by an agency to anyone other than to the persons or entities designated in the statute. ¹² If a record is simply made exempt from disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances. ¹³

The Open Government Sunset Review Act (the Act)¹⁴ provides for the systematic review, through a 5-year cycle ending October 2 of the 5th year following enactment, of an exemption from the Public Records Act or the Sunshine Law. Each year, by June 1, the Division of Statutory Revision of the Office of Legislative Services is required to certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of each exemption scheduled for repeal the following year.

The Act states that an exemption may be created, revised, or maintained only if it serves an identifiable public purpose and if the exemption is no broader than is necessary to meet the public purpose it serves. An identifiable public purpose is served if the exemption meets one of three specified criteria and if the Legislature finds that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption. The three statutory criteria are that the exemption:

⁵ s. 119.011(12), F.S.

⁶ Shevin v. Byron, Harless, Schaffer, Reid and Associates, Inc., 379 So.2d 633, 640 (Fla. 1980).

⁷ Wait v. Florida Power & Light Company, 372 So.2d 420 (Fla. 1979).

⁸ Art. I, s. 24(c) of the State Constitution.

⁹ Memorial Hospital-West Volusia v. News-Journal Corporation, 729 So. 2d 373, 380 (Fla. 1999); Halifax Hospital Medical Center v. News-Journal Corporation, 724 So.2d 567 (Fla. 1999).

¹⁰ Under s. 119.15, F.S., an existing exemption may be considered a new exemption if the exemption is expanded to cover additional records.

¹¹ Art. I, s. 24(c) of the State Constitution.

¹² Attorney General Opinion 85-62.

¹³ Williams v. City of Minneola, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).

¹⁴ s. 119.15, F.S.

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protects information of a sensitive personal nature concerning individuals, the release of which would be defamatory or cause unwarranted damage to the good name or reputation of such individuals, or would jeopardize their safety; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information that is used to protect or further a business advantage over those who do not know or use it, the disclosure of which would injure the affected entity in the marketplace.¹⁵

The Act also requires the Legislature to consider the following:

- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?
- Is the record or meeting protected by another exemption?
- Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?

While the standards in the Act may appear to limit the Legislature in the exemption review process, those aspects of the Act that are only statutory, as opposed to constitutional, do not limit the Legislature because one session of the Legislature cannot bind another.16 The Legislature is only limited in its review process by constitutional requirements.

Further, s. 119.15(8), F.S., makes explicit that:

... notwithstanding s. 778.28 or any other law, neither the state or its political subdivisions nor any other public body shall be made party to any suit in any court or incur any liability for the repeal or revival and reenactment of any exemption under this section. The failure of the Legislature to comply strictly with this section does not invalidate an otherwise valid reenactment.

Physician Licensure

Prior to engaging in the practice of medicine in this state, a physician must be licensed under ch. 458, F.S., The Medical Practice Act. ¹⁷ A license issued under the Medical Practice Act must be renewed biennially. ¹⁸

Physician Workforce Planning

The Legislature recognizes that physician workforce planning is an essential component of ensuring that there is an adequate and appropriate supply of well-trained physicians to meet Florida's future health care service needs as the general population and elderly population of the state increase. ¹⁹ Physician workforce planning encompasses, among other things, analyzing current workforce data collected through the physician workforce surveys, planning for the availability and capacity of quality medical schools and graduate medical education programs in this state, and incentivizing physicians to practice in needed specialties and underserved areas in a manner that addresses projected needs for physician manpower.

¹⁵ s. 119.15(6)(b), F.S.

¹⁶ Straughn v. Camp, 293 So.2d 689, 694 (Fla. 1974).

¹⁷ s. 458.327(1)(a), F.S., and s. 456.065(1), F.S.

¹⁸ s. 458.319, F.S.

¹⁹ s. 381.4018(2), F.S.

The DOH is charged with developing a state strategic plan and assessing the implementation of the plan. This is to be accomplished by using existing programs under the jurisdiction of the DOH and other state agencies and coordinating governmental and nongovernmental stakeholders and resources. ²⁰ In particular, the DOH shall:

- Monitor, evaluate, and report on the supply and distribution of physicians licensed under the Medical Practice Act and the Osteopathic Medical Practice Act. The DOH must maintain a database to serve as a statewide source of data concerning the physician workforce.
- Develop a model and quantify, on an ongoing basis, the adequacy of the state's current and future physician workforce as reliable data becomes available. This model must take into account demographics, physician practice status, place of education and training, generational changes, population growth, economic indicators, and issues concerning the pipeline into medical education.
- Develop and recommend strategies to determine whether the number of qualified medical school applicants who might become competent, practicing physicians in this state will be sufficient to meet the capacity of the state's medical schools. If appropriate, the DOH might also develop strategies and recommendations and identify best practice programs for grade schools and at the college level to increase this state's potential pool of medical students.
- Develop strategies to ensure that the number of graduates from the state's allopathic and osteopathic medical schools is adequate to meet physician workforce needs, based on the analysis of the physician workforce data.
- Pursue strategies and policies to create, expand, and maintain graduate medical education positions in the state based on the analysis of the physician workforce data.
- Develop strategies to maximize federal and state programs that provide for the use of incentives to attract physicians to this state or retain physicians within the state.
- Coordinate and enhance activities relative to physician workforce needs, undergraduate medical
 education, graduate medical education, and reentry of retired military and other physicians into the
 physician workforce provided by the Division of Medical Quality Assurance, area health education center
 networks and other offices and programs within the DOH.
- Work in conjunction with and act as a coordinating body for government and nongovernmental stakeholders to address matters relating to the state's physician workforce assessment and development for the purpose of ensuring an adequate supply of well-trained physicians to meet the state's future needs.
- Serve as a liaison with other states and federal agencies and programs in order to enhance resources available to the state's physician workforce and medical education continuum.
- Act as a clearinghouse for collecting and disseminating information concerning the physician workforce and medical education continuum in this state.

Physician Workforce Surveys

The requirement for the physician workforce survey was enacted in Chapter 2007-172, L.O.F., and codified in s. 458.3191, F.S., relating to allopathic physicians and s. 459.0081, F.S., relating to osteopathic physicians. Section 458.3191, F.S., requires each Florida-licensed allopathic or osteopathic physician, in conjunction with the renewal of his or her license, to furnish specified information to the DOH in a physician survey. The information required under this statute to be submitted includes but is not limited to:

- Licensee information related to:
 - o Frequency and geographic location of practice within the state,
 - o Practice setting.
 - o Percentage of time spent in direct patient care,
 - o Anticipated change to license or practice status, and
 - o Areas of specialty or certification; and
- Availability and trends relating to critically needed services including:
 - Obstetric care and services, including incidents of deliveries,
 - o Radiological services, particularly performance of mammograms and breast-imaging services,
 - o Physician services for hospital emergency departments and trauma centers, including on-call hours, and

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²⁰ s. 381.4018(4), F.S.

o Other critically needed specialty areas, as determined by the DOH.

The information furnished by the physician must include a statement that the information provided is true and accurate to the best of his or her knowledge and the submission does not contain any knowingly false information.²¹ The physician workforce survey is available on line and may be viewed at http://www.doh.state.fl.us/mqa/medical/info_Survey.pdf.

The survey must be completed on line if the medical physician renews his or her license on line. Otherwise, the physician must submit a paper copy of the survey with his or her renewal application.²² The DOH shall issue a non-disciplinary citation to a licensee who fails to complete the survey within 90 days after the renewal of his or her license to practice as a physician. The citation must notify the physician that his or her medical license will not be renewed for any subsequent license renewal unless he or she completes the survey.²³

Annually, the DOH is required to analyze the results of the physician workforce survey²⁴ to determine by geographic area and specialty the number of physicians who:

- Perform deliveries of children in Florida.
- Read mammograms and perform breast-imaging-guided procedures in Florida.
- Perform emergency care on an on-call basis for a hospital emergency department.
- Plan to reduce or increase emergency on-call hours in a hospital emergency department.
- Plan to relocate outside the state.
- Practice medicine in Florida.
- Plan to reduce or modify the scope of their practice.

The DOH is required to report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representative by November 1 of each year. Additionally, the annual report must include findings, recommendations, and strategic planning activities as provided in s. 381.4018, F.S., relating to physician workforce assessment and development. The DOH may also include other information requested by the Physician Workforce Advisory Council.²⁵

Physician Workforce Advisory Council

In 2010, the Legislature created, within the DOH, the Physician Workforce Advisory Council (the Council)²⁶ to advise and assist the State Surgeon General and the DOH on matters concerning current and future physician workforce needs in this state. Prior to creation of the Council, the State Surgeon General had created the Healthcare Practitioner Ad Hoc Committee to provide the DOH with expertise and guidance on technical and programmatic areas related to implementing the 2007 Legislation providing for physician workforce assessment and development.²⁷

The Council is composed of 19 members appointed by the State Surgeon General.²⁸ Additional responsibilities of the Council include:

- Reviewing survey materials and the compilation of survey information;
- Annually reviewing the number, location, cost, and reimbursement of graduate medical education programs and positions;
- Providing recommendations to the department regarding the physician workforce survey;
- Assisting the department in preparing the annual report to the Legislature pertaining to the physician workforce;

²¹ s. 458.3191(2), F.S.

²² Rule 64B-9.002, F.A.C.

²³ s. 458.3191, F.S.

²⁴ s. 458.3192, F.S.

