The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION Senator Garcia, Chair Senator Sobel, Vice Chair

MEETING DATE: Monday, March 14, 2011

TIME: 1:00 —3:00 p.m.

PLACE: Pat Thomas Committee Room, 412 Knott Building

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Altman, Bennett, Diaz de la Portilla,

Fasano, Gaetz, Gardiner, Jones, Latvala, Norman, and Ring

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	SB 626 Thrasher (Similar H 395, Compare S 1972)	Shands Teaching Hospital and Clinics, Inc.; Clarifies provisions relating to references to the corporation known as Shands Teaching Hospital and Clinics, Inc. Clarifies provisions regarding the purpose of the corporation. Authorizes the corporation to create corporate subsidiaries and affiliates. Provides that Shands Teaching Hospital and Clinics, Inc., Shands Jacksonville Medical Center, Inc., Shands Jacksonville Healthcare, Inc., and any not-for-profit subsidiary of such entities are instrumentalities of the state for purposes of sovereign immunity. HR 03/14/2011 HE BC	
2	SB 446 Hays (Identical H 225)	Dentistry and Dental Hygiene; Revises the locations at which dental hygienists may perform dental charting. Authorizing dental hygienists to perform certain duties without supervision or authorization by a dentist. Provides exceptions. Requires that dental hygienists in a health access setting provide a certain disclaimer to patients before a procedure is performed. Provides that a health access setting may bill for certain services, etc. HR 03/14/2011 BC RC	

This bill will be Temporarily Postponed:

COMMITTEE MEETING EXPANDED AGENDAHealth Regulation
Monday, March 14, 2011, 1:00 —3:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	CS/SB 432 Criminal Justice / Evers (Similar CS/H 155)	Privacy of Firearms Owners; Provides that inquiries by physicians or other medical personnel concerning the ownership of a firearm by a patient or the family of a patient or the presence of a firearm in a private home or other domicile of a patient or the family of a patient violates the privacy of the patient or the patient's family members, respectively. Prohibits entry of certain information concerning firearms into medical records or disclosure of such information by specified individuals. Provides noncriminal penalties. Provides for prosecution of violations, etc. CJ 02/22/2011 Fav/CS HR 03/14/2011 JU BC	
4	SB 1414 Wise (Compare H 97)	Health Insurance; Prohibits certain health insurance policies and health maintenance contracts from providing coverage for abortions. Provides exceptions. Defines the term "state." Provides that certain restrictions on coverage for abortions apply to certain group health insurance policies issued or delivered outside the state which provide coverage to residents of the state. HR 03/14/2011 BI BC	
5	SJR 1538 Flores (Identical HJR 1179)	Abortion/Public Funding/Construction of Rights; Proposes amendments to the State Constitution to prohibit public funding of abortions and prohibit the State Constitution from being interpreted to create broader rights to an abortion than those contained in the United States Constitution. HR 03/14/2011 JU BC RC	

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TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
6	SB 818 Fasano	Controlled Substances; Authorizes certain health care practitioners to complete a continuing education course relating to the prescription drug monitoring program. Prohibits certain persons from using titles or displaying signs that would lead the public to believe that they engage in the dispensing of controlled substances. Requires that the prescription drug monitoring program comply with the minimum requirements of the National All Schedules Prescription Electronic Reporting Act. Provides circumstances in which a pain-management clinic may be declared a public nuisance, etc.	
		HR 03/14/2011 CJ BC	
7	CS/SB 204 Criminal Justice / Wise (Identical CS/H 39, Compare S 336)	Controlled Substances; Defines the term "homologue" for purposes of the Florida Comprehensive Drug Abuse Prevention and Control Act. Includes certain hallucinogenic substances on the list of controlled substances in Schedule I. Reenacts provisions relating to prohibited acts and penalties regarding controlled substances and the offense severity chart of the Criminal Punishment Code, etc. CJ 01/11/2011 Fav/CS HR 03/14/2011 JU BC	
8	SB 1226 Joyner	Health Care Fraud; Revises 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. Provides an exception. Requires the department to adopt rules. HR 03/14/2011 CJ BC	
9	SB 1228 Altman (Identical H 1319)	Military Spouses; Provides for issuance of a temporary license to specified health care practitioners who are spouses of active duty members of the Armed Forces under certain circumstances. Provides for criminal history checks. Provides fees. Provides for expiration of a temporary license. HR 03/14/2011 MS BC	

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepared	d By: The Professional Sta	aff of the Health Re	gulation Committee
BILL:	SB 626			
INTRODUCER:	Senator Thra	sher, Senator Lynn, an	nd Senator Dean	
SUBJECT:	Shands Teac	hing Hospital and Clin	nics, Inc.	
DATE:	March 11, 20)11 REVISED:		
ANAL	YST	STAFF DIRECTOR	REFERENCE	ACTION
. Brown		Stovall	HR	Pre-meeting
2.			HE	
3.			BC	
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I. Summary:

The bill clarifies statutory provisions relating to the corporations known as Shands Teaching Hospital and Clinics, Inc., Shands Jacksonville Medical Center, Inc., and Shands Jacksonville Healthcare, Inc., and provisions regarding the purpose of the corporations. The bill authorizes the corporations to create corporate subsidiaries and affiliates. The bill provides the University of Florida's Board of Trustees the right to control Shands Teaching Hospital and Clinics, Inc., Shands Jacksonville Medical Center, Inc., and Shands Jacksonville Healthcare, Inc. The bill provides that Shands Teaching Hospital and Clinics, Inc., Shands Jacksonville Medical Center, Inc., Shands Jacksonville Healthcare, Inc., and any not-for-profit subsidiaries of Shands Teaching Hospital and Clinics, Inc. or Shands Jacksonville Medical Center, Inc. are instrumentalities of the state for purposes of sovereign immunity.

This bill substantially amends the following sections of the Florida Statutes: 1004.41.

II. Present Situation:

The Relationship Between Shands and the University of Florida

Shands Teaching Hospital was opened in 1958 in Gainesville for the purpose of serving the needs of the University of Florida's School of Medicine. Over the next 21 years, the hospital operated as a part of the University. In the late 1970s, however, a legislative task force concluded that a not-for-profit corporation should be formed to provide the hospital with local governance while retaining the role as a University of Florida teaching hospital. Shands Teaching Hospital

and Clinics, Inc. (Shands UF) was created for that purpose in 1980 pursuant to state law enacted in 1979.

Shands UF and Shands Jacksonville Medical Center, Inc. (Shands Jacksonville) are the established University of Florida teaching hospitals and are affiliated with the University's colleges in the J. Hillis Miller Health Science Center (UF HSC). Shands Jacksonville HealthCare, Inc. (Shands Health) was created as the not-for-profit parent of Shands Jacksonville.

Sovereign Immunity

The term "sovereign immunity" originally referred to the English common law concept that the government may not be sued because "the King can do no wrong." Sovereign immunity bars lawsuits against the state or its political subdivisions for the torts of officers, employees, or agents of such governments unless the immunity is expressly waived.

Article X, s. 13, of the Florida Constitution recognizes the concept of sovereign immunity and gives the Legislature the right to waive such immunity in part or in full by general law. Section 768.28, F.S., contains the limited waiver of sovereign immunity applicable to the state.

Under this statute, officers, employees, and agents of the state will not be held personally liable in tort or named as a party defendant in any action for any injury or damage suffered as a result of any act, event, or omission of action in the scope of her or his employment or function, unless such officer, employee, or agent acted in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property.

Instead, the state steps in as the party litigant and defends against the claim. Subsection (5) limits the recovery of any one person to \$100,000 for one incidence and limits all recovery related to one incidence to a total of \$200,000.² For purposes of this analysis, when the term sovereign immunity is used, it means the application of sovereign immunity and the limited waiver of sovereign immunity as provided in s. 768.28, F.S.

The State Risk Management Trust Fund

The Department of Financial Services (DFS) administers a program of risk management for the state in conjunction with a state self-insurance fund, designated as the State Risk Management Trust Fund (the Fund), which provides insurance for various types of proceedings against the state.³ The Fund covers, unless specifically excluded by the DFS, all departments of the state of Florida and their employees, agents, and volunteers, under conditions and parameters set in statute.⁴ The Bureau of Claims Administration within the DFS Division of Risk Management investigates and makes appropriate dispositions on all general liability, automobile liability, federal civil rights, employment, and court-awarded attorney fee claims for damages filed against the state of Florida due to alleged negligent acts of state employees.

¹ See ch. 79-248, Laws of Florida.

² Section 1, ch. 2010-26, Laws of Florida, amended s. 768.28(5), F.S., effective October 1, 2011, to increase the limits to \$200,000 for one person for one incidence and \$300,000 for all recovery related to one incidence, to apply to claims arising on or after that effective date.

³ See s. 284.30, F.S.

⁴ See s. 284.31, F.S.

Florida Case Law

The relationships between the state and various entities regarding sovereign immunity has been the subject of numerous appellate court cases in Florida, including:

- Shands Teaching Hospital and Clinics, Inc. v. Lee⁵

 The First District Court of Appeal examined the waiver of sovereign immunity under s. 768.28, F.S., and opined that to come within the purview of the waiver, entities must be state agencies or "corporations primarily acting as instrumentalities or agencies of the state, counties, or municipalities." The court found that the intent of the Legislature was to treat Shands as an autonomous and self-sufficient entity, not "primarily acting as an instrumentality on behalf of the state" because the day-to-day operations were not under direct state control and because the teaching hospital did not qualify as a state agency or corporation primarily acting as an instrumentality or agency of the state within the meaning of s. 768.28, F.S.
- Prison Rehabilitative Industries v. Betterson⁶
 The First District Court of Appeal opined that since ch. 946, F.S., provided extensive government control over the day-to-day operations of the Prison Rehabilitative Industries and Diversified Enterprises (PRIDE) and provided that PRIDE was a corporation primarily acting as an instrumentality of the state, the provisions of s. 946.5026, F.S., regarding sovereign immunity in tort actions merely clarified PRIDE's previously existing status under s. 768.28, F.S.
- Stoll v. Noel⁷
 The Florida Supreme Court opined that the physicians hired as part-time consultants at a health care facility run by the state Department of Health and Rehabilitative Services were agents of the state due to the degree of control retained or exerted by the state concerning the "final authority over all care and treatment" and thus were entitled to statutory immunity.
- Pagan v. Sarasota County Public Hospital Board⁸
 The Second District Court of Appeal opined that "the structure dictates the control" and that, in this instance, the hospital board's structural control of First Physicians Group made First Physicians Group a corporation primarily acting as an instrumentality or agency of the state.

Governance and Control of Shands Entities

The relationship between the University of Florida and the Shands entities has evolved since Shands Teaching Hospital and Clinics, Inc. was created in 1980 and since the First District Court of Appeal issued its 1985 ruling in *Shands Teaching Hospital and Clinics, Inc. v. Lee.* The University has established a significant degree of practical governance and operational control over Shands entities, as indicated by the following:

⁵ 478 So.2d 77 (Fla. 1st DCA 1985)

⁶ 648 So.2d 778 (Fla 1st DCA 1995)

⁷ 694 So.2d 701 (Fla. 1997)

⁸ 884 So.2d 257 (Fla. 2nd DCA 2004)

• The Shands UF, Shands Jacksonville, and Shands Health governing boards are under the common control of the president of the University of Florida or the president's designee, the senior vice president for health affairs (VPHA).

- The VPHA, the University Board of Trustees, and University officers, faculty, and employees have the authority to maintain a controlling majority of each Shands entity's board of directors and have continually exercised this authority.
- The University president or the VPHA:
 - o Serves as board chairman and has board appointment and removal authority;
 - Serves as president of Shands UF;
 - Actively oversees administration by the chief executive officer of each Shands entity; and
 - O Has officer appointment and removal authority except for the chief executive officers. (The chief executive officers are appointed or removed by the board of each entity, under the common control of the president of the University or the president's designee.)
- Any changes to the charter of Shands UF must be approved by the University Board of Trustees, and any changes to the Shands Jacksonville charter or bylaws must be approved by the University-controlled board of Shands Health.
- Shands UF operates a University teaching hospital on property leased by the University.

The University of Florida J. Hillis Miller Health Center Self-Insurance Program

The Florida Board of Governors⁹ has created the University of Florida J. Hillis Miller Health Center Self-Insurance Program (UF SIP) to provide comprehensive general and professional liability protection for the University of Florida's Board of Trustees in support of the colleges of the UF HSC at both the Gainesville and Jacksonville campuses and their employees, agents, and students.¹⁰

The UF SIP also provides professional liability protection to Shands UF and Shands Jacksonville, their not-for-profit health care affiliates, and their employees and agents. Professional liability protection is provided to Shands hospitals and to their professional health care employees in the amount of \$2 million per claim, with no annual aggregate.

III. Effect of Proposed Changes:

Section 1 amends s. 1004.41, F.S., as follows:

- The University of Florida's College of Health Professions is changed to the College of Public Health and Health Professions.
- Provisions relating to Shands Jacksonville, Shands Health, and the Jacksonville campus of the University of Florida are separated from provisions relating to the Gainesville

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⁹ See s. 7(d), Article IX, Constitution of the State of Florida

¹⁰ See s. 1004.24, F.S.

- campus of the University of Florida and Shands UF by being placed into a new subsection.
- The bill provides that Shands UF is a private not-for-profit corporation organized for the
 primary purpose of supporting the University of Florida Board of Trustees' health affairs
 mission of community service and patient care, education and training of health
 professionals, and clinical research. Current law indicates that Shands UF is organized
 solely for the purpose of operating Shands Teaching Hospital and ancillary health care
 facilities.
- The bill provides that the University president or the president's designee has authority to appoint and remove members of the Shands UF Board of Directors.
- The bill allows for the use of hospital facilities and personnel in support of community service and patient care, in addition to allowable uses in current law.
- The bill allows the University Board of Trustees to provide to Shands UF affiliates comprehensive general liability insurance as is already allowed for Shands UF subsidiaries under current law.
- The bill allows Shands UF, with the prior approval of the University Board of Trustees, to create for-profit and not-for-profit corporate subsidiaries and affiliates.
- The bill provides the University Board of Trustees the right to control Shands UF, and it provides that Shands UF and any not-for-profit subsidiaries are conclusively deemed corporations primarily acting as instrumentalities of the state, pursuant to s. 768.28(2), F.S., for the purposes of sovereign immunity.
- The bill provides that Shands Jacksonville and Shands Health are private not-for-profit corporations organized for the primary purpose of supporting the University of Florida Board of Trustees' health affairs mission of community service and patient care, education and training of health professionals, and clinical research.
- The bill provides that Shands Jacksonville is a teaching hospital affiliated with the University Board of Trustees, located on the University's Jacksonville campus.
- The bill allows Shands Jacksonville and Shands Health, with the prior approval of the University Board of Trustees, to create for-profit and not-for-profit corporate subsidiaries and affiliates.
- The bill provides the University Board of Trustees the right to control Shands
 Jacksonville and Shands Health, and it provides that Shands Jacksonville, Shands Health,
 and any not-for-profit subsidiary of Shands Jacksonville are conclusively deemed
 corporations primarily acting as instrumentalities of the state, pursuant to s. 768.28(2),
 F.S., for the purposes of sovereign immunity.

Section 2 provides an effective date for the bill of July 1, 2011.

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:

By designating certain not-for-profit corporations and subsidiaries as instrumentalities of the state, the bill could render those entities subject to the provisions of Article I, Section 24, of the Florida Constitution relating to access to public records and meetings. It is unclear whether those corporations and subsidiaries would qualify for the exemptions provided under s. 395.3036, F.S.

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.

D. Other Constitutional Issues:

If immunity from liability is legislatively accorded to a private entity, a potential constitutional challenge would be that the law violates the right of access to the courts. Article I, s. 21, of the Florida Constitution provides that the courts shall be open to all for redress for an injury. To impose a barrier or limitation on litigant's right to file certain actions, an extension of immunity from liability would have to meet the test announced by the Florida Supreme Court in *Kluger v. White*. ¹¹ Under the test, the Legislature would have to provide a reasonable alternative remedy or commensurate benefit, or make a legislative showing of overpowering public necessity for the abolishment of the right and no alternative method of meeting such public necessity.

However, a substitute remedy does not need to be supplied by legislation that reduces but does not destroy a cause of action. When the Legislature extends sovereign immunity to a private entity, the cause of action is not constitutionally suspect as a violation of the access to courts provision of the State Constitution because the cause of action is not completely destroyed, although recovery for negligence may be more difficult. 12

V. Fiscal Impact Statement:

A. Tax	/Fee	Issues:
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None.

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¹¹ 281 So.2d 1 (Fla. 1973)

¹² *Id.* at 4.

B. Private Sector Impact:

By deeming Shands UF, Shands Jacksonville, Shands Health, and any not-for-profit subsidiaries of Shands UF or Shands Jacksonville as instrumentalities of the state for the purposes of sovereign immunity, the bill could reduce claim payouts by the UF SIP.

C. Government Sector Impact:

The DFS advises that there is no fiscal impact to the State Risk Management Trust Fund because the Fund does not provide liability coverage to the University of Florida or any Shands entity.

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.)

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.

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.)

	Prepa	red By: The Professional	Staff of the Health Re	gulation Committee
BILL:	SB 446			
INTRODUCER:	Senators F	Hays, Sobel, and Gaetz	Z	
SUBJECT:	Dentistry a	and Dental Hygiene		
DATE:	March 11,	2011 REVISED	:	
ANA	LYST	STAFF DIRECTOR	REFERENCE	ACTION
I. O'Callaghan		Stovall	HR	Pre-meeting
2.			BC	
3.		-	RC	
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I. Summary:

This bill generally expands the scope and area of practice of dental hygienists by authorizing dental hygienists to perform certain duties unsupervised in health access settings, which includes school-based prevention programs and accredited dental hygiene programs. The bill requires dental hygienists, who perform remediable tasks without supervision, to provide a dental referral in compliance with federal and state patient referral, anti-kickback, and patient brokering laws; encourages the establishment of a dental home; and requires the dental hygienists to maintain a certain amount of professional malpractice insurance coverage.

This bill clarifies that the authorization for dental hygienists to perform some duties does not prevent a program operated by one of the health access settings or a nonprofit organization from billing and obtaining reimbursement for the services provided by a dental hygienist.