 $^{^{25}}$ Id

²⁶ ch. 2010-161, L.O.F., s. 29.

²⁷ Infra 32 and 33.

²⁸ s. 381.4018(5)(a), F.S., identifies the groups to be represented on the Council.

- Assisting the department in preparing an initial strategic plan, conducting ongoing strategic planning and providing ongoing advice on implementing the recommendations;
- Monitoring and providing recommendations regarding the need for an increased number of primary care
 or other physician specialties to provide the necessary current and projected health and medical services
 for the state; and
- Monitoring and making recommendations regarding the status of the needs relating to graduate medical education in this state.

Exemption from the Public Records Law

Section 458.3193, F.S., also enacted in 2007,²⁹ exempts all personal identifying information contained in records provided by physicians in response to the physician workforce survey required as a condition of license renewal and held by the DOH confidential and exempt from s. 119.07(1), F.S., and Article I, s. 24 of the State Constitution, with certain exceptions.

Information made confidential and exempt shall be disclosed:

- With the express written consent of the individual to whom the information pertains or the individual's legally authorized representative.
- By court order upon a showing of good cause.
- To a research entity, if the entity:
 - o Seeks the records or data pursuant to a research protocol approved by the DOH,
 - o Maintains the records or data in accordance with the approved protocol, and
 - o Enters into a purchase and data-use agreement with the department.

The DOH may deny a request for records or data if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit. The agreement between the DOH and the research entity must restrict the release of information that would identify individuals, limit the use of records or data to the approved research protocol, and prohibit any other use of the records or data.

When enacting the exemption from the public records law, the Legislature found that it is a public necessity that personal identifying information concerning a Florida-licensed allopathic physician who responds to the mandatory physician workforce survey be made confidential and exempt from disclosure. Further, the failure to maintain the confidentiality of such personal identifying information would frustrate and prevent the resolution of important state interests to implement and maintain effective strategies to ensure the availability of physicians in the state. Specific reasons stated in the law include:

- Candid and honest responses to the survey will ensure that timely and accurate information is available for the DOH to review and use in making important policy decisions regarding the use of resources to facilitate the needs of current or projected medically underserved areas in the state.
- Long-term planning, based on the information provided by physicians in the surveys, is essential for improving health care access for Florida residents and enabling the use of strategies for a well-trained supply of physicians.
- Accurate and honest information obtained through the surveys will assist state policy-makers in their
 decisions to ensure the availability of quality medical schools and graduate medical education and the
 development of strategies that might provide for physicians to practice in needed specialties and in
 underserved areas in a manner that addresses projected needs for physician manpower.

Findings and/or Conclusions

Survey / Reporting Process

Responding to the physician workforce survey is required as part of the licensure renewal process for physicians licensed under the Medical Practice Act. As of June 30, 2011, there were 62,610 allopathic physicians licensed

 $^{^{\}rm 29}$ ch. 2007-96, L.O.F. This law is also codified in s. 459.0083, F.S.

under the Medical Practice Act.³⁰ For licensure renewal, the population of licensed allopathic physicians is divided into two groups, with each group renewing every other year.

The first physician workforce survey mandated by law³¹ went live October, 2007 and included one half of the allopathic physicians (25,850) and all osteopathic (4,839) physicians renewing their licenses during that licensure cycle.³² The results and analysis of that partial survey of the physician workforce were published in the 2008 Florida Physician Workforce Annual Report.

The first report encompassing mandated survey responses for all allopathic and osteopathic physicians renewing licenses is the 2009 Florida Physician Workforce Annual Report. 33 This report combines the 2008 and 2009 mandatory physician workforce surveys responses, consisting of 12 core questions for the half of the allopathic physicians and all of the osteopathic physicians responding in 2008 and 18 core questions for the other half of the allopathic physicians responding in 2009. The 2009 survey instrument also included an expanded list of questions relating to medical specialties.

The most recent Physician Workforce Annual Report published on November 1, 2010, details the survey results from 2009 and 2010. There were 57,750 allopathic and osteopathic physicians eligible for renewal in 2009 and 2010, with 99 percent responding to the survey.³⁴

The survey instrument requests the physician's name and license number along with a series of questions addressing different aspects of his or her practice, including specific questions related to specialties, and future plans. Through a series of questions in the survey, coupled with demographic information in the physician's licensure file, the DOH is able to define physician workforce by location and specialty.³⁵

As reported in the Physician Workforce Annual Report 2010, of the 57,750 allopathic and osteopathic physicians eligible for renewal in 2009 and 2010, 41,210 were included within the published study results. Excluded are those physicians indicating he or she had not practiced medicine in Florida over the course of the year prior to renewal; failing to provide a valid Florida practice address; indicating participation in a residency, internship, or fellowship program; or having a licensure status disallowing the practice of medicine.

Stakeholder Ouestionnaire

As a part of the review required under the Open Government Sunset Review Act, Senate professional staff of the Health Regulation Committee sent questionnaires³⁶ to the DOH, Florida Board of Medicine, Florida Medical Association, and the Council. All responses supported continuing the physician workforce surveys and the Legislature reenacting the public records exemption for the personal identifying information pertaining to the responding physicians that is received in the survey and held by the DOH. One of the entities responding to the questionnaire said, "Physicians are more likely to complete these surveys with full honesty or disclosure if they feel their personal identifying information will be kept confidential."

³⁰ Email dated July 22, 2011 from by the Department of Health on file with the Senate Health Regulation Committee.

³¹ Prior to the physician workforce survey mandated in s. 458.3191, F.S., a voluntary physician workforce questionnaire had been in place since October, 2006. See infra 32.

³² Florida Department of Health 2008 Florida Physician Workforce Annual Report, published November 1, 2008, at page 13. A copy of the report is on file with the Senate Health Regulation Committee.

³³ Florida Department of Health 2009 Florida Physician Workforce Annual Report, published November 1, 2009 is available at:< http://www.doh.state.fl.us/Workforce/Physicians_Workforce_Annual_Rpt_2009.pdf> (Last visited on July 25, 2011).

³⁴ Florida Department of Health Physician Workforce Annual Report 2010, published November 1, 2010, at page 9, available at: http://www.doh.state.fl.us/Workforce/Workforce/Annual Reports/PhysicianWorkforce Nov2010.pdf (Last visited on July 25, 2011).

³⁵ *Id*.

³⁶ The questionnaires and responses are on file with the Senate Health Regulation Committee.

None of the entities responding to the stakeholder questionnaire recommended changes to the current exemption. In addition, The First Amendment Foundation is not opposed to reenactment of the exemption in its current form.³⁷

Options and/or Recommendations

Senate professional staff recommends that the exemption from the public records requirements for all personal identifying information contained in records provided by Florida-licensed allopathic physicians in response to the physician workforce survey required as a condition of license renewal and held by the DOH as provided in s. 458.3193, F.S., be reenacted by the Legislature. The exemption serves an identifiable public purpose by allowing the state to effectively and efficiently administer and plan for an adequate and appropriate supply of well-trained physicians as the general and elderly population of the state increase. Meaningful and reliable analysis can only occur if physicians respond honestly and fully disclose relevant information concerning their current and planned future activities related to their medical practice. Maintaining the confidentiality of the responses will help ensure the state receives honest and complete responses.

³⁷ Correspondence from the First Amendment Foundation dated July 18, 2010 to The Honorable Jeremy Ring, Chair, Governmental Oversight and Accountability Committee. A copy of this correspondence is on file with the Senate Health Regulation Committee.

Committee on Health Regulation

OPEN GOVERNMENT SUNSET REVIEW OF SECTION 459.0083, F.S., OSTEOPATHIC PHYSICIAN WORKFORCE SURVEYS

Issue Description

Each Florida-licensed osteopathic physician is required to furnish specified information to the Department of Health (DOH) in a physician workforce survey in conjunction with the renewal of his or her medical license. Section 459.0083, F.S., creates an exemption from the requirements of the Public Records Law to make all personal identifying information contained in records provided by physicians in response to the physician workforce survey that is held by the DOH confidential and exempt from s. 119.07(1), F.S., and Article I, s. 24 of the State Constitution. This exemption will be repealed on October 2, 2012, unless it is reviewed under the Open Government Sunset Review Act and saved from repeal through reenactment by the Legislature.

Background

Public Records and Meetings

The State of Florida has a long history of providing public access to governmental records. The Florida Legislature enacted the first public records law in 1892. One hundred years later, Floridians adopted an amendment to the State Constitution that raised the statutory right of access to public records to a constitutional level.² Article I, s. 24 of the State Constitution, provides that:

(a) Every person has the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

In addition to the State Constitution, the Public Records Act,³ which pre-dates the current State Constitution, specifies conditions under which public access must be provided to records of the executive branch and other agencies. Section 119.07(1)(a), F.S., states:

Every person who has custody of a public record shall permit the record to be inspected and copied by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records.

Unless specifically exempted, all agency⁴ records are available for public inspection. The term "public record" is broadly defined to mean:

Section 1390, 1391 Florida Statutes. (Rev. 1892).

² Article I, s. 24 of the State Constitution.

³ Chapter 119, F.S.

⁴ The word "agency" is defined in s. 119.011(2), F.S., to mean "... any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."

. . .all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.⁵

The Florida Supreme Court has interpreted this definition to encompass all materials made or received by an agency in connection with official business, which are used to perpetuate, communicate, or formalize knowledge. All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.

Article I, s. 24 of the State Constitution also provides that all meetings of any collegial public body of the executive branch of state government or of any collegial public body of a county, municipality, school district, or special district, at which official acts are to be taken or at which public business of such body is to be transacted or discussed, shall be open and noticed to the public and meetings of the Legislature shall be open and noticed as provided in Article III, Section 4(e), except with respect to meetings exempted pursuant to this section or specifically closed by this Constitution. In addition, the Sunshine Law, s. 286.011, F.S., provides that all meetings of any board or commission of any state agency or authority or of any agency or authority of any county, municipal corporation, or political subdivision, except as otherwise provided in the Constitution, at which official acts are to be taken are declared to be public meetings open to the public at all times, and no resolution, rule, or formal action shall be considered binding except as taken or made at such meeting.

Only the Legislature is authorized to create exemptions to open government requirements. An exemption must be created in general law, must state the public necessity justifying it, and must not be broader than necessary to meet that public necessity. A bill enacting an exemption may not contain other substantive provisions, although it may contain multiple exemptions that relate to one subject. 11

There is a difference between records that the Legislature has made exempt from public inspection and those that are *confidential* and exempt. If the Legislature makes a record confidential and exempt, such information may not be released by an agency to anyone other than to the persons or entities designated in the statute. ¹² If a record is simply made exempt from disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances. ¹³

The Open Government Sunset Review Act (the Act)¹⁴ provides for the systematic review, through a 5-year cycle ending October 2 of the 5th year following enactment, of an exemption from the Public Records Act or the Sunshine Law. Each year, by June 1, the Division of Statutory Revision of the Office of Legislative Services is required to certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of each exemption scheduled for repeal the following year.

The Act states that an exemption may be created, revised, or maintained only if it serves an identifiable public purpose and if the exemption is no broader than is necessary to meet the public purpose it serves. An identifiable public purpose is served if the exemption meets one of three specified criteria and if the Legislature finds that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption. The three statutory criteria are that the exemption:

⁵ s. 119.011(12), F.S.

⁶ Shevin v. Byron, Harless, Schaffer, Reid and Associates, Inc., 379 So.2d 633, 640 (Fla. 1980).

⁷ Wait v. Florida Power & Light Company, 372 So.2d 420 (Fla. 1979).

⁸ Art. I, s. 24(c) of the State Constitution.

⁹ Memorial Hospital-West Volusia v. News-Journal Corporation, 729 So. 2d 373, 380 (Fla. 1999); Halifax Hospital Medical Center v. News-Journal Corporation, 724 So.2d 567 (Fla. 1999).

¹⁰ Under s. 119.15, F.S., an existing exemption may be considered a new exemption if the exemption is expanded to cover additional records.

¹¹ Art. I, s. 24(c) of the State Constitution.

¹² Attorney General Opinion 85-62.

¹³ Williams v. City of Minneola, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).

¹⁴ s. 119.15, F.S.

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protects information of a sensitive personal nature concerning individuals, the release of which would be defamatory or cause unwarranted damage to the good name or reputation of such individuals, or would jeopardize their safety; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information that is used to protect or further a business advantage over those who do not know or use it, the disclosure of which would injure the affected entity in the marketplace.¹⁵

The Act also requires the Legislature to consider the following:

- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?
- Is the record or meeting protected by another exemption?
- Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?

While the standards in the Act may appear to limit the Legislature in the exemption review process, those aspects of the Act that are only statutory, as opposed to constitutional, do not limit the Legislature because one session of the Legislature cannot bind another. 16 The Legislature is only limited in its review process by constitutional requirements.

Further, s. 119.15(8), F.S., makes explicit that:

... notwithstanding s. 778.28 or any other law, neither the state or its political subdivisions nor any other public body shall be made party to any suit in any court or incur any liability for the repeal or revival and reenactment of any exemption under this section. The failure of the Legislature to comply strictly with this section does not invalidate an otherwise valid reenactment.

Osteopathic Physician Licensure

Prior to engaging in the practice of osteopathic medicine in this state, an osteopathic physician must be licensed under ch. 459, F.S., The Osteopathic Medical Practice Act. A license issued under the Osteopathic Medical Practice Act must be renewed biennially.¹⁸

Physician Workforce Planning

The Legislature recognizes that physician workforce planning is an essential component of ensuring that there is an adequate and appropriate supply of well-trained physicians to meet Florida's future health care service needs as the general population and elderly population of the state increase. ¹⁹ Physician workforce planning encompasses, among other things, analyzing current workforce data collected through the physician workforce surveys. planning for the availability and capacity of quality medical schools and graduate medical education programs in this state, and incentivizing physicians to practice in needed specialties and underserved areas in a manner that addresses projected needs for physician manpower.

¹⁵ s. 119.15(6)(b), F.S.

¹⁶ Straughn v. Camp, 293 So.2d 689, 694 (Fla. 1974).

¹⁷ s. 459.013(1)(a), F.S., and s. 456.065(1), F.S.

¹⁸ s. 459.008, F.S.

¹⁹ s. 381.4018(2), F.S.

The DOH is charged with developing a state strategic plan and assessing the implementation of the plan. This is to be accomplished by using existing programs under the jurisdiction of the DOH and other state agencies and coordinating governmental and nongovernmental stakeholders and resources. ²⁰ In particular, the DOH shall:

- Monitor, evaluate, and report on the supply and distribution of physicians licensed under the Medical Practice Act and the Osteopathic Medical Practice Act. The DOH must maintain a database to serve as a statewide source of data concerning the physician workforce.
- Develop a model and quantify, on an ongoing basis, the adequacy of the state's current and future physician workforce as reliable data becomes available. This model must take into account demographics, physician practice status, place of education and training, generational changes, population growth, economic indicators, and issues concerning the pipeline into medical education.
- Develop and recommend strategies to determine whether the number of qualified medical school applicants who might become competent, practicing physicians in this state will be sufficient to meet the capacity of the state's medical schools. If appropriate, the DOH might also develop strategies and recommendations and identify best practice programs for grade schools and at the college level to increase this state's potential pool of medical students.
- Develop strategies to ensure that the number of graduates from the state's allopathic and osteopathic medical schools is adequate to meet physician workforce needs, based on the analysis of the physician workforce data.
- Pursue strategies and policies to create, expand, and maintain graduate medical education positions in the state based on the analysis of the physician workforce data.
- Develop strategies to maximize federal and state programs that provide for the use of incentives to attract physicians to this state or retain physicians within the state.
- Coordinate and enhance activities relative to physician workforce needs, undergraduate medical
 education, graduate medical education, and reentry of retired military and other physicians into the
 physician workforce provided by the Division of Medical Quality Assurance, area health education center
 networks and other offices and programs within the DOH.
- Work in conjunction with and act as a coordinating body for government and nongovernmental stakeholders to address matters relating to the state's physician workforce assessment and development for the purpose of ensuring an adequate supply of well-trained physicians to meet the state's future needs.
- Serve as a liaison with other states and federal agencies and programs in order to enhance resources available to the state's physician workforce and medical education continuum.
- Act as a clearinghouse for collecting and disseminating information concerning the physician workforce and medical education continuum in this state.

Physician Workforce Surveys

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- Licensee information related to:
 - o Frequency and geographic location of practice within the state,
 - o Practice setting.
 - o Percentage of time spent in direct patient care,
 - o Anticipated change to license or practice status, and
 - o Areas of specialty or certification; and
- Availability and trends relating to critically needed services including:
 - Obstetric care and services, including incidents of deliveries,
 - o Radiological services, particularly performance of mammograms and breast-imaging services,
 - Physician services for hospital emergency departments and trauma centers, including on-call hours, and

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²⁰ s. 381.4018(4), F.S.

o Other critically needed specialty areas, as determined by the DOH.

Information furnished by the osteopathic physician must include a statement that the information provided is true and accurate to the best of his or her knowledge and the submission does not contain any knowingly false information.²¹ The physician workforce survey is available on line and may be viewed at http://www.doh.state.fl.us/mqa/medical/info_Survey.pdf.

The DOH shall issue a non-disciplinary citation to a licensee who fails to complete the survey within 90 days after the renewal of his or her license to practice as an osteopathic physician. The citation must notify the physician that his or her osteopathic medical license will not be renewed for any subsequent license renewal unless he or she completes the survey.²²

Annually, the DOH is required to analyze the results of the physician workforce survey²³ to determine by geographic area and specialty the number of physicians who:

- Perform deliveries of children in Florida.
- Read mammograms and perform breast-imaging-guided procedures in Florida.
- Perform emergency care on an on-call basis for a hospital emergency department.
- Plan to reduce or increase emergency on-call hours in a hospital emergency department.
- Plan to relocate outside the state.
- Practice medicine in Florida.
- Plan to reduce or modify the scope of their practice.