This bill substantially amends the following sections of the Florida Statutes: 466.003, 466.023, 466.023, 466.024, 466.006, and 466.0067.

This bill also reenacts s. 466.00672, F.S., for the purpose of incorporating the amendment made to s. 466.003, F.S., in the bill.

II. Present Situation:

Oral Health Care

Mouth and throat diseases, which range from cavities to cancer, cause pain and disability for millions of Americans each year. In children, cavities are the most common form of chronic

disease, which often begins at early age. Tooth decay affects more than one-fourth of U.S. children aged 2 to 5 and half of those aged 12 to 15. Low-income children are hardest hit: about two-thirds of those aged 12 to 19 have had decay. Untreated cavities can cause pain, dysfunction, absence from school, difficulty concentrating, and poor appearance - problems that can greatly affect a child's quality of life and reduce a child's capacity to succeed in life.¹

Tooth decay is also a problem for U.S. adults, especially for the increasing number of older adults who have retained most of their teeth. Despite an increase in tooth retention, tooth loss remains a problem among older adults. One-fourth of adults over age 65 have lost all of their teeth - primarily because of tooth decay. Advanced gum disease affects 4 to 12 percent of adults. Tooth loss can affect self-esteem, and it may contribute to nutrition problems by limiting the types of food that a person can eat.²

Shortage of Dentists

The pool of dentists to serve a growing population of Americans is shrinking. The American Dental Association found that 6,000 dentists retire each year in the U.S., while there are only 4,000 dental school graduates each year to replace them. The projected shortage of dentists is even greater in rural America. Of the approximately 150,000 general dentists in practice in the U.S., only 14 percent practice in rural areas, 7.7 percent in large rural areas, 3.7 percent in small rural areas, and 2.2 percent in isolated rural areas. In 2003, there were 2,235 federally designated dental supply shortage areas, 74 percent of which were located in non-metropolitan areas. In contrast, dental hygiene is predicted to be one of the top ten fastest growing health care professions over the next decade, growing by a projected 43 percent between 2006 and 2020.

In 2010, there were 9,373 practicing dentists in Florida, meaning the ratio of dentists to the population in Florida is approximately 1 dentist for every 2,016 residents.⁴ The estimated underserved population in 2008, in Florida, was 2.9 million people or 15.8 percent of the population.⁵

Access to Dental Services in Rural Areas

Most research indicates that access to dental care is significantly more limited in rural areas than in metropolitan areas. According to the National Rural Health Association:⁶

¹ Centers for Disease Control and Prevention, *Oral Health: Preventing Cavities, Gum Disease, Tooth Loss, and Oral Cancers: At a Glance 2010*, available at: http://www.cdc.gov/chronicdisease/resources/publications/AAG/doh.htm (Last visited on March 11, 2011).

² *Id*.

³ National Rural Health Association, *Issue Paper: Recruitment and Retention of a Quality Health Workforce in Rural Areas*, November 2006. A copy of this report is on file with the Senate Health Regulation Committee.

⁴ Professional staff of the Senate Health Regulation Committee received this information via email from the Department of Health on March 11, 2011. A copy of the email is on file with the committee.

⁵ The Henry J. Kaiser Family Foundation, *Florida: Estimated Underserved Population Living in Dental Health Professional Shortage Areas (HPSAs) as of September, 2008*, available at:

http://www.statehealthfacts.org/profileind.jsp?ind=681&cat=8&rgn=11 (Last visited on March 11, 2011).

⁶ National Rural Health Association, *Meeting Oral Health Care Needs in Rural America*, April 2005. A copy of this report is on file with the Senate Health Regulation Committee.

• Even after controlling for population density and income, non-metropolitan counties have lower dentist-to-population ratios (62 dentists per 100,000 population in large metropolitan areas versus 29 dentists per 100,000 population in the most rural counties).

- Rural persons are more likely to have lost all their teeth than their non-rural counterparts; in fact, adults aged 18 to 64 are nearly twice as likely to be edentulous (toothless) if they are rural residents.
- Rural adults are significantly more likely than non-rural adults to have untreated dental decay (32.6 percent versus 25.7 percent).
- In 2001, 67.1 percent of urban residents had visited a dentist in the previous year, while only 58.3 percent of rural Americans had done so.
- Rural residents are less likely than their urban counterparts to have dental insurance.
- Of the 2,235 Dental Health Professional Shortage Areas, 74 percent are in non-metropolitan areas.

According to the National Advisory Committee on Rural Health and Human Services, several factors contribute to the problems of rural oral health:

- *Geographic isolation*. People in remote rural areas have farther to travel to obtain care and fewer dentists, hygienists, and other professionals to provide it.
- Lack of adequate transportation. In many parts of rural America, private automobiles are the only source of transportation. Public transit is non-existent, as are taxicabs and other transportation for hire. Consequently, many rural residents—especially low-income residents—face great difficulty in going to the dentist or any other service provider.
- Lack of fluoridated community water supplies. This most basic preventative treatment against tooth decay is unavailable in countless rural communities.
- *Higher rates of poverty*. Low-income status prevents many people from seeking and obtaining oral health care. It also prevents them from purchasing dental insurance. In addition, rural employers are less likely to purchase or offer dental insurance for their employees due to the smaller average size for most rural employers.
- Larger percentage of elderly population. With increasing age come increasing dental and oral health problems. The percentages of rural Americans who are older and sicker are greater than those of urban Americans, and Medicare does not provide dental benefits.
- Lower dental insurance rates. Insurance reimbursement rates—both public and private—for dental procedures are typically lower in rural areas than in urban. However, the actual costs of providing the services are often higher in rural areas.
- Acute provider shortages. As indicated above, the ratio of dentists per 100,000 population in non-metropolitan counties is less than half of what it is in metropolitan counties. The acute shortage of dentists nationwide is expected to worsen in coming years as dental schools graduate fewer students, despite the fact that dental school applications were up some 18 percent between 2004 and 2005. With the closing of seven dental schools since 1986, and subsequent opening of only three new ones, more people want to become dentists than there are available slots. On top of that, many dentists are nearing retirement age especially in rural areas. In addition, it can be predicted that the combination of increasing levels of dental school indebtedness and fee disparities between urban and rural locations will lead to a reduced percentage of the dental school graduates locating in rural locations.

• Difficulty finding providers willing to treat Medicaid patients. Because of low reimbursement rates, paperwork burdens, and a perception of a higher percentage of broken appointments, many dentists simply do not accept Medicaid or State Children's Health Insurance Program (SCHIP) patients, of which there are many in rural America due to the higher proportion of people living in poverty.⁷

The Florida county health departments have several dental facilities that cannot serve patients because they do not have any dentists to provide dental care. Several other county health departments have some dentists but are in serious need of additional dentists to deliver care to low income and underserved Floridians. The DOH has had difficulty in recruiting and retaining public health dentists. There were 106 full time equivalent (FTE) dentists in county health departments during the DOH's Fiscal Year 2009-10.

Florida Board of Dentistry

Section 466.004, F.S., establishes the Board of Dentistry within the DOH. The board consists of 11 members who are appointed by the Governor and subject to confirmation by the Senate. Seven members of the board must be licensed dentists in this state; two members must be licensed dental hygienists actively engaged in the practice of dental hygiene in this state; and the remaining two members must be laypersons who are not, and have never been, dentists, dental hygienists, or members of any closely related profession or occupation.

Each member of the board who is a licensed dentist must have been actively engaged in the practice of dentistry primarily as a clinical practitioner for at least 5 years immediately preceding the date of her or his appointment to the board and must remain primarily in clinical practice during all subsequent periods of appointment to the board. At least one member of the board must be 60 years of age or older. Members shall be appointed for 4-year terms, but may serve no more than a total of 10 years.

Dental Hygienists

In Florida, dental hygienists are regulated by ss. 466.023, 466.0235, and 466.024, F.S. Dental hygienists are focused on preventing dental disease. They are educated and trained to evaluate the patient's oral health; expose, process and interpret dental X-ray films; and remove calculus deposits, stains, and plaque above and below the gumline. They also apply preventive agents such as fluorides and sealants to teeth when allowed by state regulations.

Dental hygienists provide education about oral health care, selecting toothbrushes, the use of dental floss, and oral health problems related to diet or use of tobacco products. Additionally, dental hygienists receive training in assisting and reception responsibilities so they can be comprehensive team members in the dental practice.

⁷ *Id.* (citing the National Advisory Committee on Rural Health and Human Services).

⁸ Supra fn. 4.

⁹ Section 466.023, F.S.

¹⁰ See Rule 64B5-16.006, Remediable Tasks Delegable to a Dental Hygienist, F.A.C.

Current law, s. 466.024, F.S., sets forth tasks that may be delegated and authorizes the board to identify additional tasks that are remedial and may be delegated. Other tasks cannot be performed by a dental hygienist without supervision. Delegable tasks under this section of law include:

- Taking impressions for study casts but not for the purpose of fabricating any intraoral restorations or orthodontic appliance;
- Placing periodontal dressings;
- Removing periodontal or surgical dressings;
- Removing sutures;
- Placing or removing rubber dams;
- Placing or removing matrices;
- Placing or removing temporary restorations;
- Applying cavity liners, varnishes, or bases;
- Polishing amalgam restorations;
- Polishing clinical crowns of the teeth for the purpose of removing stains but not changing the existing contour of the tooth; and
- Obtaining bacteriological cytological specimens not involving cutting of the tissue.

These limits on delegable tasks prevent the maximization of the existing workforce by prohibiting dental hygienists from providing preventive services, such as placing sealants, in public health settings without a dentist present or without prior authorization.

Other factors also limit the ability of the state to use dental hygienists to expand access to dental care. Currently, a dental hygienist may not treat a patient that has no record within the past 13 months with a facility dentist. This means that, for example, when a child shows up to receive a dental hygiene cleaning or fluoride treatment, the dental hygienist on staff may not provide these routine services without a dentist first authorizing the treatment. In effect, this means that the county health department must turn away patients at facilities that have no dentist, or limited dentists, on staff. This also means that the department's dental hygiene workforce is not being fully utilized.

III. Effect of Proposed Changes:

This bill generally expands the scope and area of practice of dental hygienists by authorizing dental hygienists to perform certain duties unsupervised in health access settings.

Section 1 amends s. 466.003, F.S., to change the definition of the term "health access setting" to include a school-based prevention program and an accredited dental hygiene program. The term "school-based prevention program" is defined to mean preventative oral health services offered at a school by one of the entities included in the definition of a health access setting or by a nonprofit organization that is exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c)(3) of the Internal Revenue Code.

¹¹ See Rule 64B5-16.001, Definitions of Remediable Tasks and Supervision Levels, F.A.C.

Section 2 amends s. 466.023, F.S., to authorize dental hygienists to perform their duties in a health access setting and perform certain services without supervision, including apply fluorides, instruct a patient in oral hygiene care, and supervise the oral hygiene care of a patient.

Section 3 amends s. 466.0235, F.S., to authorize a dental hygienist, without supervision and within the lawful scope of his or her duties as authorized by law, perform dental charting of hard and soft tissues in health access settings.

Section 4 amends s. 466.024, F.S., to authorize dental hygienists licensed in Florida to perform certain remedial tasks in health access settings without the physical presence of, prior examination by, or authorization of, a dentist. Specifically, dental hygienists are authorized to:

- Perform dental charting, which is defined under s. 466.0235, F.S. as a recording of visual observations of clinical conditions of the oral cavity without the use of X-rays, laboratory tests, or other diagnostic methods or equipment, except the instruments necessary to record visual restorations, missing teeth, suspicious areas, and periodontal pockets.
- Measure and record a patient's blood pressure rate, pulse rate, respiration rate, and oral temperature.
- Record a patient's case history.
- Apply topical fluorides, including fluoride varnishes, which are approved by the American Dental Association or the Food and Drug Administration.
- Apply dental sealants.
- Remove calculus (dental tartar) deposits, accretions, and stains from exposed surfaces of the teeth and from tooth surfaces within the gingival sulcus, if a dentist licensed under ch. 466, F.S. or a physician licensed under ch. 458 or ch. 459, F.S., gives medical clearance before the dental hygienist removes such deposits, accretions, and stains. A dentist is required to conduct a dental examination on a patient within 13 months after a dental hygienist removes such deposits, accretions, and stains and additional oral hygiene services of this type may not be performed without a clinical examination by a dentist who is licensed under ch. 466, F.S.

The authorization to perform the above services does not authorize a dental hygienist to perform root planing or gingival curettage¹² without supervision by a dentist.

A dental hygienist must provide to the patient in writing before any remediable task is performed in a health access setting without the physical presence of, prior examination by, or authorization of a dentist a disclaimer which must state that the services being offered are not a substitute for a comprehensive dental exam by a dentist and the diagnosis of caries, soft tissue disease, oral cancer, temporomandibular joint disease (TMJ), and dentofacial malocclusions will be completed only by a dentist in the context of delivering a comprehensive dental exam.

This section clarifies that authorization for dental hygienists to perform the above services does not prevent a program operated by one of the health access settings or a nonprofit organization that is exempt from federal income taxation under s. 501(a) of the Internal Revenue Code and

¹² Gingival curettage is a surgical procedure designed to remove the soft tissue lining of the periodontal pocket with a curet, leaving only a gingival connective tissue lining. American Academy of Periodontology, *The American Academy of Periodontology Statement Regarding Gingival Curettage*, available at: http://www.perio.org/resources-products/pdf/38-curettage.pdf (Last visited on March 10, 2011).

described in s. 501(c)(3) of the Internal Revenue Code from billing and obtaining reimbursement for such services or from making or maintaining any records necessary to obtain reimbursement.

This section requires dental hygienists who perform, without supervision, the above-listed remedial tasks to provide a dental referral in strict compliance with federal and state patient referral, anti-kickback, and patient brokering laws and encourages the establishment of a dental home. A dental hygienist performing such tasks must also maintain professional malpractice insurance coverage that has minimum limits of \$100,000 per occurrence and \$300,000 in the aggregate through the employing health access setting or individual policy.

Section 5 amends s. 466.006, F.S., to make cross-reference corrections to conform to changes made by the bill and clarifies that an applicant for a dental license must successfully complete the National Board of Dental Examiners dental examination within 10 years after the date of application. Currently, an applicant can take the examination anytime within 10 years of the date of application, including prior to the application.

Section 6 amends s. 466.0067, F.S., to correct a cross-reference to conform to changes made by the bill.

Section 7 reenacts s. 466.00672, F.S., for the purpose of incorporating the amendment made by the bill to s. 466.003, F.S.

Section 8 provides that the bill shall take effect upon becoming a law.

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.

BILL: SB 446 Page 8 B. **Private Sector Impact:** None. C. **Government Sector Impact:** None. 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.) None.

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

B.

Amendments:

None.

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepared By: Th	ne Professional S	staff of the Criminal	Justice Commi	ttee	
BILL:	CS/SB 432					
INTRODUCER:	Criminal Justice Co	mmittee and So	enator Evers			
SUBJECT:	Privacy of Firearm	Owners				
DATE:	February 22, 2011	REVISED:				
ANAL 1. Cellon 2. 3. 4. 5. 5.	YST STAF	on	REFERENCE CJ HR JU BC	Fav/CS	ACTION	
	Please see S A. COMMITTEE SUBST B. AMENDMENTS	TITUTE X	for Addition Statement of Subs Technical amenda Amendments were Significant amend	stantial Chang nents were rec e recommende	es commended ed	

I. Summary:

The bill creates a noncriminal violation in circumstances where a public or private physician, nurse, or other medical staff person conditions receipt of medical treatment or care on a person's willingness or refusal to disclose "personal and private information unrelated to medical treatment" in violation of the privacy right created by the bill regarding ownership or possession of firearms.

The bill also creates a noncriminal violation where a public or private physician, nurse, or other medical staff person enters information concerning firearms into any record or otherwise discloses such information to any other source, whether intentionally, inadvertently, or accidentally.

The bill states that an inquiry of a patient or his or her family regarding the ownership or possession of firearms in the home by a public or private physician, nurse, or other medical staff person constitutes an invasion of privacy.

The state attorney is given responsibility for investigating and prosecuting the noncriminal violations.

The defendant may be assessed up to a \$100,000 fine, on a third offense, if the court finds the violation is knowing and willful. The Attorney General is charged with filing suit to collect any fine that remains unpaid after 90 days.

Certain mental health care professionals as statutorily defined, and physicians, nurses, and other medical personnel are exempted from the provisions in the bill in cases where inquiries are reasonably necessary under emergency circumstances such as where the patient is exhibiting conduct that indicates the patient could pose an imminent threat to himself, herself, or others. The patient's response is private and shall not be disclosed to a third party, other than law enforcement conducting an active investigation, under the provisions of the bill.

The bill further exempts medical records created on or before the effective date of the bill from the prohibitions created by the bill.

This bill creates a new section of the Florida Statutes: 790.338.

II. Present Situation:

Physicians Inquiring About Firearms

In recent months, there has been media attention surrounding an incident in Ocala, Florida, where, during a routine doctor's visit, an Ocala pediatrician asked a patient's mother whether there were firearms in the home. When the mother refused to answer, the doctor advised her that she had 30 days to find a new pediatrician. The doctor stated that he asked all of his patients the same question in an effort to provide safety advice in the event there was a firearm in the home. He further stated that he asked similar questions about whether there was a pool at the home, and whether teenage drivers use their cell phone while driving for similar reasons — to give safety advice to patients. The mother, however, felt that the question invaded her privacy. This incident has led many to question whether it should be an accepted practice for a doctor to inquire about a patient's firearm ownership.

Various professional medical groups have adopted policies that encourage or recommend that physicians ask patients about the presence of a firearm in the home. For example, the American Medical Association (AMA) encourages its members to inquire as to the presence of household firearms as a part of childproofing the home and to educate patients to the dangers of firearms to children.⁴

¹ Family and pediatrician tangle over gun question,

http://www.ocala.com/article/20100723/news/100729867/1402/news?p=1&tc=pg (last accessed January 27, 2011).

 $^{^{2}}$ Id.

 $^{^3}$ Id.

⁴ H-145.990 Prevention of Firearm Accidents in Children https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fama1%2fpub%2fupload%2fmm%2fPolicyFinder%2fpolicyFiles%2fHnE%2fH-145.990.HTM (last accessed January 28, 2011).

Additionally, the American Academy of Pediatrics (AAP) recommends that pediatricians incorporate questions about guns into their patient history taking.⁵

Florida law contains numerous provisions relating to the regulation of the medical profession, regulation of medical professionals, and the sale, purchase, possession, and carrying of firearms. However, Florida law does not contain any provision that prohibits physicians or other medical staff from asking a patient whether he or she owns a firearm or whether there is a firearm in the patient's home.

Terminating the Doctor - Patient Relationship

The relationship between a physician and a patient is generally considered a private relationship and contractual in nature. According to the AMA, both the patient and the physician are free to enter into or decline the relationship. Once a physician-patient relationship has been established, patients are free to terminate the relationship at any time. Generally, doctors can only terminate existing relationships after giving the patient notice and a reasonable opportunity to obtain the services of another physician. Florida's statutes do not currently contain any provisions that dictate when physicians and patients can terminate a doctor-patient relationship.

III. Effect of Proposed Changes:

The bill creates s. 790.338, F.S., entitled "Medical privacy concerning firearms." The bill specifies that a verbal or written inquiry by a public or private physician, nurse, or other medical staff person regarding the ownership of a firearm by a patient or the family of a patient or the presence of a firearm in a private home or other domicile of a patient or the family of a patient violates the privacy of the patient or the patient's family members. ¹⁰

⁵ American Academy of Pediatrics: Firearm-Related Injuries Affecting the Pediatric Population. Pediatrics Vol. 105 No. 4 April 2000, pp. 888-895. http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/4/888 (last accessed January 28, 2011). See also American Academy of Pediatrics, Committee on Injury, Violence, and Poison Prevention, "TIIP (The Injury Prevention Program), A Guide to Safety Counseling in Office Practice", 1994.

⁶ See, e.g., Chapters 456, 458, 790, F.S.

⁷ AMA Code of Medical Ethics, Opinion 9.12, *Patient-Physician Relationship: Respect for Law and Human Rights*, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion912.shtml (last accessed February 7, 2011). Doctors who offer their services to the public may not decline to accept patients because of race, color, religion, national origin, sexual orientation, gender identity, or any other basis that would constitute invidious discrimination.

⁸ AMA's Code of Medical Ethics, Opinion 9.06 *Free Choice.* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion906.shtml (last accessed February 7, 2011).

A health care provider owes a duty to the patient to provide the necessary and appropriate medical care to the patient with due diligence and to continue providing those services until: 1) they are no longer needed by the patient; 2) the relationship is ended with the consent of or at the request of the patient; or 3) the health care provider withdraws from the relationship after giving the patient notice and a reasonable opportunity to obtain the services of another health care provider. The relationship typically terminates when the patient's medical condition is cured or resolved, and this often occurs at the last visit when the health care provider notes in his records that the patient is to return as needed. *See Saunders v. Lischkoff*, 188 So. 815 (Fla. 1939). *See also, Ending the Patient-Physician Relationship*, AMA White Paper http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8115.shtml (last accessed February 7, 2011).

¹⁰ Invading someone's privacy is not a criminal act. However, there is a common law tort claim of invasion of privacy. *See Allstate Insurance Company v. Ginsberg*, 863 So.2d 156 (Fla. 2003) where the Florida Supreme Court reaffirms the four types of claims of invasion of privacy recognized by Florida courts: "As recognized in *Agency for Health Care*

The bill creates a noncriminal violation if a public or private physician, nurse, or other medical staff:

• Conditions receipt of medical treatment or care on a person's willingness or refusal to disclose personal and private information unrelated to medical treatment in violation of an individual's privacy, as specified in the bill.

• Enters any intentionally, accidentally, or inadvertently disclosed information concerning firearms into any record, whether written or electronic, or discloses such information to any other source.

The bill also provides that a person who violates s. 790.338, F.S., may be assessed a fine of no less than \$10,000 for a first violation, \$25,000 for a second violation, and \$100,000 for a third violation if the court determines that the violation was knowing and willful.

The bill requires the state attorney with jurisdiction to investigate complaints of criminal violations of s. 790.338, F.S., and, if there is probable cause to indicate that a person may have committed a violation, to prosecute the violator and notify the Attorney General of the prosecution. The bill requires the Attorney General to bring a civil action to enforce any fine assessed if such fine is not paid after 90 days.

Certain mental health care professionals as statutorily defined, and physicians, nurses, and other medical personnel are exempted from the provisions in the bill in cases where inquiries are reasonably necessary under emergency circumstances such as where the patient is exhibiting conduct that indicates the patient could pose an imminent threat to himself, herself, or others. The patient's response is private and shall not be disclosed to a third party, other than law enforcement conducting an active investigation, under the provisions of the bill.

The bill further exempts medical records created on or before the effective date of the bill from the prohibitions created by the bill.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

Administration v. Associated Industries of Florida, Inc., 678 So.2d 1239, 1252 n. 20 (Fla.1996) (hereinafter AHCA), the four categories are: (1) appropriation-the unauthorized use of a person's name or likeness to obtain some benefit; (2) intrusion-physically or electronically intruding into one's private quarters; (3) public disclosure of private facts-the dissemination of truthful private information which a reasonable person would find objectionable; and (4) false light in the public eye-publication of facts which place a person in a false light even though the facts themselves may not be defamatory." As the dissenting opinion notes, the common law tort of invasion of privacy, or any common law tort is an area of the law that is subject to evolution. It would appear that SB 432 creates a new statutory category in the area of invasion of privacy torts.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Although this bill states that inquiries by certain medical professionals about the ownership of a firearm or presence of a firearm in the home of a patient or his or her family violates the patient's or the family's privacy, it should not be forgotten that the individual's right to exercise free speech is only regulated in the most egregious of circumstances.

It should also be noted that any civil action that might ensue will likely raise issues surrounding personal, professional, and contractual obligations between the parties, and the weight given to a constitutionally-protected right (free speech) versus a right to privacy created by general law, as between the two parties.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

A public or private physician, nurse, or other medical staff person who is found to have violated the law created by the bill could be assessed up to a \$100,000 fine for a third violation.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill creates s. 790.338, F.S., to make it a noncriminal violation for a *public or private physician, nurse, or other medical staff* to do certain acts. The bill does not define these terms, nor are they defined in ch. 790, F.S. Defining these terms, or using a term already defined in Florida law such as "healthcare practitioner," would clarify to whom the penalties apply.

Also, the term "unrelated to medical treatment" on line 39 of the bill may create a loophole to prosecution in that the term invites challenge and argument as to what is or is not "unrelated."

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 Criminal Justice on February 22, 2011:

- Removes the criminal penalties from the bill and instead provides for noncriminal violations which could result in graduated fines for each successive violation of the prohibitions in the bill.
- Provides limited exemptions from the prohibitions in the bill in the course of
 emergency treatment, including mental health emergencies, and where certain mental
 health professionals believe it is necessary to inquire about firearm possession. The
 patient's response is only to be disclosed to others participating in the patient's
 treatment or to law enforcement conducting an active investigation of the events
 giving rise to a medical emergency.
- Provides an exemption for medical records created on or before the effective date of the bill.

B. Amendments:

None.

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

Senator Evers has requested that we Temporarily Postpone SB 432

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepared By: The Professional Staff of the Health Regulation Committee						
BILL:	SB 1414						
INTRODUCER:	Senator Wis	se					
SUBJECT:	Health Insur	rance					
DATE:	March 11, 2	011 REVISED:					
ANAL	YST	STAFF DIRECTOR	REFERENCE	ACTION			
1. Brown		Stovall	HR	Pre-meeting			
2.			BI				
3.			BC				
1.							
5.							
5. <u> </u>							

I. Summary:

The bill creates three new sections of statute within the Insurance Code designed to prevent a health insurance policy under which coverage is purchased with any state or federal funds through an exchange created under the federal Patient Protection and Affordable Care Act (PPACA) from providing coverage for an abortion unless the pregnancy is the result of an act of rape or incest or a physician certifies in writing that an abortion is necessary to save the life of the mother. The bill deems coverage to be purchased with state or federal funds if any tax credit or cost-sharing credit is applied to the policy. The bill provides that policies are allowed to provide separate coverage for an abortion if that separate coverage is not purchased with any state or federal funds. The bill defines "state" to mean the state of Florida or any political subdivision of the state.

This bill creates the following sections of the Florida Statutes: 627.64995, 627.66995, and 641.31099.

The bill substantially amends the following section of the Florida Statutes: 627.6515.

II. Present Situation:

The Federal Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA) into law. The PPACA is a broad-based, national approach to reform various aspects of health insurance coverage, including the requirement for most U.S. citizens and legal residents to have health insurance by January 1, 2014. Under PPACA, those without coverage

pay a tax penalty of the greater of \$695 per year up to a maximum of three times that amount (\$2,085) per family or 2.5 percent of household income.

The PPACA contains a number of measures that attempt to make coverage more affordable and accessible. The PPACA allows states to create "exchanges" where individuals can purchase insurance and separate exchanges for small employers to purchase insurance, effective January 1, 2014. The PPACA allows for premium and cost-sharing subsidies to make exchange coverage more affordable. Details include:

- Individual coverage will be available through an "American Health Benefit Exchange."
- Small businesses with up to 100 employees can purchase coverage through a "Small Business Health Options Program" (SHOP) exchange. (Businesses with more than 100 employees can purchase coverage in a SHOP exchange beginning in 2017.)
- Plans in exchanges will be required to offer benefits that meet a minimum set of standards. Insurers will offer four levels of coverage that vary based on premiums, outof-pocket costs, and benefits beyond the minimum required, plus a catastrophic coverage plan.
- Premium subsidies will be provided to families with incomes between 100-400 percent of the poverty level (\$29,327 to \$88,200 for a family of four in 2009) to help them purchase insurance through the exchanges. These subsidies will be offered on a sliding scale basis and will limit the cost of the premium to between 2 percent of income for those up to 133 percent of the poverty level and 9.5 percent of income for those between 300-400 percent of the poverty level.
- Cost-sharing subsidies will also be available to people with incomes between 100-400 percent of the poverty level to limit out-of-pocket spending.

Abortion Coverage Under PPACA Exchanges

The PPACA contains specific provisions permitting states to prohibit plans participating in an exchange from providing coverage for abortions. The PPACA requires exchange plans that choose to offer coverage for abortions beyond coverage for which federal funds are permitted (to save the life of the woman and in cases of rape or incest), in states that allow such coverage, to create funding accounts for segregating premium payments for coverage of abortion services from premium payments for coverage for all other services. This is designed to ensure that no federal premium or cost-sharing subsidies are used to pay for the abortion coverage. Plans must also estimate the actuarial value of covering abortions by taking into account the cost of the abortion benefit (valued at no less than \$1 per enrollee per month) and cannot take into account any savings that might be reaped as a result of abortions. The PPACA prohibits exchange plans from discriminating against any provider because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.

Abortion in Florida Law

Under Florida law the term "abortion" means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.2 "Viability" means that

¹ 42 U.S.C. s. 18023

² Section 390.011, F.S.

stage of fetal development when the life of the unborn child may, with a reasonable degree of medical probability, be continued indefinitely outside the womb.³ Induced abortion can be elective (performed for nonmedical indications) or therapeutic (performed for medical indications). Abortion can be performed by surgical or medical means (medicines that induce a miscarriage).⁴ An abortion in Florida must be performed by a physician licensed to practice medicine or osteopathic medicine who is licensed under ch. 458, F.S., ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.⁵ No person who is a member of, or associated with, the staff of a hospital, or any employee of a hospital or physician in which, or by whom, the termination of a pregnancy has been authorized or performed, who states an objection to the procedure on moral or religious grounds is required to participate in the procedure. The refusal to participate may not form the basis for any disciplinary or other recriminatory action.⁶

The Hyde Amendment

The Hyde Amendment is the common name for a provision in the annual federal appropriations act for the U.S. Departments of Labor, Health and Human Services (HHS), and Education, which prevents Medicaid and any other programs under these departments from funding abortions, except in limited cases. The amendment is named after Rep. Henry J. Hyde (R-IL) who, as a freshman legislator, first offered the amendment.

The Hyde Amendment is not perpetually effective. By the nature of appropriations acts, which expire with each federal fiscal year unless extended temporarily, the provisions of the Hyde language must be reenacted with each annual federal budget in order to remain in effect.

The Hyde Amendment has been enacted into law in various forms since 1976, during both Democratic and Republican administrations. In 1980, the U.S. Supreme Court affirmed the constitutionality of the Hyde Amendment in *Harris v. McRae*. In *Harris*, the Court determined that funding restrictions created by the Hyde Amendment did not violate the U.S. Constitution's Fifth Amendment, and therefore, did not controvene the liberty or equal protection guarantees of the Due Process Clause of the Fifth Amendment. The court opined that although government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those obstacles that are not created by the government (in this case indigence). The court further opined that although Congress has opted to subsidize medically necessary services generally, but not certain medically necessary abortions, the Hyde Amendment leaves an indigent woman with at least the same range of choice in deciding whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all.

³ Section 390.0111, F.S.

⁴ Suzanne R. Trupin, M.D., *Elective Abortion*, December 21, 2010, available at: http://www.emedicine.com/med/TOPIC3312.HTM (Last visited on March 11, 2011).

⁵ Section 390.0111(2), F.S.

⁶ Section 390.0111(8), F.S.

⁷ 448 U.S. 297 (1980). See also Rust v. Sullivani, 500 U.S. 173 (1991) and Webster v. Reproductive Health Services, 492 U.S. 490 (1989), upholding Harris v. McRae.

⁸ *Harris*, 448 U.S. at 316-317.

In Florida, based on the Hyde Amendment, Medicaid reimburses for abortions for one of the following reasons:

- The woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused or arising from the pregnancy itself, that would place the woman in danger of death unless an abortion is performed;
- When the pregnancy is the result of rape (sexual battery) as defined in s. 794.011, F.S.; or
- When the pregnancy is the result of incest as defined in s. 826.04, F.S.⁹

In such cases, the state Medicaid program requires an Abortion Certification Form to be completed and signed by the physician who performed the abortion. The form must be submitted with the facility claim, the physician's claim, and the anesthesiologist's claim. The physician must record the reason for the abortion in the physician's medical records for the recipient.¹⁰

III. Effect of Proposed Changes:

Sections 1, 2, and 3 create s. 627.64995, F.S., s. 627.66995, F.S., and s. 641.31099, F.S., respectively, relating to individual health insurance policies, group health insurance policies, and health maintenance organization contracts, respectively, to prevent coverage issued under those sections that is purchased with any state or federal funds through an exchange created under the PPACA from providing coverage for an abortion unless the pregnancy is the result of an act of rape or incest or a physician certifies in writing that an abortion is necessary to save the life of the mother. The bill deems coverage to be purchased with state or federal funds if any tax credit or cost-sharing credit is applied to the policy.

The bill provides that such policies are allowed to provide separate coverage for an abortion if that separate coverage is not purchased with any state or federal funds.

The bill defines "state" to mean the state of Florida or any political subdivision of the state.

Section 4 amends s. 627.6515, F.S., relating to out-of-state health insurance policies, to provide that part VII of ch. 627, F.S., relating to group, blanket, and franchise health insurance policies, does not apply to a group health insurance policy issued or delivered outside of Florida under which a Florida resident is provided coverage if the policy provides benefits specified in a list of multiple sections of statute. The bill adds s. 627.66995 to that list, indicating that if an out-of-state group policy provides separate coverage for abortion that is not purchased with any state or federal funds, then part VII of ch. 627, F.S., would not apply to that policy.

Section 5 provides an effective date for the bill of July 1, 2011.

⁹ Agency for Health Care Administration, *Florida Medicaid: Ambulatory Surgery Center Services Coverage and Limitations Handbook*, January 2005, available at:

http://www.baccinc.org/medi/CD_April_2005/Provider_Handbooks/Medicaid_Coverage_and_Limitations_Handbooks/Amb ulatory_Surgical_Center_Updated_January_2005.pdf (Last visited on March 11, 2011).

10 Id.

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:

None.

B. Private Sector Impact:

The Office of Insurance Regulation (OIR) advises that if health plans offer coverage through a PPACA exchange and those plans operate a separate accounting for coverage paid for with any amount of state or federal funds versus coverage not paid for with any state or federal funds, as indicated in the bill, the health plans could incur some measure of administrative cost resulting from this legislation.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The OIR notes that in section 1 of the bill, the language created in s. 627.64995, F.S., relating to individual health insurance policies, includes "or group health insurance policy" and advises that "or group health insurance policy" should be deleted. Section 627.601(2), F.S., specifically excludes application of provisions within part VI of ch. 627 to group policies within part VII.

VII. Related Issues:

If section 2 of the bill is intended to apply to small group policies under s. 627.6699, F.S., the bill should be amended to specifically apply to that section of statute. The provisions of s. 627.6699(16), F.S., could prevent the provisions of s. 627.66995, F.S., which is created by the bill, from applying to small group policies under s. 627.6699, 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.



LEGISLATIVE ACTION Senate House

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

Senate Amendment (with title amendment)

Between lines 91 and 92 insert:

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Section 5. (1) Any qualified health plan offered through an exchange established in this state pursuant to and as a result of the federal Patient Protection and Affordable Care Act, Pub. L. No. 111-148, may not use any state funds to pay for any abortion services except for those abortions for which public funding is allowed under 42 U.S.C. s. 18023.

(2) Any qualified health plan offered through an exchange established in this state pursuant to and as a result of the



federal Patient Protection and Affordable Care Act, Pub. L. No. 111-148, which covers abortion services beyond those permitted in 42 U.S.C. s. 18023 must ensure compliance with the segregation-of-funds requirements under 42 U.S.C. s. 18023.

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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:

Delete line 11

and insert:

residents of the state; prohibiting any qualified health plan offered through an exchange established under the federal Patient Protection and Affordable Care Act from using any state funds to pay for abortion services; providing an exception; requiring such qualified health plan to ensure compliance with the segregation-of-funds requirements under the Patient Protection and Affordable Care Act; providing an effective date.