The DOH is required to report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representative by November 1 of each year. Additionally, the annual report must include findings, recommendations, and strategic planning activities as provided in s. 381.4018, F.S., relating to physician workforce assessment and development. The DOH may also include other information requested by the Physician Workforce Advisory Council.²⁴

Physician Workforce Advisory Council

In 2010, the Legislature created, within the DOH, the Physician Workforce Advisory Council (the Council)²⁵ to advise and assist the State Surgeon General and the DOH on matters concerning current and future physician workforce needs in this state. Prior to creation of the Council, the State Surgeon General had created the Healthcare Practitioner Ad Hoc Committee to provide the DOH with expertise and guidance on technical and programmatic areas related to implementing the 2007 Legislation providing for physician workforce assessment and development.²⁶

The Council is composed of 19 members appointed by the State Surgeon General.²⁷ Additional responsibilities of the Council include:

- Reviewing survey materials and the compilation of survey information;
- Annually reviewing the number, location, cost, and reimbursement of graduate medical education programs and positions;
- Providing recommendations to the department regarding the physician workforce survey;
- Assisting the department in preparing the annual report to the Legislature pertaining to the physician workforce;
- Assisting the department in preparing an initial strategic plan, conducting ongoing strategic planning and providing ongoing advice on implementing the recommendations;

²⁵ ch. 2010-161, L.O.F., s. 29.

²¹ s. 459.0081(2), F.S.

²² s. 459.0081(3), F.S.

²³ s. 459.0082, F.S.

 $^{^{24}}$ Id

²⁶ Infra 31 and 32.

²⁷ s. 381.4018(5)(a), F.S., identifies the groups to be represented on the Council.

- Monitoring and providing recommendations regarding the need for an increased number of primary care
 or other physician specialties to provide the necessary current and projected health and medical services
 for the state; and
- Monitoring and making recommendations regarding the status of the needs relating to graduate medical education in this state.

Exemption from the Public Records Law

Section 459.0083, F.S., also enacted in 2007,²⁸ exempts all personal identifying information contained in records provided by physicians in response to the physician workforce survey required as a condition of license renewal and held by the DOH confidential and exempt from s. 119.07(1), F.S., and Article I, s. 24 of the State Constitution, with certain exceptions.

Information made confidential and exempt shall be disclosed:

- With the express written consent of the individual to whom the information pertains or the individual's legally authorized representative.
- By court order upon a showing of good cause.
- To a research entity, if the entity:
 - o Seeks the records or data pursuant to a research protocol approved by the DOH,
 - o Maintains the records or data in accordance with the approved protocol, and
 - o Enters into a purchase and data-use agreement with the department.

The DOH may deny a request for records or data if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit. The agreement between the DOH and the research entity must restrict the release of information that would identify individuals, limit the use of records or data to the approved research protocol, and prohibit any other use of the records or data.

When enacting the exemption from the public records law, the Legislature found that it is a public necessity that personal identifying information concerning a Florida-licensed physician who responds to the mandatory physician workforce survey be made confidential and exempt from disclosure. Further, the failure to maintain the confidentiality of such personal identifying information would frustrate and prevent the resolution of important state interests to implement and maintain effective strategies to ensure the availability of physicians in the state. Specific reasons stated in the law include:

- Candid and honest responses to the survey will ensure that timely and accurate information is available
 for the DOH to review and use in making important policy decisions regarding the use of resources to
 facilitate the needs of current or projected medically underserved areas in the state.
- Long-term planning, based on the information provided by physicians in the surveys, is essential for improving health care access for Florida residents and enabling the use of strategies for a well-trained supply of physicians.
- Accurate and honest information obtained through the surveys will assist state policy-makers in their
 decisions to ensure the availability of quality medical schools and graduate medical education and the
 development of strategies that might provide for physicians to practice in needed specialties and in
 underserved areas in a manner that addresses projected needs for physician manpower.

Findings and/or Conclusions

Survey / Reporting Process

Responding to the physician workforce survey is required as part of the licensure renewal process for physicians licensed under the Osteopathic Medical Practice Act. As of June 30, 2011, there were 6,070 osteopathic

 $^{^{28}}$ ch. 2007-96, L.O.F. This law is also codified in s. 458.3193, F.S.

physicians licensed under the Osteopathic Medical Practice Act.²⁹ Osteopathic physicians must renew their license to practice osteopathic medicine every 2 years. Current licenses will expire on March 31, 2012.

The first physician workforce survey mandated by law³⁰ went live October 2007 and included one half of the allopathic physicians (25,850) and all osteopathic (4,839) physicians renewing their licenses during that licensure cycle.³¹ The results and analysis of that partial survey of the physician workforce were published in the 2008 Florida Physician Workforce Annual Report.

The first report encompassing mandated survey responses for all allopathic and osteopathic physicians renewing licenses is the 2009 Florida Physician Workforce Annual Report.³² This report combines the 2008 and 2009 mandatory physician workforce surveys responses, consisting of 12 core questions for the half of the allopathic physicians and all of the osteopathic physicians responding in 2008 and 18 core questions for the other half of the allopathic physicians responding in 2009. The 2009 survey instrument also included an expanded list of questions relating to medical specialties.

The most recent Florida Physician Workforce Annual Report published on November 1, 2010, details the survey results from 2009 and 2010. There were 57,750 allopathic and osteopathic physicians eligible for renewal in 2009 and 2010, with 99 percent responding to the survey.³³

The survey instrument requests the physician's name and license number along with a series of questions addressing different aspects of his or her practice, including specific questions related to specialties, and future plans. Through a series of questions in the survey, coupled with demographic information in the physician's licensure file, the DOH is able to define physician workforce by location and specialty.³⁴

As reported in the 2010 Florida Physician Workforce Annual Report, of the 57,750 allopathic and osteopathic physicians eligible for renewal in 2009 and 2010, 41,210 were included within the published study results. Excluded are those physicians indicating he or she had not practiced medicine in Florida over the course of the year prior to renewal; failing to provide a valid Florida practice address; indicating participation in a residency, internship, or fellowship program; or having a licensure status disallowing the practice of medicine.

Stakeholder Ouestionnaire

As a part of the review required under the Open Government Sunset Review Act, Senate professional staff of the Health Regulation Committee sent questionnaires³⁵ to the DOH, the Florida Board of Osteopathic Medicine, the Florida Osteopathic Medical Association, and the Council. All responses supported continuing the physician workforce surveys and the Legislature reenacting the public records exemption in s. 459.0083, F.S., for the personal identifying information pertaining to the responding physicians that is received in the survey and held by the DOH.

None of the entities responding to the stakeholder questionnaire recommended changes to the current exemption. In addition, The First Amendment Foundation is not opposed to reenactment of the exemption in its current form.³⁶

²⁹ Email dated July 22, 2011 from by the Department of Health on file with the Senate Health Regulation Committee.

³⁰ Prior to the physician workforce survey mandated in s. 458.3191, F.S., and s. 459.0081, F.S., a voluntary physician workforce questionnaire had been in place since October, 2006. *See infra 31*.

³¹ Florida Department of Health 2008 Florida Physician Workforce Annual Report, published November 1, 2008, at page 13. A copy of the report is on file with the Senate Health Regulation Committee.

³² Florida Department of Health 2009 Florida Physician Workforce Annual Report, published November 1, 2009 is available at:< http://www.doh.state.fl.us/Workforce/Physicians_Workforce_Annual_Rpt_2009.pdf> (Last visited on July 25, 2011).

³³ Florida Department of Health Physician Workforce Annual Report 2010, published November 1, 2010, at page 9, available at: http://www.doh.state.fl.us/Workforce/Workforce/Annual Reports/PhysicianWorkforce Nov2010.pdf (Last visited on July 25, 2011).

³⁴ *Id*.

The questionnaires and responses are on file with the Senate Health Regulation Committee.

³⁶ Correspondence from the First Amendment Foundation dated July 18, 2010 to The Honorable Jeremy Ring, Chair,

Options and/or Recommendations

Senate professional staff recommends that the exemption from the public records requirements for all personal identifying information contained in records provided by Florida-licensed allopathic and osteopathic physicians in response to the physician workforce survey required as a condition of license renewal and held by the DOH as provided in s. 459.0083, F.S., be reenacted by the Legislature. The exemption serves an identifiable public purpose by allowing the state to effectively and efficiently administer and plan for an adequate and appropriate supply of well-trained physicians as the general and elderly population of the state increase. Meaningful and reliable analysis can only occur if physicians respond honestly and fully disclose relevant information concerning their current and planned future activities related to their medical practice. Maintaining the confidentiality of the responses will help ensure the state receives honest and complete responses.

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepar	ed By: The	Professional Sta	aff of the Health Re	gulation Commit	tee
BILL:	SPB 7010					
INTRODUCER:	For consideration by the Health Regulation Committee					
SUBJECT:	OGSR/Physician Workforce Surveys/Department of Health					
DATE:	October 31	, 2011	REVISED:			
ANALYST Davlantes		STAFF DIRECTOR Stovall		REFERENCE	Pre-meeting	ACTION g
·						
·						
•						_

I. Summary:

This bill saves from repeal the exemptions from the requirements of the Public Records Law for all personal identifying information contained in records provided by allopathic and osteopathic physicians in response to the Department of Health (DOH) physician workforce survey. The bill is the result of a review of the exemptions under the Open Government Sunset Review Act. The exemptions will expire on October 2, 2012, unless re-enacted by the Legislature before that date.

This bill amends the following sections of the Florida Statutes: 458.193 and 459.0083.

II. Present Situation:

Public Records

Article I, s. 24 of the State Constitution, provides that:

(a) Every person has the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, commission, or entity created pursuant to law or this Constitution.

BILL: SPB 7010 Page 2

In addition to the State Constitution, the Public Records Act, which pre-dates the current State Constitution, specifies conditions under which public access must be provided to records of the executive branch and other agencies. Section 119.07(1)(a), F.S., states:

Every person who has custody of a public record shall permit the record to be inspected and copied by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public records.