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	red By: Th	ne Professional S	taff of the Health Re	gulation Committee
BILL:	SJR 1538				
INTRODUCER:	Senator Flo	ores			
SUBJECT:	Abortion/P	Public Fu	ınding/Construc	ction of Rights	
DATE:	March 11,	2011	REVISED:	3/14/2011	
ANAI	LYST	STA	FF DIRECTOR	REFERENCE	ACTION
I. O'Callaghan/Brown		Stov	all	HR	Pre-meeting
2.				JU	
3.				BC	
4.				RC	
5.					
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I. Summary:

This is a joint resolution proposing the creation of Section 28 of Article I of the Florida Constitution, to prohibit the spending of public funds for any abortion or for health-benefits coverage that includes the coverage of abortion, unless such expenditure is required by federal law or is required to save the life of the mother. The joint resolution specifies that the Florida Constitution may not be interpreted to create broader rights to an abortion than those contained in the U.S. Constitution.

This joint resolution also includes a ballot summary, which outlines the provisions of the joint resolution.

This joint resolution does not amend, create, or repeal any sections of the Florida Statutes.

II. Present Situation:

Background

Under Florida law the term "abortion" means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead fetus. "Viability" means that stage of fetal development when the life of the unborn child may, with a reasonable degree of medical probability, be continued indefinitely outside the womb. Induced abortion can be elective (performed for nonmedical indications) or therapeutic (performed for medical

¹ Section 390.011, F.S.

² Section 390.0111, F.S.

BILL: SJR 1538 Page 2

indications). Abortion can be performed by surgical or medical means (medicines that induce a miscarriage).³ An abortion in Florida must be performed by a physician licensed to practice medicine or osteopathic medicine who is licensed under ch. 458, F.S., ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.⁴ No person who is a member of, or associated with, the staff of a hospital, or any employee of a hospital or physician in which, or by whom, the termination of a pregnancy has been authorized or performed, who states an objection to the procedure on moral or religious grounds is required to participate in the procedure. The refusal to participate may not form the basis for any disciplinary or other recriminatory action.⁵

In 2007, a total of 91,954 abortions were performed in Florida: for 83,890 of those, the gestational age of the fetus was 12 weeks and under; for 8,063, the gestational age of the fetus was 13 to 24 weeks; and for 1, the gestational age was over 25 weeks.⁶

Abortion Clinics

Abortion clinics are licensed and regulated by the Agency for Health Care Administration (Agency) under ch. 390, F.S., and part II of ch. 408, F.S. The Agency has adopted rules in Chapter 59A-9, Florida Administrative Code, related to abortion clinics. Section 390.012, F.S., requires these rules to address the physical facility, supplies and equipment standards, personnel, medical screening and evaluation of patients, abortion procedures, recovery room standards, and follow-up care. The rules relating to the medical screening and evaluation of each abortion clinic patient, at a minimum, require:

- A medical history including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history;
- A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa;
- The appropriate laboratory tests, including:
 - For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy performed before the abortion procedure,
 - o A test for anemia.
 - o Rh typing, unless reliable written documentation of blood type is available, and
 - Other tests as indicated from the physical examination;
- An ultrasound evaluation for patients who elect to have an abortion after the first trimester. If a person who is not a physician performs the ultrasound examination, that person must have documented evidence that he or she has completed a course in the operation of ultrasound equipment. If a patient requests, the physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant must review the ultrasound evaluation results and the estimate of the probable gestational age of the fetus with the patient before the abortion procedure is performed; and

³ Suzanne R. Trupin, M.D., *Elective Abortion*, December 21, 2010, available at: http://www.emedicine.com/med/TOPIC3312.HTM (Last visited on March 11, 2011).

⁴ Section 390.0111(2), F.S.

⁵ Section 390.0111(8), F.S.

⁶ Florida Vital Statistics Annual Report 2007, available at: http://www.flpublichealth.com/VSBOOK/VSBOOK.aspx# (Last visited on March 11, 2011).

BILL: SJR 1538 Page 3

• The physician to estimate the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age and write the estimate in the patient's medical history. The physician must keep original prints of each ultrasound examination in the patient's medical history file.

Relevant Case Law

In 1973, the landmark case of *Roe v. Wade* established that restrictions on a woman's access to secure an abortion are subject to a strict scrutiny standard of review. In *Roe*, the Court determined that a woman's right to have an abortion is part of the fundamental right to privacy guaranteed under the Due Process clause of the Fourteenth Amendment of the U.S. Constitution, justifying the highest level of review. Therefore, a state regulation limiting these rights may be justified only by a compelling state interest and the legislative enactments must be narrowly drawn to express only legitimate state interests at stake.⁷

In 1992, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the U.S. Supreme Court relaxed the standard of review in abortion cases involving adult women from strict scrutiny to unduly burdensome, while still recognizing that the right to an abortion emanates from the constitutional penumbra of privacy rights. In *Planned Parenthood*, the Court determined that prior to fetal viability, a woman has the right to an abortion without being unduly burdened by government interference.

The unduly burdensome standard, generally considered to be a hybrid between strict scrutiny and intermediate level scrutiny, shifted the Court's focus to whether a restriction creates a substantial obstacle to access. This is the prevailing standard today applied in cases in which abortion access is statutorily restricted.

However, the undue burden standard was held not to apply in Florida. The 1999 Legislature passed a parental notification law, the Parental Notice of Abortion Act, requiring a physician to give at least 48 hours of actual notice to one parent or to the legal guardian of a pregnant minor before terminating the pregnancy of the minor. Although a judicial waiver procedure was included, the act was never enforced. In 2003, the Florida Supreme Court ruled this legislation unconstitutional on the grounds that it violated a minor's right to privacy, as expressly protected under Article I, s. 23 of the Florida Constitution. Citing the principle holding of *In re T.W.*, the Court reiterated that, as the privacy right is a fundamental right in Florida, any

⁷ 410 U.S. 113, 114, 152 (1973).

⁸ 505 U.S. 833, 834 (1992).

⁹ *Id.* at 837.

 $^{^{10}}$ See s. 390.01115, F.S. (Repealed by s. 1, ch. 2005-52, Laws of Florida). Subsequent legislation was enacted in s. 390.01114, F.S.

¹¹ North Florida Women's Health and Counseling Services, Inc., et al., v. State of Florida, 866 So.2d 612, 619 (Fla. 2003)

¹² The constitutional right of privacy provision reads: "Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law." FLA. CONST. art. I, s. 23. ¹³ 551 So.2d 1186, 1192 (Fla. 1989).

restrictions on privacy warrant a strict scrutiny review, rather than that of an undue burden. Here, the Court held that the state failed to show a compelling state interest.¹⁴

In 1997, the Florida Legislature enacted the Woman's Right to Know Act. This act essentially prohibits termination of pregnancy procedures from being performed or induced unless voluntary and informed consent is obtained. The Woman's Right to Know Act was challenged shortly after enactment. The Florida Supreme Court ruled on the constitutionality of one part of the informed consent, that portion in s. 390.0111(3)(a)1, F.S., related to the oral information required to be provided to the patient by the referring physician or physician who is to perform the procedure. 15 The court ruled that the informational requirements of s. 390.0111(3)(a)1., F.S., are comparable to those of the common law and other Florida informed consent statutes implementing the common law. 16 The Court adopted the state's interpretation of the "reasonable patient" language to require a physician to consider only and exclusively the individual circumstances of each patient presenting herself for treatment in determining what information is material to that patient's decision, and therefore the statute is not unconstitutionally vague. The Court also adopted the state's contention that the risks that a physician must discuss with the patient is limited to medical risks pertaining to terminating or not terminating a pregnancy, not information with regard to social, economic, or any other risks. The Court noted that physicians are not sociologists, economists, theologians, or philosophers, and it is implausible to conclude that the Legislature intended that physicians be required to venture far beyond their professional specialty and expertise to advise patients of nonmedical matters.

One element of the Court's discussion related to informed consent included a footnote noting, "...to the extent that the [Women's Right to Know] Act permits only the performing physician or a referring physician to provide the informed consent information, we note that other informed consent statutes, including the general medical consent statute, require a physician to provide the informed consent information."

The Hyde Amendment

The Hyde Amendment is a rider to the annual appropriations bill for the U.S. Departments of Labor, Health and Human Services (HHS), and Education, which prevents Medicaid and any other programs under these departments from funding abortions, except in limited cases. The amendment is named after Rep. Henry J. Hyde (R-IL) who, as a freshman legislator, first offered the amendment.

The Hyde Amendment has been enacted into law in various forms since 1976, during both Democratic and Republican administrations. In 1980, the U.S. Supreme Court affirmed the constitutionality of the Hyde Amendment in *Harris v. McRae*.¹⁷ In *Harris*, the Court determined that funding restrictions created by the Hyde Amendment did not violate the U.S. Constitution's

¹⁴ North Florida Women's Health and Counseling Services, supra note 8, at 642.

¹⁵ State of Florida v. Presidential Women's Center, et al.,937 So.2d 114 (Fla. 2006).

¹⁶ The Court referred to: s. 766.103, F.S. (2005), which addresses medical informed consent generally; s. 458.324, F.S. (2005), addressing breast cancer; s. 458.325, F.S., (2005), addressing electroconvulsive and psychosurgical procedures; and s. 945.48, F.S., (2005), addressing inmates receiving psychiatric treatment.

¹⁷ 448 U.S. 297 (1980). *See also Rust v. Sullivani*, 500 U.S. 173 (1991) and *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989), upholding *Harris v. McRae*.

Fifth Amendment, and therefore, did not controvene the liberty or equal protection guarantees of the Due Process Clause of the Fifth Amendment. The court opined that although government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those obstacles that are not created by the government (in this case indigence). The court further opined that although Congress has opted to subsidize medically necessary services generally, but not certain medically necessary abortions, the Hyde Amendment leaves an indigent woman with at least the same range of choice in deciding whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all. 18

In Florida, based on the Hyde Amendment, Medicaid reimburses for abortions for one of the following reasons:

- The woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused or arising from the pregnancy itself, that would place the woman in danger of death unless an abortion is performed;
- When the pregnancy is the result of rape (sexual battery) as defined in s. 794.011, F.S.; or
- When the pregnancy is the result of incest as defined in s. 826.04, F.S. 19

An Abortion Certification Form must be completed and signed by the physician who performed the abortion for the covered procedures. The form must be submitted with the facility claim, the physician's claim, and the anesthesiologist's claim. The physician must record the reason for the abortion in the physician's medical records for the recipient.²⁰

State Legislation in Response to the Patient Protection and Affordable Care Act²¹

The federal Patient Protection and Affordable Care Act (PPACA) includes provisions that govern insurance coverage of abortion in state insurance exchanges, which are scheduled by the PPACA to be launched in 2014. The 'Special Rules' (Section 1303) of the law and the related White House executive order contain these new provisions. The law maintains current Hyde Amendment restrictions that govern abortion policy, which prohibit federal funds from being used for abortion services (except in cases of rape or incest, or when the life of the woman would be endangered), and extends those restrictions to the health insurance exchanges.

The PPACA also maintains federal "conscience" protections for health care providers who object to performing abortion or sterilization procedures that conflict with their beliefs. In addition, the law provides new protections that prohibit discrimination against health care facilities and providers who are unwilling to provide, pay for, provide coverage of, or refer women for abortions. The law allows states (through legislation) to prohibit abortion coverage in qualified health plans offered through an exchange. If insurance coverage for abortion is included in a plan

¹⁸ *Harris*, 448 U.S. at 316-317.

¹⁹ Agency for Health Care Administration, Florida Medicaid: Ambulatory Surgery Center Services Coverage and Limitations Handbook, January 2005, available at:

http://www.baccinc.org/medi/CD_April_2005/Provider_Handbooks/Medicaid_Coverage_and_Limitations_Handbooks/Amb ulatory_Surgical_Center_Updated_January_2005.pdf (Last visited on March 11, 2011).

²¹ National Conference of State Legislatures, *Health Reform and Abortion Coverage in the Insurance Exchanges*, November 2010, available at: http://www.ncsl.org/default.aspx?tabid=21099 (Last visited on March 11, 2011).

in the exchange, a separate premium is required for this coverage, to be paid for by the policyholder. In addition, the "Patient Protection and Affordable Care Act's Consistency with Longstanding Restrictions on the Use of Federal Funds for Abortion" executive order establishes an enforcement mechanism to ensure that federal funds are not used for abortion services, consistent with existing federal statute.²²

Since enactment of the PPACA in March 2010, at least five states (Arizona, Louisiana, Mississippi, Missouri and Tennessee) have enacted legislation to restrict coverage for abortion in their insurance exchanges.

Arizona law expands on provisions that prohibit the use of public funds to finance abortions, by prohibiting the funding of abortion in insurance coverage; the law also provides a few exemptions. The law prohibits any qualified health insurance policy, contract or plan offered through any state health care exchange from providing coverage for abortions unless the coverage is offered as a separate optional rider for which an additional insurance premium is charged. The law prohibits public and tax monies of the state or any political subdivision of the state from directly or indirectly paying the costs, premiums, or charges associated with a health insurance policy, contract or plan that provides coverage, benefits, or services related to the performance of any abortion. Exemptions to this provision include, saving the life of the woman having the abortion and averting impairment of a major bodily function. In addition, this law does not prohibit the state from complying with the federal law requirements.

Louisiana law prohibits elective abortions to be included in a policy available through the state health exchange. In accordance with the PPACA as well as longstanding policies of the state related to abortion, the law states that no health care plan required to be established in the state through an exchange shall offer coverage for abortion services.

Mississippi law creates the Federal Abortion-Mandate Opt-Out Act, which prohibits the use of federal funds to pay for elective abortions covered by private insurance in the state through a health care exchange. The law provides that no abortion coverage may be provided by a qualified health plan offered through an exchange created pursuant to the PPACA within the State of Mississippi. The act states that this limitation shall not apply to an abortion performed when the life of the mother is endangered by a physical disorder, physical illness or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself, or when the pregnancy is the result of an alleged act of rape or incest. The physician is required to maintain sufficient documentation in the medical record that supports the medical necessity or reason for the abortion.

In Missouri, among other abortion-related provisions, the law prohibits insurance plans or policies that provide coverage for elective abortions from inclusion in the state health insurance exchange. Elective abortions are defined as any abortion for any reason other than a spontaneous abortion or to prevent the death of the woman receiving the abortion. The law also prohibits coverage for elective abortions through the purchase of an optional rider within the exchange.

²² *Id*.

Tennessee law prohibits coverage for abortion services under any health care plan through an exchange required to be established in the state pursuant to PPACA.

State Legislation Prior to the Patient Protection and Affordable Care Act²³

Prior to the enactment of the PPACA, at least five states (Idaho, Kentucky, Missouri, North Dakota, and Oklahoma) had laws that restrict health insurance policies covering abortion.

Idaho's law requires various insurance policies to exclude coverage for elective abortions. Exclusion of this coverage may be waived if a separate premium is paid, and the availability of coverage is the option of the insurance carrier. Elective abortion is defined as an abortion for any reason other than to preserve the life of the female upon whom the abortion is performed.

In Kentucky, the law prohibits health insurance and health care contracts in the state from providing coverage for elective abortions, except by an optional rider for which there must be paid an additional premium. Elective abortion is defined as an abortion for any reason other than to preserve the life of the female upon whom the abortion is performed.

In Missouri, the law prohibits health insurance contracts, plans, or policies from providing coverage for elective abortions except by an optional rider for which there must be paid an additional premium. Elective abortion is defined as an abortion for any reason other than a spontaneous abortion or to prevent the death of the female upon whom the abortion is performed.

In North Dakota, the law states that health insurance contracts, plans, or policies may not provide coverage for abortions except by an optional rider for which there must be paid an additional premium. This does not apply to an abortion necessary to prevent the death of the woman.

In Oklahoma, the law prohibits health insurance contracts, plans, or policies from providing coverage for elective abortions except by an optional rider paid by an additional premium. Elective abortion is defined as an abortion for any reason other than a spontaneous miscarriage, to prevent the death of the woman, or when the pregnancy resulted from rape reported to the proper law enforcement authorities or when the pregnancy resulted from incest committed against a minor and the perpetrator has been reported to the proper law enforcement authorities.

Constitutional Amendments

Section 1, Article XI, of the Florida Constitution authorizes the Legislature to propose constitutional amendments by joint resolution approved by a three-fifths vote of the membership of each house. The amendment must be placed before the electorate at the next general election held after the proposal has been filed with the Secretary of State's office, or at a special election held for that purpose. Section 5(e), Article XI, of the Florida Constitution requires 60-percent voter approval for a constitutional amendment to take effect. An approved amendment will be effective on the first Tuesday after the first Monday in January following the election at which it is approved, or on such other date as may be specified in the amendment or revision. ²⁵

²³ T.J

²⁴ FLA. CONST. art. XI, s. 5(a).

²⁵ FLA. CONST. art. XI, s. 5(e).

III. Effect of Proposed Changes:

This is a joint resolution proposing the creation of Section 28 of Article I of the Florida Constitution, to prohibit the spending of public funds for any abortion or for health-benefits coverage that includes the coverage of abortion, unless such expenditure is *required* by federal law or to save the life of the mother. The joint resolution specifies that the Florida Constitution may not be interpreted to create broader rights to an abortion than those contained in the U.S. Constitution, meaning that the joint resolution, should it become law, would overrule court decisions²⁶ which have concluded that the right of privacy under Article I, Section 23, of the Florida Constitution is broader in scope than that of the U.S. Constitution.

An effective date for the amendment is not specified. Therefore, the amendment, if approved by the voters, will take effect on the first Tuesday after the first Monday in January following the election at which it is approved.²⁷

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

C. Trust Funds Restrictions:

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

D. Other Constitutional Issues:

As exemplified by the cases discussed above, under the subheadings "Relevant Case Law" and "The Hyde Amendment," this joint resolution, should it become a state constitutional amendment, may be challenged under the state and federal constitution's Equal Protection and Due Process Clauses and the state constitution's Right of Privacy Clause.

V. Fiscal Impact Statement:

	Issues

None.

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²⁶ See, e.g., supra fn. 11.

 $^{^{27}}$ Ld

B. Private Sector Impact:

Persons would not have access to public funding for any abortion or health-benefits coverage that includes coverage of abortion, unless required by federal law or to save the life of the mother. If federal law were to change, such that it no longer required the use of federal funds for an abortion if the pregnancy is the result of an act of rape or incest, then the use of public funds in such cases would not be authorized, unless that abortion would also save the life of the mother.

C. Government Sector Impact:

The state will not incur costs other than the state is presently required to incur under federal law or to provide abortion services for those who qualify for Medicaid and the abortion is required to save the life of the mother.²⁸

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VI.	i ecni	nıcaı	Detici	encies:

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.)