Unless specifically exempted, all agency² records are available for public inspection. The term "public record" is broadly defined to mean:

. . . all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.³

The Florida Supreme Court has interpreted this definition to encompass all materials made or received by an agency in connection with official business, which are used to perpetuate, communicate, or formalize knowledge.⁴ All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.⁵

There is a difference between records that the Legislature has made exempt from public inspection and those that are *confidential* and exempt. If the Legislature makes a record confidential and exempt, such information may not be released by an agency to anyone other than to the persons or entities designated in the statute. If a record is simply made exempt from disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances.

The Open Government Sunset Review Act (the Act)⁸ provides for the systematic review, through a 5-year cycle ending October 2 of the 5th year following enactment, of an exemption from the Public Records Act. The Act states that an exemption may be created, revised, or maintained only if it serves an identifiable public purpose and if the exemption is no broader than is necessary to meet the public purpose it serves. An identifiable public purpose is served if the exemption meets one of three specified criteria and if the Legislature finds that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption. The three statutory criteria are that the exemption:

² The word "agency" is defined in s. 119.011(2), F.S., to mean ". . . any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf any public agency."

¹ Chapter 119, F.S.

³ s. 119.011(12), F.S.

⁴ Shevin v. Byron, Harless, Schaffer, Reid and Associates, Inc., 379 So.2d 633, 640 (Fla. 1980).

⁵ Wait v. Florida Power & Light Company, 372 So.2d 420 (Fla. 1979).

⁶ Attorney General Opinion 85-62.

⁷ *Williams v. City of Minneola*, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).

⁸ s. 119.15, F.S.

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Allows the state or its political subdivisions to effectively and efficiently administer a
governmental program, which administration would be significantly impaired without the
exemption;

- Protects information of a sensitive personal nature concerning individuals, the release of which would be defamatory or cause unwarranted damage to the good name or reputation of such individuals, or would jeopardize their safety; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information that is used to protect or further a business advantage over those who do not know or use it, the disclosure of which would injure the affected entity in the marketplace.

The Act also requires the Legislature to consider the following:

- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?
- Is the record or meeting protected by another exemption?
- Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?

Physician Licensure

Prior to engaging in the practice of medicine in this state, an allopathic physician must be licensed under ch. 458, F.S., The Medical Practice Act. ¹⁰ Prior to engaging in the practice of osteopathic medicine in this state, an osteopathic physician must be licensed under ch. 459, F.S., The Osteopathic Medical Practice Act. ¹¹ A license issued under either act must be renewed biennially. ¹²

The requirement for the physician workforce survey was enacted in ch. 2007-172, L.O.F., and codified in s. 458.3191, F.S., relating to allopathic physicians and s. 459.0081, F.S., relating to osteopathic physicians. Sections 458.3191 and 459.0081, F.S., require each Florida-licensed allopathic or osteopathic physician, in conjunction with the renewal of his or her license, to furnish specified information to the DOH in a physician survey. The information required to be submitted under this statute includes:

- Licensee information
 - o Frequency and geographic location of practice within the state,
 - o Practice setting,
 - o Percentage of time spent in direct patient care,
 - o Anticipated changes to license or practice status, and
 - Areas of specialty or certification; and

⁹ s. 119.15(6)(b), F.S.

¹⁰ s. 458.327(1)(a), F.S., and s. 456.065(1), F.S.

¹¹ s. 459.013(1)(a), F.S., and s. 456.065(1), F.S.

¹² s. 458.319, F.S., and s. 459.008, F.S.

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- Availability and trends relating to critically needed services
 - o Obstetric care and services, including incidents of deliveries,
 - Radiological services, particularly performance of mammograms and breast-imaging services,
 - Physician services for hospital emergency departments and trauma centers, including oncall hours, and
 - Other critically needed specialty areas, as determined by the DOH.

Each physician survey must include a statement that the information provided is true and accurate to the best of the licensee's knowledge and that the submission does not contain any knowingly false information. The DOH issues a non-disciplinary citation to a licensee who fails to complete the survey within 90 days after the renewal of his or her license to practice as a physician. The citation notifies the physician that his or her medical license will not be renewed for any subsequent licensing period unless he or she completes the survey. ¹⁴

Annually, the DOH is required to analyze the results of the physician workforce survey¹⁵ to determine by geographic area and specialty the number of physicians who:

- Perform deliveries of children in Florida.
- Read mammograms and perform breast-imaging-guided procedures in Florida.
- Perform emergency care on an on-call basis for a hospital emergency department.
- Plan to reduce or increase emergency on-call hours in a hospital emergency department.
- Plan to relocate outside the state.
- Practice medicine in Florida.
- Plan to reduce or modify the scope of their practices.

The DOH is required to report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1 of each year. Additionally, the annual report must include findings, recommendations, and strategic planning activities as provided in s. 381.4018, F.S., relating to physician workforce assessment and development. The DOH may also include other information requested by the Physician Workforce Advisory Council. ¹⁶

Physician Workforce Planning

The Legislature recognizes that physician workforce planning is essential to ensuring an adequate and appropriate supply of well-trained physicians to meet Florida's future health care service needs as the general population and elderly population of the state increase. ¹⁷ Physician workforce planning encompasses, among other things, analyzing current workforce data collected through the physician workforce surveys, planning for the availability and capacity of quality medical schools and graduate medical education programs in this state, and incentivizing physicians to practice in needed specialties and underserved areas in a manner that addresses projected needs for physician manpower.

¹³ ss. 458.3191(2) and 459.0081(2), F.S.

¹⁴ ss. 458.3191 and 459.0081(3), F.S.

 $^{^{15}}$ ss. 458.3192 and 459.0082, F.S.

¹⁶ *Id.* The Physician Workforce Advisory Council is created in s. 29, ch. 2010-161, L.O.F., to advise and assist the State Surgeon General and the DOH on matters concerning current and future physician workforce needs in this state.

¹⁷ s. 381.4018(2), F.S.

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Exemption from the Public Records Law

Sections 458.3193 and 459.0083, F.S., also enacted in 2007, ¹⁸ exempt all personal identifying information contained in records provided by physicians in response to the physician workforce survey required as a condition of license renewal and held by the DOH confidential and exempt from s. 119.07(1), F.S., and Article I, s. 24 of the State Constitution, with certain exceptions.

Information made confidential and exempt shall be disclosed:

- With the express written consent of the individual to whom the information pertains or the individual's legally authorized representative.
- By court order upon a showing of good cause.
- To a research entity, if the entity:
 - o Seeks the records or data pursuant to a research protocol approved by the DOH,
 - o Maintains the records or data in accordance with the approved protocol, and
 - o Enters into a purchase and data-use agreement with the department.

The DOH may deny a request for records or data if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit. The agreement between the DOH and the research entity must restrict the release of information that would identify individuals, limit the use of records or data to the approved research protocol, and prohibit any other use of the records or data.

When enacting the exemptions from the public records law, the Legislature found that it is a public necessity that personal identifying information concerning Florida-licensed physicians who respond to the mandatory physician workforce survey be made confidential and exempt from disclosure. Further, the failure to maintain the confidentiality of such personal identifying information would frustrate and prevent the resolution of important state interests to implement and maintain effective strategies to ensure the availability of physicians in the state. Specific reasons stated in the law include:

- Candid and honest responses to the survey will ensure that timely and accurate information is
 available for the DOH to review and use in making important policy decisions regarding the
 use of resources to facilitate the needs of current or projected medically underserved areas in
 the state.
- Long-term planning, based on the information provided by physicians in the surveys, is essential for improving health care access for Florida residents and enabling the use of strategies for a well-trained supply of physicians.
- Accurate and honest information obtained through the surveys will assist state policy-makers
 in their decisions to ensure the availability of quality medical schools and graduate medical
 education and the development of strategies that might provide for physicians to practice in
 needed specialties and in underserved areas in a manner that addresses projected needs for
 physician manpower.

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¹⁸ ch. 2007-96, L.O.F.

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Senate Open Government Sunset Review Interim Project Reports

Senate professional staff of the Health Regulation Committee completed two reviews of the exemptions pertaining to responses to the physician workforce surveys. The findings are reported in Interim Project Report 2012-309, which reviewed s. 458.3193, F.S., and Interim Project Report 2012-310, which reviewed s. 459.0083, F.S. Both reports recommend that the Legislature re-enact the exemptions from the Public Records Law for personal identifying information contained in the physician workforce surveys.

III. Effect of Proposed Changes:

Personal identifying information from physician workforce survey data collected by the DOH in conjunction with medical license renewal will continue to be confidential and exempt from the requirements of the Public Records Law under s. 119.07(1), F.S., and Article I, s.24 of the State Constitution.

This bill amends s. 458.193 and 459.0083, F.S., to remove the scheduled repeal of these exemptions from public record.

- **Section 1** repeals the provision relating to allopathic provisions.
- **Section 2** repeals the provision relating to osteopathic physicians.
- Section 3 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

This bill will preserve the exemption for personal identifying information contained in physician workforce survey data collected by the DOH in conjunction with medical license renewal from the requirements of s. 119.07(1), F.S., and Article I, s.24 of the State Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

	T /	
^		e Issues:
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None.

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¹⁹ The reports are available at: http://www.flsenate.gov/PublishedContent/Session/2012/InterimReports/2012-319hr.pdf (Last visited on October 31, 2011).

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	B.	Private Sector Impact:				
		None.				
	C.	Government Sector Impact:				
		None.				
VI.	Tech	Technical Deficiencies:				
	None).				
VII.	Rela	elated Issues:				
	None).				
VIII.	Additional Information:					
	A.	Committee Substitute – Statement of Substantial Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.)				
		None.				
	B.	Amendments:				

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

None.

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A bill to be entitled

An act relating to a review under the Open Government Sunset Review Act; amending ss. 458.3193 and 459.0083, F.S., relating to exemptions from public records requirements provided for personal identifying information contained in physician workforce surveys submitted to the Department of Health by physicians and osteopathic physicians; saving the exemptions from repeal under the Open Government Sunset Review Act; removing the scheduled repeal of each exemption; providing an effective date.

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

Section 1. Section 458.3193, Florida Statutes, is amended to read:

458.3193 Confidentiality of certain information contained in physician workforce surveys.—

(1) All personal identifying information contained in records provided by physicians licensed under this chapter or chapter 459 in response to physician workforce surveys required as a condition of license renewal and held by the Department of Health is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution, except as otherwise provided in this section subsection. Information made confidential and exempt by this section subsection shall be disclosed:

 $\underline{\text{(1)}}$ With the express written consent of the individual to whom the information pertains or the individual's legally

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 ${\tt CODING:}$ Words ${\tt stricken}$ are deletions; words ${\tt \underline{underlined}}$ are additions.

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authorized representative.

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(2) (b) By court order upon a showing of good cause.

(3) (c) To a research entity, if the entity seeks the records or data pursuant to a research protocol approved by the Department of Health, maintains the records or data in accordance with the approved protocol, and enters into a purchase and data-use agreement with the department, the fee provisions of which are consistent with s. 119.07(4). The department may deny a request for records or data if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit. The agreement must restrict the release of information that would identify individuals, must limit the use of records or data to the approved research protocol, and must prohibit any other use of the records or data. Copies of records or data issued pursuant to this subsection paragraph remain the property of the department.

(2) This section is subject to the Open Government Sunset
Review Act in accordance with s. 119.15 and shall stand repealed
on October 2, 2012, unless reviewed and saved from repeal
through reenactment by the Legislature.

Section 2. Section 459.0083, Florida Statutes, is amended to read:

459.0083 Confidentiality of certain information contained in physician workforce surveys.—

(1) All personal identifying information contained in records provided by physicians licensed under chapter 458 or this chapter in response to physician workforce surveys required

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as a condition of license renewal and held by the Department of Health is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution, except as otherwise provided in this <u>section</u> <u>subsection</u>. Information made confidential and exempt by this <u>section</u> <u>subsection</u> shall be disclosed:

 $\underline{\text{(1)}}$ With the express written consent of the individual to whom the information pertains or the individual's legally authorized representative.

(2) (b) By court order upon a showing of good cause.

(3) (c) To a research entity, if the entity seeks the records or data pursuant to a research protocol approved by the Department of Health, maintains the records or data in accordance with the approved protocol, and enters into a purchase and data-use agreement with the department, the fee provisions of which are consistent with s. 119.07(4). The department may deny a request for records or data if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit. The agreement must restrict the release of information that would identify individuals, must limit the use of records or data to the approved research protocol, and must prohibit any other use of the records or data. Copies of records or data issued pursuant to this subsection paragraph remain the property of the department.

(2) This section is subject to the Open Covernment Sunset
Review Act in accordance with s. 119.15 and shall stand repealed
on October 2, 2012, unless reviewed and saved from repeal

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 ${\tt CODING:}$ Words ${\tt stricken}$ are deletions; words ${\tt \underline{underlined}}$ are additions.

588-00650-12 20127010__ 88 through reenactment by the Legislature.
89 Section 3. This act shall take effect July 1, 2012.

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

THE FLORIDA SENATE

APPEARANCE RECORD



(Deliver BOTH copies of this form to the Senator or Senate Profession Meeting Date	nal Staff conducting the meeting)
Topic Physician Workforce Survey	Bill Number 43 7010 (if applicable)
Name 48 11 Miller	Amendment Barcode
Job Title Assistant General Counsel	(if applicable)
Address 1430 E Predmont Dr	Phone 850 224 6496
Tallahossee F 32308 State Zip	E-mail hmiller & Amedical ary
Speaking: Against Information	•
Representing Florida Melical Association	
Appearing at request of Chair: Yes No Lobbyis	et registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

Health Regulation Committee November 3, 2011

Thomas Liberti
Chief, Bureau of HIV/AIDS
Florida Department of Health

Florida AIDS Program Update



The Epidemic in Florida 2010

Population: 18.8 million → (4th in nation)
Cumulative AIDS cases: 121,161

(3rd in nation)

Cumulative pediatric AIDS cases: 1,542

(2nd in nation)

Cumulative HIV (not AIDS) cases: 46,795

(since July 1997)

Persons living with HIV/AIDS (PLWHAs): 95,335 →

(reported cases through 2010 as of 05/26/11)

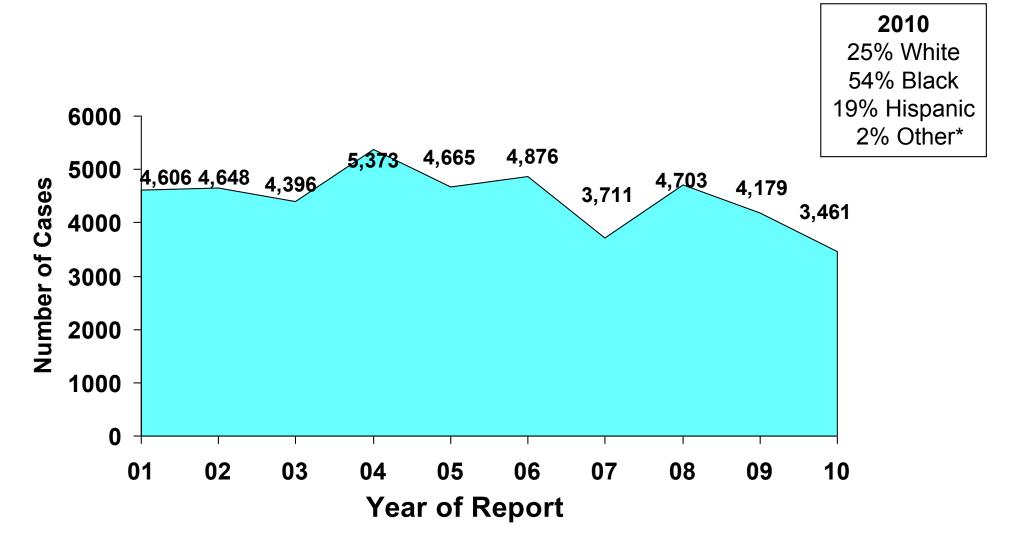
HIV prevalence estimate: 135,000

60% White 16% Black 22% Hispanic 2% Other*

> 30% White 49% Black 19% Hispanic 2% Other*

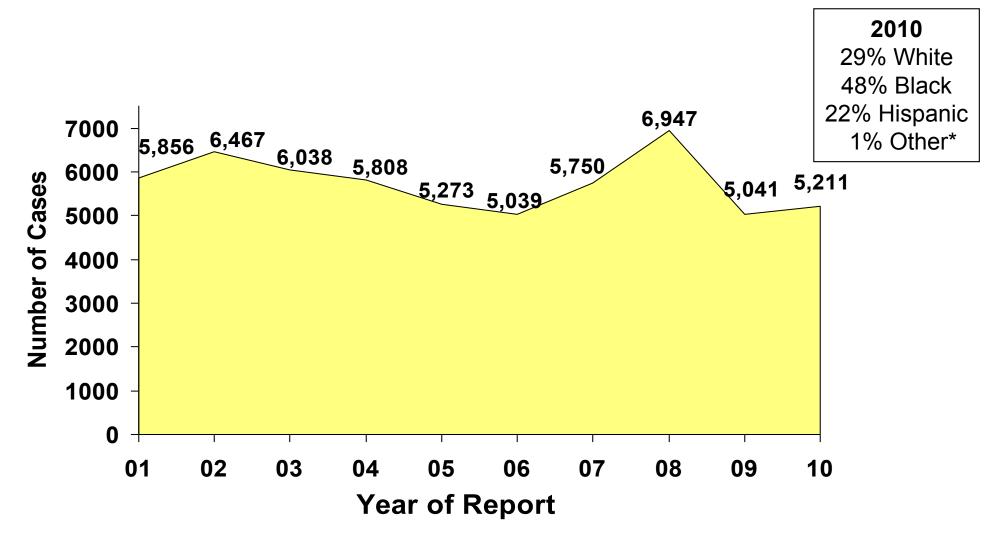


AIDS Cases By Year of Report, Florida, 2001-2010



Comment: Generally, AIDS cases remained fairly stable in the early 2000's, with an increase in 2004 due to increased CD4 testing statewide. Electronic laboratory reporting delays in late 2007 decreased cases in that year, while contributing to a spike in 2008. The expansion of electronic lab reporting increased the timeliness of reporting, which further contributed to the artificial spike in 2008 followed by the artificial dip in 2009 & 2010.

HIV Cases By Year of Report, Florida, 2001-2010



Comment: Generally, HIV cases remained fairly stable with an increase in 2002 due to increased HIV testing statewide as part of the "Get to Know Your Status" campaign. Since that time, newly reported HIV cases have decreased each year until 2007. Since then, reporting changes have caused fluctuations in HIV cases. For example, enhanced reporting laws were implemented in Nov. 2006, and the expansion of electronic lab reporting in 2007 led to an artificial peak in HIV cases in 2007 and 2008 followed by an artificial decrease in 2009 and an expected approach to leveling in 2010.