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.

²⁸ See, supra fn. 19. The state policy mirrors the federal Hyde Amendment, which allows for Medicaid reimbursement under certain circumstances.

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 S	taff of the Health Re	egulation Committee
BILL:	SB 818			
INTRODUCER:	Senator Fas	sano		
SUBJECT:	Controlled	Substances		
DATE:	March 12, 2	2011 REVISED:		
ANAL	YST	STAFF DIRECTOR	REFERENCE	ACTION
. Stovall		Stovall	HR	Pre-meeting
2.			CJ	
3.			ВС	
1.				
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I. Summary:

This bill further refines the regulation of controlled substances by:

- Authorizing a 3-hour continuing education course relating to the Prescription Drug Monitoring Program (PDMP) to count toward requirements for the initial and renewal licensure of a practitioner whose lawful scope of practice authorizes the practitioner to prescribe, administer, or dispense controlled substances;
- Prohibiting certain persons from advertising that the individual or business is engaged in the
 dispensing of controlled substances, and a person who violates any of these provisions is
 subject to criminal prosecution;
- Revising the physician survey instrument to collect data concerning the use of the PDMP and requiring the aggregated reporting of this data;
- Establishing additional criminal penalties for fraudulently registering or attempting to register a pain-management clinic, failing to perform a physical examination of a patient at a pain-management clinic on the day in which a controlled substance is dispensed or prescribed to a patient, and prescribing or dispensing controlled substances in excess of a 72-hour dose without documenting that the dosage is within the standard of care;
- Requiring the Board of Medicine or the Board of Osteopathic Medicine to suspend a physician's license for at least 6 months and impose a fine of at least \$10,000 per count when a physician in a pain-management clinic violates the standard of practice as set forth in law or rule:
- Requiring a pharmacist or any person working under the direction of a pharmacist to report
 to the Department of Law Enforcement (FDLE) and the local county sheriff's office
 identifying information concerning a person obtaining or attempting to obtain a controlled
 substance from the pharmacy through a fraudulent method or representation within 24 hours

- of learning of the fraud or attempted fraud, to avoid committing a misdemeanor of the first degree;
- Requiring a dispensing practitioner to register with the Board of Pharmacy as a dispensing practitioner who dispenses controlled substances, upon payment of a fee not to exceed \$100, prior to dispensing controlled substances and to renew the registration every 4 years;
- Amending the elements of the crimes of burglary and grand theft to include certain activities related to controlled substances;
- Prohibiting a person from adulterating a controlled substance by altering its manufactured form or changing its integrity or composition without the prescribing physician's direction to do so based on the patient's medical need for such alteration. If a person unlawfully adulterates a controlled substance in this manner, the issuance of the entire prescription for the controlled substance becomes invalid. A law enforcement officer is authorized to seize the controlled substance as evidence and the bill provides for the return of the controlled substance under certain circumstances. The bill also prohibits a prescribing practitioner from writing a prescription for a controlled substance for a patient, another person, or an animal and authorize or direct the adulteration of the dispensed form when it is not medically necessary for the treatment of the patient;
- Enhancing provisions pertaining to the PDMP and the monitoring database to:
 - Require the database comply with the National All Schedules Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner who requests information in the database;
 - Allow corrections to the database when notified by a health care practitioner or pharmacist;
 - Collect additional information in the database concerning refills;
 - o Reduce the timeframe for reporting to 7 days;
 - Modifying who must report data;
 - Requiring a pharmacy, prescriber, practitioner, or dispenser to register with the Department of Health (Department) before being authorized to access information in the database;
 - o Requiring persons supporting the PDMP who may have access to the information in the database to undergo fingerprinting for state and federal background screening;
 - Authorize the Attorney General to access the database under certain conditions for Medicaid investigations as well as the Agency for Health Care Administration (Agency) for Medicaid fraud cases or Medicaid investigation, involving prescribed controlled substances;
 - Require a government-issued photo identification to be provided in person by a person requesting access to verify the accuracy of the database information;
 - Delete the provision that all costs for administering the PDMP must be funded through federal grants or private funding; and
 - Authorize the State Surgeon General to enter into a reciprocal agreement for the sharing of PDMP information with another state that has a compatible PDMP, within certain parameters, and providing for the related exceptions for the public records exemption;
- Requiring certain persons who are required to maintain records and inventory controlled substances to report the theft or loss of a controlled substance to a local county sheriff's office and the FDLE within 48 hours after the discovery of the theft or loss. The failure to report a loss or theft as required subjects the person to an administrative fine not to exceed

\$100 per incident or \$500 per incident if the loss or theft relates to a Schedule II controlled substance;

- Codifying into law certain judicial opinions that construe the Legislature's intent concerning
 inspection powers previously conferred upon law enforcement officers which allows them to
 access, review, examine, and copy pharmacy records concerning controlled substances
 without a subpoena or search warrant and without giving prior notice of the records'
 examination and copying to the person to whom the particular pharmacy records refer;
- Prohibiting and clarifying prohibited acts relating to a person obtaining or attempting to obtain from a practitioner controlled substances or a prescription for controlled substances that are not medically necessary or a health care practitioner providing such controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. A material fact includes whether the person has an existing prescription for a controlled substance issued for the same time period by another practitioner or has received a controlled substance or a prescription for a controlled substance of like therapeutic use within the previous 30 days; and
- Authorizing local administrative action to abate activity at a pain-management clinic upon the declaration of a public nuisance based on the occurrence of certain criminal activity.

This bill substantially amends the following sections of the Florida Statutes: 400.9905; 456.013; 458.305; 458.3191; 458.3192; 458.3265; 458.327; 458.331; 459.003; 459.013; 459.0137; 459.015; 465.015; 465.0276; 766.101; 810.02; 812.014; 893.04; 893.055; 893.0551; 893.07; 893.13; and 893.138.

The bill creates s. 893.021 and one unnumbered section of law.

The effective date of the bill is October 1, 2011.

II. Present Situation:

Prescription drug abuse is the most threatening substance abuse issue in the State of Florida. ¹ The number of deaths caused by at least one prescription drug increased from 1,234 in 2003 to 2,488 in 2009 (a 102 percent increase). This translates to seven Floridians dying per day. The drugs that caused the most deaths were oxycodone; all benzodiazepines, including Alprazolam; methadone, ethyl alcohol, cocaine, morphine, and hydrocodone.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.

• A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.

¹ Florida Office of Drug Control 2010 Annual Report, prepared by the Executive Office of the Governor.

A Schedule II substance has a high potential for abuse, a currently accepted but severely
restricted medical use in treatment in the United States, and abuse may lead to severe
psychological or physical dependence. Examples: cocaine and morphine.

- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.
- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III.
 Examples: alprazolam; diazepam; and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by Department rule, it may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.² A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.³

Dispensing, Prescribing, and Administering

"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.⁴

"Prescribing" is issuing a prescription. For purposes of the bill, a "prescription" includes an order for drugs that is written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a practitioner licensed by the laws of the state to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled or dispensed by another person licensed to do so.⁵

"Administer," for purposes of the bill, means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person.⁶

² s. 893.04(1)(f), F.S.

³ s. 893.04(2)(e), F.S.

⁴ s. 893.02(7), F.S.

⁵ s. 893.02(20), F.S.

⁶ s. 893.02(1), F.S.

Dispensing Practitioner

Chapter 465, F.S., relating to the practice of pharmacy, contains the provisions for a dispensing practitioner. Under this chapter, a practitioner authorized by law to prescribe drugs may dispense those drugs to his or her patients in the regular course of his or her practice. If a practitioner intends to dispense drugs for human consumption for a fee or remuneration of any kind, the practitioner must register with his or her professional licensing board as a dispensing practitioner, comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, and give the patient a written prescription and advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

A dispensing practitioner is prohibited from dispensing more than a 72-hour supply of a controlled substance for any patient in a pain-management clinic who pays for the medication by cash, check, or credit card, except if the controlled substance is dispensed:

- To a workers' compensation patient;
- To an insured patient who pays a copayment or deductible with cash, check, or credit card; or
- As a complimentary package to the practitioner's own patient without remuneration of any kind, whether direct or indirect.⁸

Practitioners in Florida who are authorized to prescribe include medical physicians, physician assistants, osteopathic physicians, advanced registered nurse practitioners, podiatrists, naturopathic physicians, dentists, and veterinarians.

However, s. 893.02, F.S., of the Florida controlled substances act defines which practitioners may prescribe a controlled substance under Florida law. A "practitioner" is defined to mean a licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. Accordingly, the prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Regulation of Pain-Management Clinics

Chapter 2010-211, Laws of Florida, (the pill mill bill) was enacted to more aggressively regulate pain-management clinics. The requirement to register pain-management clinics and initial regulation was enacted by the 2009 Legislature.

The pill mill bill requires businesses that meet the definition of a pain-management clinic to register with the Department, unless exempted from registration. Ownership of pain-management clinics is limited to allopathic physicians, osteopathic physicians, or groups of allopathic physicians and osteopathic physicians, and health care clinics that are licensed under part X of ch. 400, F.S.

⁷ s. 465.0276, F.S.

⁸ s. 465.0276(1)(b), F.S., enacted in 2010-211.

⁹ See sections 3 and 4 of ch. 2009-198, L.O.F.

Each pain-management clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with the law. Only a physician licensed under ch. 458, F.S., relating to the practice of medicine, (The Medical Practice Act), or ch. 459, F.S., relating to the practice of osteopathic medicine may dispense a controlled substance on the premises of a registered pain-management clinic.

The pill mill bill requires allopathic physicians and osteopathic physicians practicing in a painmanagement clinic to comply with specific provisions, including but not limited to:

- Performing a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance;
- Documenting in a patient's record the reason for prescribing or dispensing more than a 72-hour does of controlled substances for the treatment of chronic nonmalignant pain, ¹⁰ if he or she prescribes or dispenses in excess of that quantity; and
- Maintaining control and security of his or her prescription blanks and any other method used for prescribing controlled substances, and notifying the Department within 24 hours following a theft, loss, or breach of these instruments.

The pill mill bill provides for various forms of enforcement against a pain-management clinic or practitioner through administrative means including fines and suspension or revocation of a license and through the imposition of criminal penalties. The additional criminal violations created include: a third degree felony to knowingly operate, own, or manage a non-registered pain-management clinic that is required to be registered; a first degree misdemeanor to knowingly prescribe or dispense, or cause to be prescribed or dispensed, controlled substances in an unregistered pain-management clinic that is required to be registered; and a third degree felony to dispense more than a 72-hour supply of controlled substances to a patient in a pain-management clinic who pays for the medication by cash, check, or credit card.

Prescription Drug Monitoring Program (PDMP)

Chapter 2009-197, L.O.F, established the PDMP in s. 893.005, F.S. This law requires the Department, by December 1, 2010, to design and establish a comprehensive electronic system to monitor the prescribing and dispensing of certain controlled substances. Prescribers and dispensers of certain controlled substances must report specified information to the Department for inclusion in the system. Vendor protests to the procurement process for a contractor to develop the PDMP have delayed implementation of the PDMP database.

Data regarding the dispensing of each controlled substance must be submitted to the Department no more than 15 days after the date the drug was dispensed, by a procedure and in a format established by the Department, and must include minimum information specified in s. 893.005, F.S. Any person who knowingly fails to report the dispensing of a controlled substance commits a first-degree misdemeanor. This law provides exemptions from the data reporting requirements for controlled substances when specified acts of dispensing or administering occur.

¹⁰ Chronic nonmalignant pain is defined as pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery. *See* s. 458.3265(4), F.S., and s. 459.0137(4), F.S.

Section 893.0551, F.S., enacted at the same time, provides for a public records exemption for certain personal information of a patient and certain information concerning health care professionals. This section sets forth enumerated exceptions for disclosure of this information after the Department ensures the legitimacy of the person's request for the information.

The National Alliance for Model State Drug Laws identifies the benefits of a PDMP: as a tool used by states to address prescription drug abuse, addiction, and diversion. It may serve several purposes such as:

- Support access to legitimate medical use of controlled substances,
- Identify and deter or prevent drug abuse and diversion,
- Facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs,
- [Provide data on use and abuse trends for public health initiatives], and
- Educate individuals about PDMPs and the use, abuse and diversion of and addiction to prescription drugs. ¹¹

As of July 2010, 34 states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users. States with operational programs include: Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wyoming. Washington State's PDMP was operational but has been suspended due to fiscal constraints. 12

Seven states, Alaska, Florida, Kansas, New Jersey, Oregon, South Dakota and Wisconsin and one U.S. territory (Guam) have enacted legislation to establish a PDMP, but are not fully operational. Delaware has legislation pending to establish a PDMP.

Program Implementation and Oversight Task Force

The Program Implementation and Oversight Task Force¹³ is created within the Executive Office of the Governor. The purpose of the Implementation and Oversight Task Force is to monitor the implementation and safeguarding of the PDMP monitoring database, and to ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to request information from the electronic system.

National All Schedules Prescription Electronic Reporting (NASPER) Act

NASPER was signed into law on August 11, 2005, making it the only statutorily authorized program to assist states in combating prescription drug abuse of controlled substances through a

¹¹ See The United State Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Q & A, found at: < http://www.deadiversion.usdoj.gov/faq/rx monitor.htm,>, (Last visited on March 11, 2011). The fourth purpose as reported in the Q & A reads: "inform public health initiatives through outlining of use and abuse trends."

12 Id

¹³ See section 2, ch. 2009-198, L.O.F.

prescription monitoring program (PDMP). NASPER fosters interstate communication by providing grants to set up or improve state systems that meet basic standards of information collection and privacy protections that will make it easier for states to share information. This will enable authorities to identify prescription drug abusers as well as the "problem doctors" who betray the high ethical standards of their profession by over or incorrectly prescribing prescription drugs.¹⁴

Health Care Clinics

Currently, cash-only health care clinics are not licensed by the Agency. A "clinic" as defined in s. 400.9905(4), F.S., means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services.... This definition applies only to clinics that seek reimbursement from third-party payers, such as insurance, Medicaid, Medicare, etc. Cash-only or point-of-sale clinics are not covered by this definition.

The Agency indicates it has licensed approximately 200 health care clinics that are pain-management clinics which are not fully owned by medical or osteopathic physicians.¹⁵

III. Effect of Proposed Changes:

Section 1 amends s. 400.9905, F.S., to revise the definition of "clinic" and "portable equipment provider" for purposes of the licensure of health care clinics by the agency. "Clinic" is defined to mean an entity at which health care services are provided to individuals and which tenders charges for *payment* for such services, including a mobile clinic and a portable equipment provider. The word payment is substituted for the word *reimbursement*. The definition of "portable medical equipment provider" deletes the modifier that a portable equipment provider bills third-party payors for providing portable equipment to multiple locations performing treatment or diagnostic testing of individuals.

Section 2 amends s. 456.013, F.S., related to general licensing provisions for the professions licensed by the Department or a board. The bill allows allopathic physicians, osteopathic physicians, podiatrists, pharmacists, and dentists to complete a 3-hour continuing education course relating to the PDMP upon license renewal on or after July 1, 2012. Each applicant for licensure in one of these professions that is approved for licensure on or after January 1, 2013 must also complete a course.. The course must address the purpose of the PDMP; the practitioners' capabilities for improving the standard of care for patients by using the PDMP; how the PDMP can help practitioners detect doctor shopping; the involvement of law enforcement personnel, the Attorney General's Medicaid Fraud Control Unit, and medical regulatory investigators with the PDMP; and the procedures for registering for access to the PDMP.

The course may be included in the total number of hours of required continuing education and must be approved by the board or by the Department if there is no board. The boards or the Department is required to approve a course offered through a Florida-licensed hospital,

¹⁴ See: <http://www.nasper.org/database.htm>, (Last visited on March 11, 2011).

¹⁵ Agency 2011 Bill Analysis & Economic Impact Statement for SB 818, on file with the Senate Health Regulation Committee.

ambulatory surgical center, or mobile surgical facility. The boards or the Department must adopt rules as necessary to implement these provisions by October 1, 2011.

Sections 3 and 10 amend s. 458.305, F.S., and s. 459.003, respectively, to add a definition for "dispensing physician to the terms used under the Medical Practice Act. "Dispensing physician" is defined to mean a physician who is registered as a dispensing practitioner under the Pharmacy Practice Act in s. 465.0276, F.S.

Section 4 creates an unnumbered section of law relating to advertising controlled substances by a dispensing physician. This section prohibits a person, other than a dispensing physician, from using the title "dispensing physician" or "dispenser" or otherwise leading the public to believe that he or she is engaged in the dispensing of controlled substances. A person, other than the owner of a registered pain-management clinic or health clinic licensed under ch. 400, F.S., may not display any sign or take any other action that would lead the public to believe that the person is engaged in the business of dispensing a controlled substance. This could be construed as authorizing a registered pain-management clinic or any other health clinic licensed under ch. 400, F.S., may display a sign or otherwise communicate that the entity is in the business of dispensing a controlled substance and authorizes them to advertise that the entity dispenses onsite. The bill provides that any advertisement that states "dispensing onsite" or "onsite pharmacy" violates the prohibition.

This section prohibits a person who is not a dispensing physician or who is not otherwise exempt from the requirement to register as a dispensing practitioner, from performing the functions of a dispensing physician.

A person who violates any of the above provisions commits a misdemeanor of the first degree.

A person, firm, or corporation that is not licensed or registered under the acts related to the practice of medicine or osteopathic medicine may not:

- Use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "onsite pharmacy," "dispensing," dispensing onsite," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to dispense prescription drugs in this state, or
- Hold himself or herself out to the public as a person, firm, or corporation that is licensed or registered to dispense controlled substances in this state.

A person who violates this provision commits a felony of the third degree.

The bill provides that in any warrant, information, or indictment, it is not necessary to negate any exceptions, and the burden of any exception is upon the defendant.

Section 5 amends s. 458.3191, F.S., to add to the information collected by the Department in the physician survey that is completed upon licensure renewal. The additional information includes:

- Whether the Department has ever approved or denied the physician's registration for access to a patient's information in the PDMP database, and
- Whether the physician uses the PDMP with patients in his or her medical practice.

Section 6 amends s. 458.3192, F.S., to require the Department, by November 1 of each year, to provide non-identifying information to the PDMP's Implementation and Oversight Task Force regarding the number of physicians who are registered with the PDMP and who also use the database from the PDMP for their patients in their medical practice.

Sections 7 and 12 amend s. 458.3265, F.S., and s. 459.0137, F.S., respectively, to clarify the physician's responsibilities with respect to prescribing or dispensing more than a 72-hour dose of controlled substance for the treatment of chronic nonmalignant pain when practicing in a pain-management clinic that is required to be registered. The bill requires a physician to document in the patient's record the reason that dosage is within the standard of care. Current law requires the physician to document in the patient's record the reason for prescribing or dispensing that quantity.

This section also creates a new crime for a licensee or other person who serves as the designated physician of a pain-management clinic to register a pain-management clinic through misrepresentation or fraud or procure or attempt to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation. This is a felony of the third degree.

Sections 8 and 11 amend s. 458.327, F.S., and s. 459.013, F.S., respectively, to designate the commission of certain acts criminal acts. These include:

Acts that are a felony of the third degree:

- Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic three or more times within a 6-month period;
- Failing to perform a physical examination on three or more different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period; and
- Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient without documenting in the patient's record the reason that such dosage is within the standard of care, three or more times within a 6-month period.

Acts that are a misdemeanor of the first degree:

- Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic two or more times within a 6-month period;
- Failing to perform a physical examination on two or more different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period; and
- Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient without documenting in the patient's record the reason that such dosage is within the standard of care, two or more times within a 6-month period.

Acts that are a misdemeanor of the second degree:

A first offense of failing to perform a physical examination of a patient on the same day that
the treating physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic; and

• A first offense of prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient without documenting in the patient's record the reason that such dosage is within the standard of care.

Sections 9 and 13 amend s. 458.331, F.S., and s. 459.015, F.S., respectively, to provide for additional disciplinary action when the board finds that a physician has prescribed or dispensed a controlled substance in a pain-management clinic in a manner that violates the standard of practice as set forth in the practice act or rules. This includes at a minimum, suspending the physician's license for at least 6 months and imposing a fine of at least \$10,000 per count. Increased penalties are required for repeated violations.

Section 14 amends s. 465.015, F.S., to prohibit a licensed pharmacist, pharmacy technician or any person working under the direction or supervision of a pharmacist or pharmacy technician, from knowingly failing to timely report to the FDLE and the local county sheriff's office the name of any person who obtains or attempts to obtain a controlled substance which the person knows or reasonably should have known was obtained or attempted to be obtained from the pharmacy through a fraudulent method or representation. A pharmacy, pharmacy intern or other person employed by or at a pharmacy is required to report within 24 hours after learning of the fraud or attempted fraud, otherwise he or she commits a misdemeanor of the first degree.

The report must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacy regarding:

- The transaction, such as the name and telephone number of the prescribing physician;
- The name, description, and any personal identification information pertaining to the person presenting the prescription; and
- All other material information, such as photographic or video surveillance of the transaction.

Section 15 amends s. 465.0276, F.S., relating to dispensing practitioners under the Pharmacy Practice Act. The bill requires a practitioner to register with the Board of Pharmacy as a dispensing practitioner who dispenses controlled substances in order to dispense controlled substances that are listed in Schedules II – V and pay a fee that is not to exceed \$100. The Department is required to adopt rules for renewal of the registration every four years.

Section 16 amends s. 766.101, F.S., related to medical review committees to conform a cross-reference.

Section 17 amends s. 810.02, F.S., to modify the elements of burglary that is a felony of the second degree. This occurs if, in the course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a dangerous weapon or explosive, and the offender enters or remains in a dwelling, structure, or conveyance when the offense intended to be committed is theft of a substance controlled by s. 893.03, F.S. Further, the bill provides that notwithstanding any contrary provisions of law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance and for any applicable offense for possession of a controlled substance or an offense for trafficking in a

controlled substance, may be imposed if all such offenses involve the same amount or amounts of a controlled substance.

Section 18 amends s. 812.014, F.S., to modify the elements of grand theft of the third degree that is a felony of the third degree. This occurs if the property stolen is any amount of a controlled substance. Further, the bill provides that notwithstanding any contrary provisions of law, separate judgments and sentences for theft of a controlled substance and for any applicable offense for possession of a controlled substance or an offense for trafficking in a controlled substance, may be imposed if all such offenses involve the same amount or amounts of a controlled substance.

Section 19 creates s. 893.021, F.S., to define an adulterated drug for purposes of ch. 893, F.S., related to Drug Abuse Prevention and Control. An adulterated drug includes:

- A controlled substance approved by the Federal Drug Administration, or on the list of controlled substance in ch. 893, F.S., and its manufactured form has been altered by breaking, crushing, dissolving, or combining with an additive substance that may cause a difference in the strength, quality, or purity of the drug which could render the substance injurious to a person's health; and
- A controlled substance that:
 - Has been produced, prepared, packed, and marketed for oral consumption by the manufacturer; and
 - Has had any change to its integrity or composition for off-label use by means of inhalation, injection, or any other form of ingestion not in accordance with the manufacturer's recommended use, and such off-label use has not been previously directed and approved by the prescribing physician.

The bill provides that a physician is not prevented from directing or prescribing a change to the recognized manufactured recommendations for use in a patient who presents a medical need for the changed controlled substance. The prescribing physician is required to clearly indicate any deviation of the recognized manufacturer's recommended use of a controlled substance on the original prescription, and the licensed pharmacist is required to clearly indicate the deviation on the label of the prescription upon dispensing the controlled substance.

Section 20 amends s. 893.04, F.S., to require that in addition to existing required elements for a prescription for a controlled substance, the directions for use must specify the authorization by the physician, any instructions requiring the adulteration of the dispensed form of the medication, and the medical necessity for the adulteration as provided in s. 893.021, F.S., which is created in this bill.

Section 21 amends s. 893.055, F.S., relating to the PDMP to require:

- The electronic system (database) comply with the National All Schedules Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner who requests information in the PDMP database and certification of the purpose for which information is requested;
- The Department to establish a method to allow corrections to the database when notified by a health care practitioner or pharmacist;

• Information that is reported by the dispenser to include the number of refills ordered and whether the drug was dispensed as a refill of a prescription or was a first-time request; and

• The reporting of a dispensed controlled substance within 7 days as opposed to 15 days.

This section also modifies the exemptions from reporting to the PDMP to:

- Delete the exemption for a practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections, so that if this provision is enacted, this event must be reported;
- Exempt reporting by a health care practitioner when administering or dispensing a controlled substance to a person under the age of 16, but only if the amount of the controlled substance is adequate to treat the patient during that particular treatment session; and
- Reduce the timeframe for a pharmacist or a dispensing practitioner when dispensing a onetime emergency resupply of a controlled substance to a patient from a 72-hour emergency resupply to a 48-hour emergency resupply.

The bill requires a pharmacy, prescriber, practitioner, or dispenser to register with the Department in order to access the information in the PDMP database related to their patient. The Department must approve the documentation submitted for registration prior to granting the person access to the appropriate information in the PDMP database.

The PDMP program manager and persons who have access to the database for management purposes must submit fingerprints for a statewide and federal criminal background screening.

The bill expands the authority of the Attorney General to access the database, through the program manager, for Medicaid investigations involving prescribed controlled substances. It also authorized the Agency similar access for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.

The bill requires additional identifying information related to a patient or the patient's legal guardian or surrogate to access the database to verify the accuracy of the information in the database. The additional information includes the patient's phone number and a copy of a government-issued photo identification which must be provided in person to the program manager along with the notarized request.

The bill eliminates the requirement that all costs incurred by the Department in administering the PDMP be funded through federal grants or private funding.

After the database has been operational for 12 months, the State Surgeon General is required to enter into reciprocal agreements for the sharing of prescription drug monitoring information with other states that have a compatible program. The factors to consider when determining compatibility include:

- The essential purposes of the program and the success of the program in fulfilling those purposes;
- The safeguards for privacy of patient records and the success of the program in protecting patient privacy;

• The persons authorized to view the data. The bill lists those who are authorized access upon approval by the State Surgeon General;

- The schedules of controlled substances that are monitored;
- The data required to be submitted for each prescription; and
- Any implementing criteria deemed essential for a thorough comparison.

Priority for access by another state shall be given to a state that is contiguous with the borders of this state. The State Surgeon General is required to annually review the agreement to determine continued compatibility. Any agreement between states must prohibit the sharing of information for any purpose that is not otherwise authorized in Florida Statutes relating to the PDMP and its confidentiality and public records exemptions.

Section 22 amends s. 893.0551, F.S., to authorize additional exemptions for disclosures related to the reciprocal agreement for the sharing of prescription drug monitoring information with another state that has a compatible PDMP. The bill specifies who the reciprocal agreement may authorize to receive information from the PDMP and for what purpose. These individuals include:

- State regulators of professionals authorized to prescribe or dispense controlled substances from the investigation of a designated person;
- A health care practitioner or pharmacist licensed in that state for providing medical or pharmaceutical treatment to a current patient; and
- A law enforcement officer whose duty it is to enforce the laws of his or her state relating to controlled substances and who is engaged in a specific, active investigation involving a designated person.

The program manager may review the request for information received from one of these individuals and validate it.

Section 23 amends s. 893.07, F.S., to require a person who engages in the manufacture, compounding, mixing, cultivating, growing, or by other means producing or preparing, or in the dispensing, importation, or as a wholesaler or distributor of controlled substance to report a theft or loss of a controlled substance to a local county sheriff's office and the FDLE within 48 hours after the discovery of the theft or loss. If one of these people fails to report the theft or loss, the person is subject to an administrative fine not to exceed \$100 per incident or not to exceed \$500 per incident if it is a theft or loss of a controlled substance listed under Schedule II.

The bill adopts into law two judicial opinions that the inspection powers previously conferred upon law enforcement officer which allow them to access and review pharmacy records concerning controlled substances are to be exercised properly by the law enforcement officers without the requirement of a subpoena or search warrant. Further, the officer may examine and copy such records without the requirement that those persons to whom particular pharmacy records refer be given notice of the records' examination and copying.

Section 24 amends s. 893.13, F.S., to add the following prohibited acts:

• A person may not, with the intent to obtain a controlled substance, or amount of controlled substance, that is not medically necessary for the person, obtain or attempt to obtain from a

practitioner a controlled substance or prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. A material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or to withhold information from a practitioner that the person has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days;

- A health care practitioner, with the intent to provide a controlled substance or an amount of controlled substances that is not medically necessary to his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. A material fact include whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or to withhold information from a practitioner that the person has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.
- Any person who adulterates a controlled substance for directed off-label use without authorization by a prescribing physician, violates existing provisions of law and causes the issuance of the entire prescription for the controlled substance to become invalid. A law enforcement officer in the performance of his or her duties may seize the adulterated or off-label prescribed controlled substance as evidence. The controlled substance may be returned to the owner only with a notarized affidavit from the original prescribing practitioner who gave authorization and explicit directions for the adulteration or off-label use of the controlled substance.

A person or health care practitioner who violates any of these new prohibited acts commits a felony of the third degree if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV. It is a misdemeanor of the first degree if any controlled substance that is the subject of the offense is listed in Schedule V.

A prescribing practitioner may not write a prescription for a controlled substance for a patient, other person, or an animal and authorize or direct the adulteration of the dispensed form of the controlled substance for the purpose of ingestion by means of inhalation, injection, or any other means that is not medically necessary for the treatment of that patient. To do so, the practitioner commits a felony of the third degree.

Section 25 amends s. 893.138, F.S., to authorize any pain-management clinic which has been used on more than two occasions within a 6-month period as the site of a violation of state laws related to assault and battery, burglary, dealing in theft, robbery by sudden snatching, or unlawful distribution of controlled substance to be declared a public nuisance. As such it may be abated pursuant to the procedures provided in s. 893.138, F.S. Under that statute, a county or municipality may create an administrative board to hear complaints regarding nuisances as defined in that statute and take action such as ordering the closure of the business or activity on the premises. Such an order expires after one year or at an earlier time if so stated in the order.

Section 26 provides an effective date of October 1, 2011.

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.

D. Other Constitutional Issues:

The advertising restriction in lines 403 through 427 may violate the First Amendment to the United States Constitution and Article I, Section 4 of the Florida Constitution.

The Central Hudson Test is the standard used for determining the constitutionality of a restriction on commercial speech. ¹⁶ The four prongs of the *Central Hudson* test, as modified by *Board of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989), are: (1) whether the speech at issue is not misleading and concerns lawful activity; (2) whether the government has a substantial interest in restricting that speech; (3) whether the regulation directly advances the asserted governmental interest; and (4) whether the regulation is narrowly tailored, but not necessarily the least restrictive means available, to serve the asserted governmental interest.

Article I, Section 4 of the Florida Constitution, related to Freedom of speech and press states:

Every person may speak, write and publish sentiments on all subjects but shall be responsible for the abuse of that right. No law shall be passed to restrain or abridge the liberty of speech or of the press. In all criminal prosecutions and civil actions for defamation the trust may be given in evidence. If the matter charged as defamatory is true and was published with good motives, the party shall be acquitted or exonerated.

¹⁶ See: Central Hudson Gas & Elec. Corp. v. Public Service Com'n, 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980)

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill requires a \$100 fee to register as a dispensing practitioner who dispenses controlled substances. This registration must be renewal every 4 years.

B. Private Sector Impact:

All practitioners who are authorized under their practice act to dispense controlled substances and who choose to do so will be required to register with the Board of Pharmacy and pay a \$100 registration fee initially and every 4 years thereafter to renew the registration.

Pharmacy employees will be required to report to law enforcement persons who have allegedly engaged in fraud or deception to obtain or attempt to obtain a controlled substance from the pharmacy.

Certain persons who are required to maintain records of controlled substances will be required to report losses or thefts to law enforcement.

Due to the additional criminal violations established in this bill, medical practitioners, pain management clinics, and the general public are all potentially impacted.

C. Government Sector Impact:

The Department and the boards will be required to adopt rules to implement provisions in the bill. Additional criminal violations will impact resources for law enforcement, the court system, and jails and prisons. The impact of this bill has not been determined. The PDMP database may require modification, if completed before this law is enacted, to capture the additional information required to be reported.

VI. Technical Deficiencies:

Professional staff has discussed several technical deficiencies in the bill with the sponsor's staff and the sponsor of the bill has indicated his intention to offer a strike-all amendment to address some of the deficiencies as well as other areas of interest.

VII. Related Issues:

Section 499.006, F.S., defines adulterated drugs and this definition also applies to controlled substances. Having a separate, more specific definition for an adulterated controlled substance in this bill may supersede the definition under the Florida Drug and Cosmetic Act. This might create inconsistencies and unintentional consequences with respect to the ability to use the provisions under the Florida Drug and Cosmetic Act as necessary to protect the public health, safety, and welfare. In addition, under current law, the dispensing of an adulterated drug is a criminal offense, but this bill authorizes a controlled substance that has become adulterated, as defined under the bill, to be dispensed.

Section 23 of the bill provides for an administrative fine for the failure to report a theft or loss of a controlled substance. However, it is not clear what agency is to enforce this provision and collect the fine.

The Department advises that it is authorized to comply with all requirements of the NASPER Act. However, the bill fails to authorize the PDMP program manager to provide health care practitioners with unsolicited reports. This authority is necessary for the Department / PDMP to be eligible to receive federal grant funding under the NASPER Act.

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.



LEGISLATIVE ACTION

Senate House

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsections (4) and (7) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.-

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

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of this part do not apply to:

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

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

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



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- (e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.
- (f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.
- (g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, which are wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner, so long as one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's

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compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) that provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

- (h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.
- (i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.
- (i) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.
- (k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.
- (1) Orthotic or prosthetic clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that

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issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(7) "Portable equipment provider" means an entity that contracts with or employs persons to provide portable equipment to multiple locations performing treatment or diagnostic testing of individuals, that bills third party payors for those services, and that otherwise meets the definition of a clinic in subsection (4).

Section 2. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.-

(7)(a) The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The 2-hour course counts shall count towards the total number of continuing education hours required for the profession. The board or department shall approve the course shall be approved by the board or department, as appropriate, which must and shall include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine <u>must</u> shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed <u>under</u> pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

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- (b) As a condition of initial licensure and at each subsequent license renewal, the boards, or the department if there is no board, shall allow each practitioner licensed under chapter 458, chapter 459, chapter 461, chapter 465, or chapter 466 whose lawful scope of practice authorizes the practitioner to prescribe, administer, or dispense controlled substances to complete a 1-hour continuing education course relating to the prescription drug monitoring program. The course must include, but need not be limited to:
 - 1. The purpose of the prescription drug monitoring program.
- 2. The practitioners' capabilities for improving the standard of care for patients by using the prescription drug monitoring program.
- 3. How the prescription drug monitoring program can help practitioners detect doctor shopping.
- 4. The involvement of law enforcement personnel, the Attorney General's Medicaid Fraud Unit, and medical regulatory investigators with the prescription drug monitoring program.
- 5. The procedures for registering for access to the prescription drug monitoring program.

The course hours may be included in the total number of hours of continuing education required by the profession and must be approved by the board or by the department if there is no board. The boards, or the department if there is no board, shall approve the course offered through a facility licensed under chapter 395 for its employees if the course is at least 3 hours and covers the education requirements.

(c) The course requirements in paragraph (b) apply to each



187 licensee renewing his or her license on or after July 1, 2012, and to each applicant approved for licensure on or after January 188 1, 2013. 189 190 (d) By October 1, 2011, the boards, or the department if 191 there is no board, shall adopt rules as necessary to administer 192 this subsection. 193 Section 3. Section 458.305, Florida Statutes, is amended to 194 read: 195 458.305 Definitions.—As used in this chapter: 196 (1) "Board" means the Board of Medicine. (2) "Department" means the Department of Health. 197 198 (3) "Dispensing physician" means a physician who is 199 registered as a dispensing practitioner under s. 465.0276. 200 (4) (3) "Practice of medicine" means the diagnosis, 201 treatment, operation, or prescription for any human disease, 202 pain, injury, deformity, or other physical or mental condition. 203 (5) (4) "Physician" means a person who is licensed to 204 practice medicine in this state. Section 4. Advertising of controlled substances by a 205 206 dispensing physician.-207 (1) (a) Only a dispensing physician licensed under chapter 458 or chapter 459, Florida Statutes, may use the title 208 209 "dispensing physician" or "dispenser" or otherwise lead the 210 public to believe that he or she is engaged in the dispensing of 211 controlled substances. 212 (b) A person, other than an owner of a: 213 1. Pain-management clinic registered under chapter 458 or

2. Health clinic licensed under chapter 400, Florida

chapter 459, Florida Statutes; or

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may not display any sign or take any other action that would lead the public to believe that such person is engaged in the business of dispensing a controlled substance. Any advertisement that states "dispensing onsite" or "onsite pharmacy" violates this paragraph. This paragraph does not preclude a person who is not licensed as a medical practitioner from owning a painmanagement clinic.