HIV Rates per 100,000 Population Reported by County of Residence* Florida, 2010

N= 5,211

Case Rate per 100,000

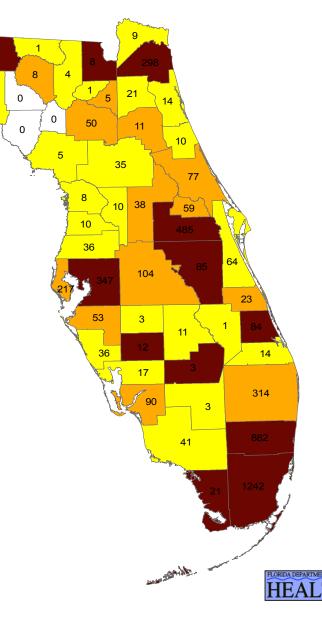
0.1 to 15.0

15.1 to 30.0

> 30.0

Based on 2010 statewide population estimates, the 2010 state rate is 32.8 per 100,000 population.

*County totals exclude Department of Corrections cases (N=79). Numbers on counties are cases reported.

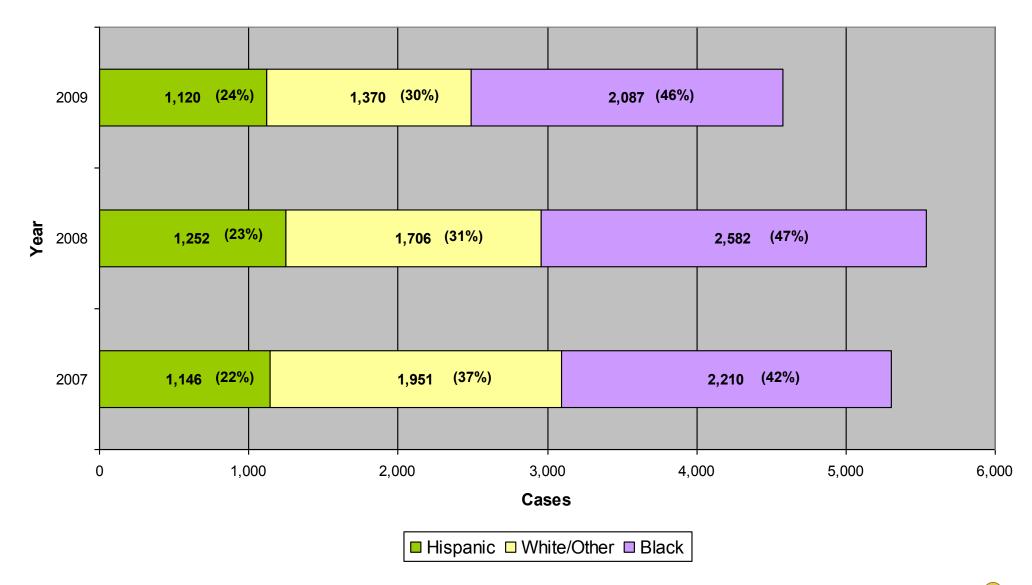


2007-2009 HIV Incidence Estimates National vs. Florida

	2007	2008	2009
National	56,000	47,800	48,100
Florida	5,307	5,541	4,577

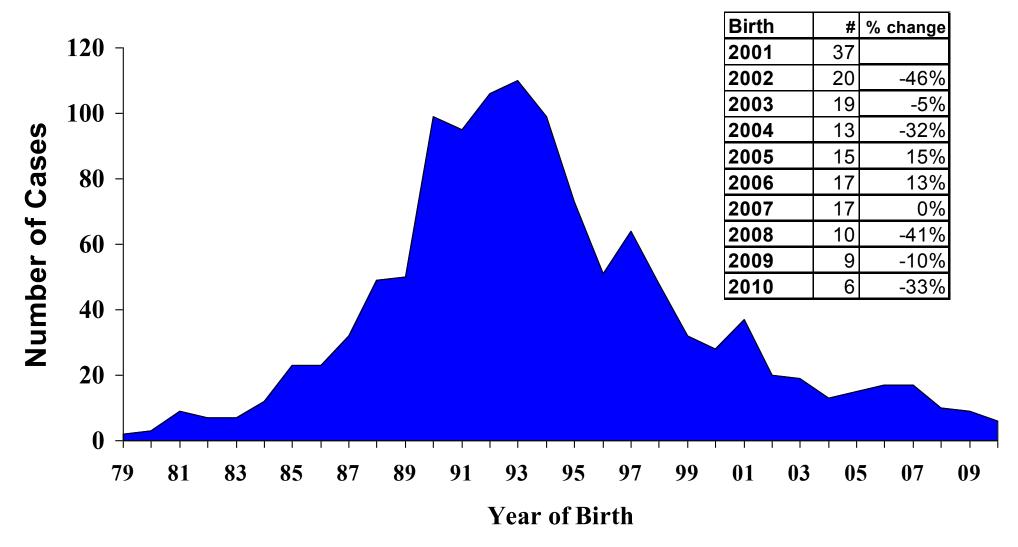


Florida 2007-2009 HIV Incidence Estimates by Race/Ethnicity





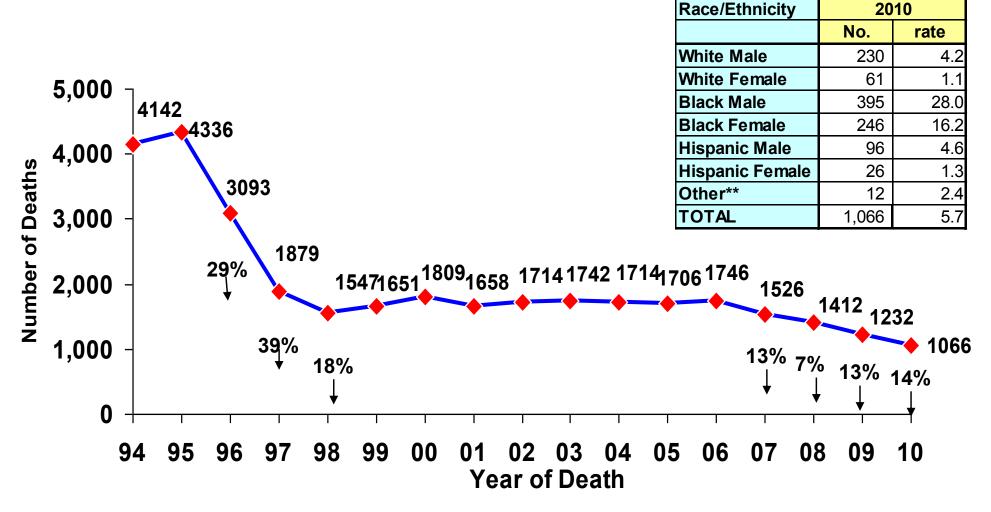
Perinatally Acquired HIV Infected Cases Born in Florida, By Year of Birth, 1979-2010 (N=1,185)



Note: These data represent a 95% decline in HIV-perinatally infected births from 1993 (N=110) to 2010 (N=6) Includes ALL perinatally acquired HIV Infection cases BORN in Florida.

HIV Infection Reporting began July, 2007. 2010 data are provisional. Data as of 08/31/2011

Resident HIV/AIDS Deaths By Year, Florida, 1994 – 2010



Rates are expressed as deaths per 100,000 population based on Florida Population Estimates, DOH, Office of Planning, Evaluation and Data Analysis.

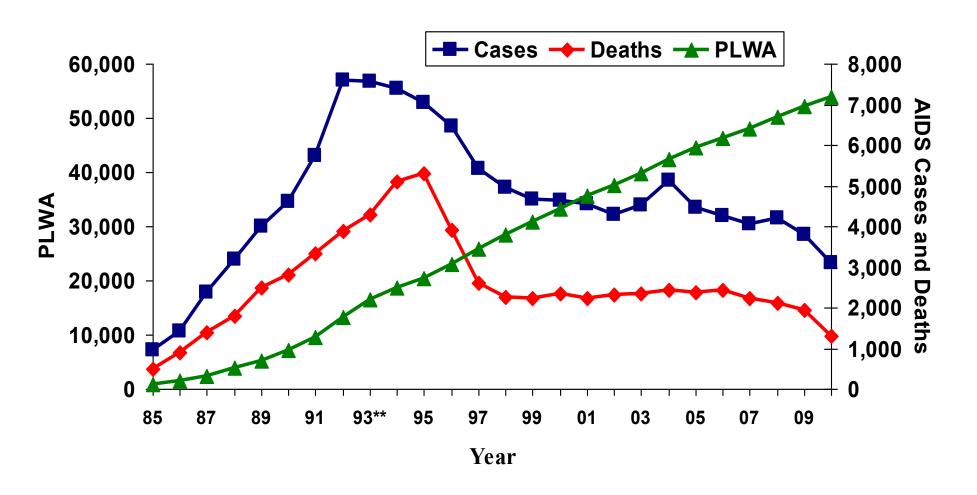
Comment: HIV/AIDS deaths decreased markedly from 1996-1998, associated with the advent of HAART in 1996. A leveling of the trend during 2000-2006 may reflect factors such as viral resistance, late diagnosis of HIV, adherence problems, and lack of access to or acceptance of care. Yearly declines of since 20007 appear to be very promising. Racial/ethnic disparities continue to be evident in the death rate data. Blacks also had a 14% decrease from 2009 to 2010 with 641 deaths in 2010.

Source: Office of Vital Statistics and Bureau of HIV/AIDS, death certificates coded to

Data as of 10/25/11

HIV/AIDS as underlying cause.

AIDS Cases, Case Deaths and Persons Living with AIDS (PLWA), by Year Florida, 1985-2010*



^{*}AIDS cases by year of diagnosis in FL, regardless of state of HIV diagnosis. AIDS case deaths by year of death, regardless of cause of death. PLWAs are AIDS cases who were not known to be deceased. Data as of 05/26/2011



Ryan White Funding

	2007	2008	2009	2010
Part A	69,791,744	70,817,429	67,503,982	72,984,428
Part B	116,325,376	116,146,263	116,269,183	118,435,571**
Part C	10,009,713	9,713,246	7,526,095	7,335,918*
Part D	7,019,701	7,093,539	7,522,963	6,629,567*
Part F	2,854,951	2,854,951	8,006,179*	7,448,947*
Total	206,001,485	206,625,428	206,828,402	212,804,431

^{**} Part B includes MAI and Supplemental funds.



ADAP – The Perfect Storm

Minimal increases in federal appropriations

Fluctuations in state funding

Increased demand due to unemployment and other economic challenges

ADAP

Heightened national efforts on HIV testing and linkages into care

High drug costs

Revised HIV treatment guidelines; earlier treatment



Funding Increases

- ➤ The ADAP Ryan White earmark was increased by \$1 million from the previous year's funding, for a total of \$86.2 million.
- The Program received \$6.6 million in ADAP supplemental dollars
- > \$1,077,279 in Part B Supplemental dollars
- > \$6.9 million in ADAP Emergency Relief Funding
- The bureau redirected an additional \$1 million in General Revenue for ADAP services. (for a total of \$10.5 million)



Program Forecast

- Based on new funding from HRSA, the ADAP will be able to serve its existing clients and enroll and serve an additional 1,500 applicants from the ADAP waiting list.
- As of October 31, 2011, 3,280 applicants remain on the ADAP waiting list.
- In addition, the bureau plans to clear the existing 362 clients from the AIDS Insurance Continuation Program (AICP) waiting list.



Counseling & Testing, Florida

Number of HIV Tests in Publicly Funded Sites

	2001	2002	2003	2004	2005	2006
Whites	110,562	122,558	118,520	114,103	105,316	103,490
Blacks	101,492	107,668	110,509	105,072	106,083	106,042
Hispanics	46,023	51,562	58,543	64,472	73,830	75,329
Total	258,077	281,788	287,572	283,647	285,229	284,861
						% Change
	2007	2008	2009	2010	_	2001-2010
Whites	107,566	111,509	113,470	116,021		5%
Blacks	126,884	154,493	170,115	182,356		80%
Hispanics	79,997	91,338	94,426	95,925		108%
Total	314,447	357,340	378,011	394,302		53%



HIV Prevention Programs

- Expanded HIV Testing
- Partner Services (HIV/STD)
- Linkage to Care
- Perinatal HIV Prevention
- Faith Initiative
- Business/Labor Responds to AIDS



HIV Prevention Programs

- Approximately 80 contracts with community-based organizations
- Testing Campaigns (Miami-Dade, Broward, Orange, Hillsborough, Pinellas, Palm Beach)
- Silence is Death (anti-stigma)
- Sistas Organizing to Survive (black women)
- Test 112,000 Latinos by 2012
- Public/private partnerships (Greater than AIDS)
- Enhanced prevention activities for Miami-Dade County (12 cities initiative)







Greater Than AIDS – Florida Billboards







THE FLORIDA SENATE

APPEARANCE RECORD



(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	
Topic TOM LIBERTI	Bill Number Presentation
Name ADAP	(if applicable) Amendment Barcode
Job Title Chief Bureau of HIV/AIDS	(if applicable)
Address 4052 Bald Cypress Way	Phone 245-4477
TLH FL 32359 City State Zip	E-mail
Speaking: Against Information	
Representing Department at Healt	
Appearing at request of Chair: Yes No Lobbyis	t registered with Legislature: Yes 🔀 No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

CourtSmart Tag Report

Room: KN 412 Case: Type:

Caption: Senate Health Regulation Judge:

Started: 11/3/2011 10:42:57 AM

Ends: 11/3/2011 11:29:38 AM Length: 00:46:42

10:42:59 AM Opening Remarks

10:43:13 AM Roll Call

10:43:28 AM Welcome back John Wilson **10:43:45 AM** Tab 3 SB 364 by Senator Gaetz

10:44:19 AM Eric Edwards presents bill for Senator Gaetz **10:45:08 AM** Amendment 330410 by Diaz de la Portilla

10:45:28 AM Explains amendment **10:45:38 AM** On bill as amended

10:45:44 AM Waives close

10:45:50 AM Brian Pitts, Justice-2-Jesus w/comments

10:46:44 AM Senator Sobel w/question

10:46:51 AM Roll call on bill

10:47:19 AM CS 364 reported favorably

10:47:33 AM Tab 4 - SPB 7010

10:47:42 AM Elizabeth Davlantes explains bill

10:48:03 AM Holly Miller, Assistant General Counsel, FMA waives in support

10:48:29 AM Diaz de la Portilla moves as committee bill

10:48:47 AM Tab 1 SB 80 by Senator Joyner

10:49:15 AM Randi Rosete presents bill for Senator Joyner

10:50:50 AM Janet Maybry, Florida State Massage Assoc, waives in support

10:51:04 AM Brian Pitts, Justice-2-Jesus w/comments

10:52:13 AM Roll Call on SB 80

10:52:41 AM Tab 2 SB 208 by Senator Joyner

10:52:57 AM Randi Rosete to present bill

10:56:02 AM Strike all amendment by Senator Sobel

10:56:33 AM Strike all adopted

10:56:51 AM Senator Garcia w/questions
10:57:00 AM Senator Fasano w/questions
10:57:08 AM Elizabeth Davlantes to answer

10:58:14 AM Brian Pitts w/comments **10:59:21 AM** Roll Call on SB 208

10:59:49 AM SB 208 reported favorably

10:59:59 AM Tab 5 Tom Liberii HIV/AIDS update presentation

11:06:52 AM Senator Sobel w/questions

11:07:10 AM Tom Liberti answers

11:08:48 AM Senator Sobel w/questions

11:08:58 AM Tom Liberti

11:16:50 AM Senator Garcia w/question Senator Sobel w/questions

11:18:17 AM Tom Liberti to answer.

11:25:12 AM Senator Sobel w/question

11:25:24 AM Tom Liberti to answer

11:26:27 AM Senator Sobel w/question

11:27:39 AM Senator Garcia w/question

11:28:03 AM Tom Liberti to answer

11:29:03 AM Senator Garcia w/comment

11:29:17 AM Senator Jones w/motions to vote after

11:29:27 AM Meeting Adjourned

THE FLORIDA SENATE

SENATOR DON GAETZ

4th District

Tallahassee, Florida 32399-1100

COMMITTEES:
Budget - Subcommittee on Transportation, Tourism, and Economic Development Appropriations, Chair Reapportionment, Chair Budget
Budget - Subcommittee on Health and Human Services

Appropriations
Commerce and Tourism Health Regulation

Rules - Subcommittee on Ethics and Elections

JOINT COMMITTEE: Legislative Budget Commission

November 3, 2011

The Honorable Rene Garcia Chairman Senate Committee on Health Regulation 310 Senate Office Building 404 South Monroe Street Tallahassee, FL 32399-1100

Dear Senator Garcia.

l respectfully request to be excused from the Senate Committee on Health Regulation meeting today, Thursday, November 3, 2011.

Thank you for your consideration.

Respectfully,

Senator Don Gaetz

cc: Sandra Stovall

REPLY TO:

3 4300 Legendary Drive, Suite 230, Destin, Florida 32541 (850) 897-5747

🗖 420 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5009

Senate's Website: www.flsenate.gov

THE FLORIDA SENATE



Tallahassee, Florida 32399-1100

COMMITTEES:

Community Affairs, Vice Chair
Budget - Subcommittee on Finance and Tax
Budget - Subcommittee on Transportation, Tourism,
and Economic Development Appropriations
Health Regulation
Military Affairs, Space, and Domestic Security
Transportation

JOINT COMMITTEE:

Legislative Auditing Committee, Alternating Chair

November 3, 2011

SENATOR JIM NORMAN

Ms. Sandra R. Stovall, Staff Director Committee on Health Regulation 531 Knott Building 404 S. Monroe St. Tallahassee, FL 32399-1100

Dear Ms. Stovall,

Please accept this letter as Senator Norman's request to be excused from the Committee on Health Regulation's meeting today, November 3, 2011 at 8:30 am.

If you should have any other questions please refer them to Senator Norman's chief legislative assistant, Ben Kelly at 813-265-6260.

Sincerely,

Dennis Cadle

Legislative Assistant

State Senator Jim Norman, 12th District

Cc: Celia Georgiades CCA

REPLY TO:

14031 North Dale Mabry Boulevard, Tampa, Florida 33618 (813) 265-6260

☐ 214 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5068

Senate's Website: www.flsenate.gov