- (c) A person, firm, or corporation, unless licensed under chapter 465, Florida Statutes, may not use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "onsite pharmacy," "dispensing," "dispensing onsite," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to dispense prescription drugs in this state.
- (2) A person who violates paragraph (1) (a) or paragraph (1) (b) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, Florida Statutes. A person who violates paragraph (1)(c) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes. In any warrant, information, or indictment, it is not necessary to negate any exceptions, and the burden of any exception is upon the defendant.

Section 5. Paragraph (a) of subsection (1) of section 458.3191, Florida Statutes, is amended to read:

458.3191 Physician survey.-

(1) Each person who applies for licensure renewal as a physician under this chapter or chapter 459 must, in conjunction

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with the renewal of such license under procedures adopted by the Department of Health and in addition to any other information that may be required from the applicant, furnish the following to the Department of Health in a physician survey:

- (a) Licensee information, including, but not limited to:
- 1. Frequency and geographic location of practice within the state.
 - 2. Practice setting.
 - 3. Percentage of time spent in direct patient care.
 - 4. Anticipated change to license or practice status.
 - 5. Areas of specialty or certification.
- 6. Whether the department has ever approved or denied the physician's registration for access to a patient's information in the prescription drug monitoring program's database.
- 7. Whether the physician uses the prescription drug monitoring program with patients in his or her medical practice.

Section 6. Subsection (3) is added to section 458.3192, Florida Statutes, to read:

- 458.3192 Analysis of survey results; report.-
- (3) By November 1 each year, the Department of Health shall provide nonidentifying information to the prescription drug monitoring program's Implementation and Oversight Task Force regarding the number of physicians who are registered with the prescription drug monitoring program and who also use the database from the prescription drug monitoring program for their patients in their medical practice.

Section 7. Paragraphs (a) of subsection (1), and paragraphs (a) and (c) of subsection (2) of section 458.3265, Florida Statutes, are amended, and paragraphs (f) and (g) are added to

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subsection (5) of that section, to read: 458.3265 Pain-management clinics.

- (1) REGISTRATION.-
- (a) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless:
- 1. That clinic is licensed as a facility pursuant to chapter 395;
- 2. The majority of the physicians who provide services in the clinic primarily provide surgical services;
- 3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-thecounter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- 4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- 5. The clinic does not prescribe or dispense controlled substances for the treatment of pain; or
- 6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3); or-
- 7. The majority of the physicians who provide services in the clinic are physicians who specialize in interventional pain management in accordance with the American Society of Interventional Pain Physicians.
 - (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities



apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

- (a) A physician may not practice medicine in a painmanagement clinic, as described in subsection (4), if+
- 1. the pain-management clinic is not registered with the department as required by this section .; or
- 2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or, prior to July 1, 2012, does not comply with rules adopted by the board.

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Any physician who qualifies to practice medicine in a painmanagement clinic pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(c) A physician must perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason such dosage is within the standard of care.

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For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code for prescribing or dispensing that quantity.

- (5) PENALTIES; ENFORCEMENT.-
- (f) A licensee or other person who serves as the designated physician of a pain-management clinic as defined in this section or s. 459.0137 and registers a pain-management clinic through misrepresentation or fraud or procures or attempts to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
- (q) Any person who registers a pain-management clinic through misrepresentation or fraud or who procures or attempts to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
- Section 8. Paragraphs (f) and (g) are added to subsection (1), paragraphs (g) and (h) are added to subsection (2), and subsection (3) is added to section 458.327, Florida Statutes, to read:
 - 458.327 Penalty for violations.-
- (1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:
- (f) Failing to perform a physical examination of a patient by a physician or a licensed designee acting under the physician's supervision on the same day that the treating

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physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic occurring three or more times within a 6-month period, or failing to perform a physical examination on three or more different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.

- (q) Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient occurring three or more times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.
- (2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:
- (q) Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic two times in a 6-month period, or failing to perform a physical examination on two different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.
- (h) Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient occurring two times within a 6month period without documenting in the patient's record the

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reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

- (3) Each of the following acts constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:
- (a) A first offense of failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic.
- (b) A first offense of failing to document in a patient's record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain.

Section 9. Subsection (11) is added to section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.-

(11) Notwithstanding subsection (2), upon finding that a physician has prescribed or dispensed, or caused to be prescribed or dispensed, a controlled substance in a painmanagement clinic in a manner that violates the standard of practice as set forth in chapter 458 or rules adopted pursuant to chapter 458, the board shall, at a minimum, suspend the physician's license for at least 6 months and impose a fine of at least \$10,000 per count. Repeated violations shall result in increased penalties.

Section 10. Present subsections (3), (4), and (5) of

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section 459.003, Florida Statutes, are redesignated as subsections (4), (5), and (6), respectively, and a new subsection (3) is added to that section, to read:

459.003 Definitions.—As used in this chapter:

(3) "Dispensing physician" means an osteopathic physician who is registered as a dispensing practitioner under s. 465.0276.

Section 11. Paragraphs (f) and (g) are added to subsection (1), paragraphs (e) and (f) are added to subsection (2), and paragraphs (d) and (e) are added to subsection (3) of section 459.013, Florida Statutes, to read:

459.013 Penalty for violations.-

- (1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:
- (f) Failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic occurring three or more times within a 6-month period, or failing to perform a physical examination on three or more different patients on the same day that the osteopathic physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.
- (g) Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient occurring three or more times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is

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set forth in rule 64B8-9.013(3), Florida Administrative Code.

- (2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:
- (e) Failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic occurring two times within a 6-month period, or failing to perform a physical examination on two different patients on the same day that the osteopathic physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.
- (f) Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient occurring two times within a 6month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.
- (3) Each of the following constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:
- (d) A first offense of failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic.
- (e) A first offense of failing to document in a patient's record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose

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of controlled substances for the treatment of chronic nonmalignant pain. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

Section 12. Paragraph (c) of subsection (2) of section 459.0137, Florida Statutes, is amended, and a new paragraphs (f) and (q) are added to subsection (5) of that section, to read: 459.0137 Pain-management clinics.

- (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).
- (c) An osteopathic physician must perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for which prescribing or dispensing a dosage in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain is within the standard of care for prescribing or dispensing that quantity.
 - (5) PENALTIES; ENFORCEMENT.-
- (f) A licensee or other person who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137 and registers a pain-management clinic through intentional misrepresentation or fraud or procures or attempts to procure the registration of a pain-management clinic for any

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other person by making or causing to be made any false or fraudulent representation commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(q) Any person who registers a pain-management clinic through misrepresentation or fraud or who procures or attempts to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 13. Subsection (11) is added to section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department. -

(11) Notwithstanding subsection (2), upon finding that an osteopathic physician has prescribed or dispensed, or caused to be prescribed or dispensed, a controlled substance in a painmanagement clinic in a manner that violates the standard of practice as set forth in chapter 459 or rules adopted pursuant to chapter 459, the board shall, at a minimum, suspend the osteopathic physician's license for at least 6 months and impose a fine of at least \$10,000 per count. Repeated violations shall result in increased penalties.

Section 14. Subsections (3) and (4) of section 465.015, Florida Statutes, are renumbered as subsections (4) and (5), respectively, and subsection (3) is added to that section, to read:

465.015 Violations and penalties.-

(3) (a) A licensed pharmacist, pharmacy technician, or any person working under the direction or supervision of a

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pharmacist or pharmacy technician, may not knowingly fail to timely report to the local county sheriff's office the name of any person who obtains or attempts to obtain a substance controlled by s. 893.03 which the pharmacist, pharmacy intern, or other person employed by or at a pharmacy knows or reasonably should have known was obtained or attempted to be obtained from the pharmacy through any fraudulent method or representation. A pharmacist, pharmacy intern, or other person employed by or at a pharmacy who fails to make such a report within 24 hours after learning of the fraud or attempted fraud commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

- (b) A sufficient report of the fraudulent obtaining of or attempt to obtain a controlled substance under this section must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacy regarding:
- 1. The transaction, such as the name and telephone number of the prescribing physician;
- 2. The name, description, and any personal identification information pertaining to the person presenting the prescription; and
- 3. All other material information, such as photographic or video surveillance of the transaction.

A pharmacist, pharmacy intern, or other person employed by or at a pharmacy is not subject to disciplinary action for reporting under this subsection.

Section 15. Subsection (6) is added to section 465.0276,



Florida Statutes, to read:

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465.0276 Dispensing practitioner.-

(6) In order to dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03, a practitioner authorized by law to prescribe a controlled substance shall register with the Board of Pharmacy as a dispensing practitioner who dispenses controlled substances and pay a fee not to exceed \$100. The department shall adopt rules establishing procedures for renewal of the registration every 4 years.

Section 16. Paragraph (a) of subsection (1) of section 766.101, Florida Statutes, is amended to read:

766.101 Medical review committee, immunity from liability.-

- (1) As used in this section:
- (a) The term "medical review committee" or "committee" means:
- 1.a. A committee of a hospital or ambulatory surgical center licensed under chapter 395 or a health maintenance organization certificated under part I of chapter 641,
- b. A committee of a physician-hospital organization, a provider-sponsored organization, or an integrated delivery system,
- c. A committee of a state or local professional society of health care providers,
- d. A committee of a medical staff of a licensed hospital or nursing home, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home,
 - e. A committee of the Department of Corrections or the

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Correctional Medical Authority as created under s. 945.602, or employees, agents, or consultants of either the department or the authority or both,

- f. A committee of a professional service corporation formed under chapter 621 or a corporation organized under chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in $\underline{s.458.305(4)}$ $\underline{s.458.305(3)}$, and which has at least 25 health care providers who routinely provide health care services directly to patients,
- q. A committee of the Department of Children and Family Services which includes employees, agents, or consultants to the department as deemed necessary to provide peer review, utilization review, and mortality review of treatment services provided pursuant to chapters 394, 397, and 916,
- h. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines which have been approved by the governing board of the agency,
- i. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the guidelines which have been approved by the governing board of the agency,
- j. A peer review or utilization review committee organized under chapter 440,
- k. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these entities when reviewing mortality records, or



1. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

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which committee is formed to evaluate and improve the quality of health care rendered by providers of health service, to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care, or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

Section 17. Subsection (3) of section 810.02, Florida Statutes, is amended to read:

810.02 Burglary.

- (3) Burglary is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a dangerous weapon or explosive, and the offender enters or remains in a:
- (a) Dwelling, and there is another person in the dwelling at the time the offender enters or remains;
- (b) Dwelling, and there is not another person in the dwelling at the time the offender enters or remains;
- (c) Structure, and there is another person in the structure at the time the offender enters or remains;
 - (d) Conveyance, and there is another person in the



conveyance at the time the offender enters or remains; or

- (e) Authorized emergency vehicle, as defined in s. 316.003; or.
- (f) Structure or conveyance when the offense intended to be committed is theft of a substance controlled by s. 893.03. Notwithstanding any contrary provisions of law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under this paragraph and for any applicable offense for possession of a controlled substance under s. 893.13, or an offense for trafficking in a controlled substance under s. 893.135, may be imposed if all such offenses involve the same amount or amounts of a controlled substance.

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However, if the burglary is committed within a county that is subject to a state of emergency declared by the Governor under chapter 252 after the declaration of emergency is made and the perpetration of the burglary is facilitated by conditions arising from the emergency, the burglary is a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. As used in this subsection, the term "conditions arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or response time for first responders or homeland security personnel. A person arrested for committing a burglary within a county that is subject to such a state of emergency may not be released until the person appears before a committing magistrate at a first appearance hearing. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this subsection is ranked one level above



the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

Section 18. Paragraph (c) of subsection (2) of section 812.014, Florida Statutes, is amended to read:

812.014 Theft.-

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- (c) It is grand theft of the third degree and a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property stolen is:
 - 1. Valued at \$300 or more, but less than \$5,000.
 - 2. Valued at \$5,000 or more, but less than \$10,000.
 - 3. Valued at \$10,000 or more, but less than \$20,000.
 - 4. A will, codicil, or other testamentary instrument.
 - 5. A firearm.
 - 6. A motor vehicle, except as provided in paragraph (a).
- 7. Any commercially farmed animal, including any animal of the equine, bovine, or swine class, or other grazing animal, and including aquaculture species raised at a certified aquaculture facility. If the property stolen is aquaculture species raised at a certified aquaculture facility, then a \$10,000 fine shall be imposed.
 - 8. Any fire extinguisher.
- 9. Any amount of citrus fruit consisting of 2,000 or more individual pieces of fruit.
- 10. Taken from a designated construction site identified by the posting of a sign as provided for in s. 810.09(2)(d).
 - 11. Any stop sign.
 - 12. Anhydrous ammonia.
 - 13. Any amount of a substance controlled by s. 893.03.



Notwithstanding any contrary provisions of law, separate judgments and sentences for theft of a controlled substance under this subparagraph, and for any applicable offense for possession of a controlled substance under s. 893.13, or an offense for trafficking in a controlled substance under s. 893.135 may be imposed if all such offenses involve the same amount or amounts of controlled substance.

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However, if the property is stolen within a county that is subject to a state of emergency declared by the Governor under chapter 252, the property is stolen after the declaration of emergency is made, and the perpetration of the theft is facilitated by conditions arising from the emergency, the offender commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property is valued at \$5,000 or more, but less than \$10,000, as provided under subparagraph 2., or if the property is valued at \$10,000 or more, but less than \$20,000, as provided under subparagraph 3. As used in this paragraph, the term "conditions arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or the response time for first responders or homeland security personnel. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this paragraph is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

to read: 893.021 Adulterated drug.-

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Section 19. Section 893.021, Florida Statutes, is created

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- (1) As used in this chapter, a drug is adulterated if it is a controlled substance that:
- (a) Has been produced, prepared, packed, and marketed for oral consumption by the manufacturer; and
- (b) Has had any change to its integrity or composition for use by means of inhalation, injection, or any other form of ingestion not in accordance with the manufacturer's recommended use, and such mode of use has not been previously directed and approved by the prescribing physician.
- (2) A physician is not prevented from directing or prescribing a change to the recognized manufactured recommendations for use in a patient who presents a medical need for such a requirement change of any controlled substance. The prescribing physician shall clearly indicate any deviation of the recognized manufacturer's recommended use of a controlled substance on the original prescription, and the licensed pharmacist shall clearly indicate such deviation on the label of the prescription upon dispensing the controlled substance.

Section 20. Paragraphs (c), (d), and (e) of subsection (1) of section 893.04, Florida Statutes, are amended to read:

893.04 Pharmacist and practitioner.

- (1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:
- (c) The following information must There shall appear on the face of the prescription or written record of a thereof for the controlled substance the following information:
 - 1. The full name and address of the person for whom, or the

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owner of the animal for which, the controlled substance is dispensed.

- 2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.
- 3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.
- 4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof. The directions for use must specify the authorization by the physician, any instructions requiring the adulteration of the dispensed form of the medication, and the medical necessity for the adulteration in accordance with s. 893.021.
- 5. The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.
- 6. The initials of the pharmacist filling the prescription and the date filled.
- (d) The prescription must shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.
- (e) A label bearing the following information must be affixed to the original container in which a controlled substance is delivered <u>as</u> upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label bearing the following information:
- 1. The name and address of the pharmacy from which such controlled substance was dispensed.
- 2. The date on which the prescription for such controlled substance was filled.

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- 3. The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.
 - 4. The name of the prescribing practitioner.
- 5. The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.
- 6. The directions for the use of the controlled substance prescribed in the prescription.
- 7. A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Section 21. Section 893.055, Florida Statutes, is amended to read:

893.055 Prescription drug monitoring program.-

- (1) As used in this section, the term:
- (a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory

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report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

- (b) "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.
- (c) "Dispenser" means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.
- (d) "Health care practitioner" or "practitioner" means any practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465, or chapter 466.
- (e) "Health care regulatory board" means any board for a practitioner or health care practitioner who is licensed or regulated by the department.
- (f) "Pharmacy" means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.
- (g) "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.
- (h) "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.
 - (i) "Law enforcement agency" means the Department of Law

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Enforcement, a Florida sheriff's department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

- (j) "Program manager" means an employee of or a person contracted by the Department of Health who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2)(a) and (b).
- (2) (a) By December 1, 2010, the department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), the National All Schedules

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Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner who requests information in the prescription drug monitoring program database and certification of the purpose for which information is requested, and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7) (b) and (c) and s. 893.0551.

(b) The department, when the direct support organization receives at least \$20,000 in nonstate moneys or the state receives at least \$20,000 in federal grants for the prescription drug monitoring program, and in consultation with the Office of Drug Control, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient

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advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Office of Drug Control, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

- (c) All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements.
- (d) The program manager shall work with professional health care licensure boards and the stakeholders listed in paragraph (b) to develop rules appropriate for identifying indicators of controlled substance abuse.
- (e) The department shall establish a method to allow corrections to the database when notified by a health care practitioner or pharmacist.
- (3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the database:

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- (a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.
- (b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.
- (c) The full name, address, and date of birth of the person for whom the prescription was written.
- (d) The name, national drug code, quantity, and strength of the controlled substance dispensed.
- (e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.
- (f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).
- (q) Other appropriate identifying information as determined by department rule.
- (h) The number of refills ordered and whether the drug was dispensed as a refill of a prescription or was a first-time request.
 - (4) Each time a controlled substance is dispensed to an

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individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than $7 \, \frac{15}{10}$ days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

- (5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:
- (a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- (b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- (c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- (c) (d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

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- (d) (e) A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16 if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- (e) (f) A pharmacist or a dispensing practitioner when dispensing a one-time, 48-hour 72-hour emergency resupply of a controlled substance to a patient.
- (6) The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.
- (7) (a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.
- (b) 1. In order for a pharmacy, prescriber, practitioner, or dispenser to shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, practitioner, or dispenser, the pharmacy, prescriber, practitioner, or dispenser shall register with the department by submitting a registering document provided by the department. The document and validation of that document shall be determined by the department. Before a pharmacy, prescriber, practitioner, or dispenser is granted

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access to information in the database from the prescription drug monitoring program, the department shall approve the submitted document. Upon approval, the department shall grant the registrant access to the appropriate information in the prescription drug monitoring program's database in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history.

2. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

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- (c) The following entities may shall not have be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:
- 1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.
- 2. The Attorney General for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.
- 3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.
- 4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of

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birth, and includes the same information if the legal guardian or health care surrogate submits the request. The patient's phone number, current address, and a copy of a government-issued photo identification must be provided in person to the program manager along with the notarized request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal quardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

5. The Agency for Health Care Administration for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

- (d) The following entities may shall not have be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:
 - 1. Department staff for the purpose of calculating

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1115 performance measures pursuant to subsection (8).

- 2. The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.
- (e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.
- (f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)8., (8) (a), or (8) (b) has occurred, may provide relevant information to the applicable law enforcement agency.
- (8) To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve



the following outcomes:

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- (a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.
- (b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.
- (c) Increased coordination among partners participating in the prescription drug monitoring program.
- (d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.
- (9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- (10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial costs for this purpose include, but are not limited to, the

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costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitivesolicitation requirements under s. 287.057(3)(f), the department shall comply with the competitive-solicitation requirements under s. 287.057 for the procurement of any goods or services required by this section.

- (11) The Office of Drug Control, in coordination with the department, may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.
- (a) As used in this subsection, the term "direct-support organization" means an organization that is:
- 1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.
- 2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.
- (b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.
- (c) The director of the Office of Drug Control shall appoint a board of directors for the direct-support organization. The director may designate employees of the Office

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of Drug Control, state employees other than state employees from the department, and any other nonstate employees as appropriate, to serve on the board. Members of the board shall serve at the pleasure of the director of the Office of Drug Control. The director shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

- (d) The direct-support organization shall operate under written contract with the Office of Drug Control. The contract must, at a minimum, provide for:
- 1. Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.
- 2. Submission of an annual budget for the approval of the Office of Drug Control.
- 3. Certification by the Office of Drug Control in consultation with the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.
- 4. The reversion, without penalty, to the Office of Drug Control, or to the state if the Office of Drug Control ceases to exist, of all moneys and property held in trust by the direct-

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support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.

- 5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.
- 6. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the Office of Drug Control and the directsupport organization.
- 7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the director of the Office of Drug Control. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:
- a. Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.
- b. Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in



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- c. Providing funds for future enhancements of the program within the intent of this section.
- d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.
 - e. Providing funds for travel expenses.
- f. Providing funds for administrative costs, including personnel, audits, facilities, and equipment.
- g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.
- (e) The activities of the direct-support organization must be consistent with the goals and mission of the Office of Drug Control, as determined by the office in consultation with the department, and in the best interests of the state. The directsupport organization must obtain a written approval from the director of the Office of Drug Control for any activities in support of the prescription drug monitoring program before undertaking those activities.
- (f) The Office of Drug Control, in consultation with the department, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use

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such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the Office of Drug Control and the department may be held by the Office of Drug Control or in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the Office of Drug Control. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the Office of Drug Control if the direct-support organization is no longer approved by the Office of Drug Control to operate in the best interests of the state.

- (g) The Office of Drug Control, in consultation with the department, may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.
- (h) The Office of Drug Control may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.
- (i) The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the Office of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.
- (j) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).
 - (12) A prescriber or dispenser may have access to the

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information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, in collaboration with the Office of Drug Control, shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department, in collaboration with the Office of Drug Control, to conduct training for health care

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practitioners and other appropriate persons in using the monitoring program to support the program enhancements.

- (14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).
- (15) The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.
- (16) By October 1, 2010, the department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the

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reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the monitoring program's system.

- (17) After the prescription drug monitoring program has been operational for 12 months, the State Surgeon General shall enter into reciprocal agreements for the sharing of prescription drug monitoring information with any other state that has a compatible prescription drug monitoring program. If the State Surgeon General evaluates the prescription drug monitoring program of another state as authorized in this subsection, priority shall be given to a state that is contiquous with the borders of this state.
- (a) In determining compatibility, the State Surgeon General shall consider:
- 1. The essential purposes of the program and the success of the program in fulfilling those purposes.
- 2. The safeguards for privacy of patient records and the success of the program in protecting patient privacy.
- 3. The persons authorized to view the data collected by the program. Comparable organizations and professions for practitioners in other states, law enforcement agencies, the Attorney General's Medicaid Fraud Unit, medical regulatory boards, and, as needed, management staff who have similar duties as management staff who work with the prescription drug monitoring program as authorized in s. 893.0551 are authorized access upon approval by the State Surgeon General.
- 4. The schedules of the controlled substances that are monitored.
 - 5. The data required to be submitted for each prescription.

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- 1405 6. Any implementing criteria deemed essential for a thorough comparison. 1406 1407 (b) The State Surgeon General shall annually review any 1408 agreement to determine its continued compatibility with the 1409 prescription drug monitoring program in this state.
 - (c) Any agreement between the State Surgeon General and another state shall prohibit the sharing of information concerning a resident of this state or a practitioner, pharmacist, or other prescriber for any purpose that is not otherwise authorized by this section or s. 893.0551.

Section 22. Present subsections (4), (5), (6), and (7) of section 893.0551, Florida Statutes, are redesignated as subsections (5), (6), (7), and (8), respectively, and a new subsection (4) is added to that section, to read:

893.0551 Public records exemption for the prescription drug monitoring program.-

- (4) The department may disclose confidential and exempt information contained in records held by the department under s. 893.055 if the State Surgeon General has entered into a reciprocal agreement for the sharing of prescription drug monitoring information with any other state that has a compatible prescription drug monitoring program.
- (a) The reciprocal agreement may allow the following persons from another state to receive information from the prescription drug monitoring program if approved by the State Surgeon General:
- 1. A designated representative of a state professional licensing, certification, or regulatory agency charged with oversight of those persons authorized to prescribe or dispense

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controlled substances for the purpose of a bona fide, specific investigation of a prescription of a controlled substance which involves a designated person. As required in s. 893.055, this authorization does not preclude the requirement for the program manager to review the request for information and validate it.

- 2. A health care practitioner or pharmacist licensed in the state from which the request originates. Such health care practitioner or pharmacist shall certify that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide, current patient. The health care practitioner or pharmacist shall follow all the procedures required in s. 893.055 and rules established by the department for a health care practitioner or pharmacist to request information from the database.
 - 3. A law enforcement officer from another state:
- a. Who is a member of a sheriff's department or a police department;
- b. Who is authorized by law to conduct criminal investigations and make arrests;
- c. Whose duty it is to enforce the laws of his or her state relating to controlled substances; and
- d. Who is engaged in a bona fide specific, active investigation involving a designated person regarding prescriptions for controlled substances.

As required in s. 893.055, this authorization does not preclude 1459 1460 the requirement for the program manager to review the request for information and validate it. This authorization also does 1461

not preclude the ability to provide a report to a law 1462

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enforcement agency in another state under s. 893.055(7) or this subsection.

(b) Any agreement between the State Surgeon General and another state shall prohibit the sharing of information concerning a resident of this state, a patient whose information is in the program's database, or a practitioner, pharmacy, pharmacist, health care practitioner, or other prescriber for any purpose that is not otherwise authorized by this section or s. 893.055, and the information must be provided according to the State Surgeon General's determination of compatibility as described in s. 893.055(17).

Section 23. Subsections (1), (4), and (5) of section 893.07, Florida Statutes, are amended, and a new subsection (6) is added to that section to read:

893.07 Records.-

- (1) Notwithstanding any other provision of law and in consonance with the authority of State v. Carter, 23 So. 3d 798 (Fla. 1st DCA 2009) and State v. Tamulonis, 39 So. 3d 524 (Fla. 2nd DCA 2010), every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:
- (a) On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that



would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b) On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

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Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

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(4) Every inventory or record required by this chapter, including prescription records, shall be maintained:

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(b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

(a) Separately from all other records of the registrant, or

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In either case, such records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. This subsection does not require a law enforcement officer to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

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(5) Each person shall maintain a record that contains which shall contain a detailed list of controlled substances lost,

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destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft. If a person discovers the theft or loss of a controlled substance, such person shall report the theft or loss to a local county sheriff's office within 48 hours after the discovery of such theft or loss. A person who fails to report the theft or loss of a controlled substance under this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. However, a person who fails to report the theft or loss of a Schedule II controlled substance commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. (6) The Legislature finds that the opinions rendered in

State v. Carter, 23 So. 3d 798 (Fla. 1st DCA 2009), and State v. Tamulonis, 39 So. 3d 524 (Fla. 2nd DCA 2010), correctly construe this Legislature's intent that the inspection powers previously conferred upon law enforcement officers which allow such officers to access and review pharmacy records concerning controlled substances are to be exercised properly by such law enforcement officers without the requirement of a subpoena or search warrant being sought or issued to examine and copy such records, and without the requirement that those persons to whom particular pharmacy records refer be given notice of the records' examination and copying under this section.

Section 24. Subsections (7) and (8) of section 893.13, Florida Statutes, are amended to read:

893.13 Prohibited acts; penalties.-

- (7) (a) A It is unlawful for any person may not:
- 1. To Distribute or dispense a controlled substance in



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- 2. To Refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter.
- 3. To Refuse an entry into any premises for any inspection or to refuse to allow any inspection authorized by this chapter.
- 4. To Distribute a controlled substance named or described in s. 893.03(1) or (2) except pursuant to an order form as required by s. 893.06.
- 5. To Keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances, or which is used for keeping or selling them in violation of this chapter.
- 6. To Use to his or her own personal advantage, or to reveal, any information obtained in enforcement of this chapter except in a prosecution or administrative hearing for a violation of this chapter.
- 7. To Possess a prescription form which has not been completed and signed by the practitioner whose name appears printed thereon, unless the person is that practitioner, is an agent or employee of that practitioner, is a pharmacist, or is a supplier of prescription forms who is authorized by that practitioner to possess those forms.
- 8. To Withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a

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prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.

- 9. To Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.
- 10. To Affix any false or forged label to a package or receptacle containing a controlled substance.
- 11. To Furnish false or fraudulent material information in, or omit any material information from, any report or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.
- 12. To Store anhydrous ammonia in a container that is not approved by the United States Department of Transportation to hold anhydrous ammonia or is not constructed in accordance with sound engineering, agricultural, or commercial practices.
- 13. With the intent to obtain a controlled substance or combination of controlled substances that are not medically necessary for the person or an amount of a controlled substance or substances that are not medically necessary for the person, obtain or attempt to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this subparagraph, a material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph 8.
- (b) A health care practitioner, with the intent to provide a controlled substance or combination of controlled substances

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that are not medically necessary to his or her patient or an amount of controlled substances that are not medically necessary for his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph (a)8.

(c) Any person who adulterates a controlled substance for directed off-label use without authorization by a prescribing physician violates the provisions of subparagraph (a)1. and causes the issuance of the entire prescription for the controlled substance to become invalid. A law enforcement officer in the performance of his or her official duties may seize the adulterated or off-label prescribed controlled substance as evidence. The controlled substance may be returned to the owner only with a notarized affidavit from the original prescribing practitioner who has knowledge and gave authorization and explicit directions for the adulteration or off-label use of the controlled substance.

(d) (b) Any person who violates the provisions of subparagraphs (a) 1.-7. commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083; except that, upon a second or subsequent violation, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(e) (c) Any person who violates the provisions of

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subparagraphs (a) 8.-12. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

- (f) A person or health care practitioner who violates the provisions of paragraph (b) or subparagraph (a) 13. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.
- (8) (a) Notwithstanding subsection (9), a prescribing practitioner may not:
- 1. Knowingly assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;
- 2. Employ a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;
- 3. Knowingly write a prescription for a controlled substance for a fictitious person; or
- 4. Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner; or.
- 5. Write a prescription for a controlled substance for a patient, other person, or an animal and authorize or direct the adulteration of the dispensed form of the controlled substance

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for the purpose of ingestion by means of inhalation, injection, or any other means that is not medically necessary for the treatment of the patient.

- (b) If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a) 1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (a)1.
- (c) A person who violates paragraph (a) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
- (d) Notwithstanding paragraph (c), if a prescribing practitioner has violated paragraph (a) and received \$1,000 or more in payment for writing one or more prescriptions or, in the case of a prescription written for a controlled substance described in s. 893.135, has written one or more prescriptions for a quantity of a controlled substance which, individually or in the aggregate, meets the threshold for the offense of trafficking in a controlled substance under s. 893.15, the violation is reclassified as a felony of the second degree and ranked in level 4 of the Criminal Punishment Code.

Section 25. Present subsections (3) through (10) of section 893.138, Florida Statutes, are redesignated as subsections (4)



1695 through (11), respectively, and a new subsection (3) is added to 1696 that section, to read: 1697 893.138 Local administrative action to abate drug-related, 1698 prostitution-related, or stolen-property-related public 1699 nuisances and criminal gang activity.-1700 (3) Any pain-management clinic, as described in s. 458.3265 or s. 459.0137, which has been used on more than two occasions 1701 within a 6-month period as the site of a violation of: 1702 (a) Section 784.011, s. 784.021, s. 784.03, or s. 784.045, 1703 1704 relating to assault and battery; 1705 (b) Section 810.02, relating to burglary; 1706 (c) Section 812.014, relating to dealing in theft; 1707 (d) Section 812.131, relating to robbery by sudden 1708 snatching; or 1709 (e) Section 893.13, relating to the unlawful distribution of controlled substances, 1710 1711 1712 may be declared to be a public nuisance, and such nuisance may 1713 be abated pursuant to the procedures provided in this section. Section 26. (1) DEFINITIONS.—As used in this section, the 1714 1715 term: 1716 (a) "Interchange or substitution of an opioid analgesic 1717 drug" means the substitution of any opioid analgesic drug, brand 1718 or generic, for the opioid analgesic drug incorporating a 1719 tamper-resistance technology originally prescribed, irrespective 1720 of whether the substituted drug is rated as pharmaceutically and 1721 therapeutically equivalent by the United States Food and Drug Administration or the Board of Pharmacy or whether the opioid 1722

analgesic drug with tamper-resistance technology bears a

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labeling claim with respect to reduction of tampering, abuse, or abuse potential.

- (b) "Opioid analgesic drug" means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release form and whether or not combined with other drug substances to form a single tablet or other dosage form.
- (c) "Opioid analgesic drug incorporating a tamperresistance technology" means an opioid analgesic drug listed as such by the Board of Pharmacy based on a submission of evidence by the drug manufacturer or distributor that the drug:
 - 1. Incorporates a tamper-resistance technology; and
- 2. Has been approved by the United States Food and Drug Administration pursuant to an application that includes at least one study on human tampering or abuse potential or a laboratory study comparing the tamper- or abuse-resistance properties of the drug to one or more opioid analgesic drugs that:
- a. Have been approved by the United States Food and Drug Administration; and
 - b. Serve as a positive control.
- (d) "Pharmacist" means any person licensed under chapter 465, Florida Statutes, to practice the profession of pharmacy, including, but not limited to, a community pharmacist and a pharmacist in a hospital-based pharmacy, when filling prescriptions for inpatient or outpatient care.
- (2) LIST OF OPIOID ANALGESIC DRUGS INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY.—The Board of Pharmacy shall create a list of opioid analgesic drugs for which information has been submitted consistent with paragraph (1)(c). Inclusion of a drug

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on such list does not require that the drug bear a labeling claim with respect to reduction of tampering, abuse, or abuse potential at the time of listing. Such list must also include a determination by the Board of Pharmacy as to which listed opioid analgesic drugs incorporating tamper-resistance technologies provide substantially similar tamper-resistance properties, based solely on studies submitted by the drug manufacturer consistent with paragraph (1)(c). (3) PROHIBITION.—Notwithstanding s. 465.025, Florida

- Statutes, a pharmacist may not interchange or substitute an opioid analgesic drug, brand or generic, for an opioid analgesic drug incorporating a tamper-resistance technology which is listed pursuant to subsection (2) without:
- (a) Verifying that the opioid analgesic drug has been listed by the Board of Pharmacy under subsection (2) as providing tamper-resistance properties substantially similar to the prescribed opioid analgesic drug incorporating a tamperresistance technology; or
- (b) Obtaining written, signed consent from the prescribing physician for such interchange or substitution.

Section 27. This act shall take effect October 1, 2011.

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

Delete everything before the enacting clause and insert:

> A bill to be entitled An act relating to controlled substances; amending s. 400.9905, F.S.; redefining the terms "clinic" and

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"portable equipment provider" within the Health Care Clinic Act; amending s. 456.013, F.S.; authorizing certain health care practitioners to complete a continuing education course relating to the prescription drug monitoring program; providing requirements for the course; requiring the Department of Health or a board that is authorized to exercise regulatory or rulemaking functions within the department to approve the course offered through a facility licensed under ch. 395, F.S., under certain circumstances; providing application of the course requirements; requiring a board or the Department of Health to adopt rules; amending s. 458.305, F.S.; defining the term "dispensing physician" as it relates to the practice of medicine in this state; prohibiting certain persons from using titles or displaying signs that would lead the public to believe that they engage in the dispensing of controlled substances; prohibiting certain persons, firms, or corporations from using a trade name, sign, letter, or advertisement that implies that the persons, firms, or corporations are licensed or registered to dispense prescription drugs; prohibiting certain persons, firms, or corporations from holding themselves out to the public as licensed or registered to dispense controlled substances; prohibiting certain persons from performing the functions of a dispensing physician; providing penalties; amending s. 458.3191, F.S.; revising the information in the physician survey

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that is submitted by persons who apply for licensure renewal as a physician under ch. 458 or ch. 459, F.S.; amending s. 458.3192, F.S.; requiring the Department of Health to provide nonidentifying information to the prescription drug monitoring program's Implementation and Oversight Task Force regarding the number of physicians that are registered with the prescription drug monitoring program and that use the database from the program in their practice; amending s. 458.3265, F.S.; revising the list of entities that are not required to register as a pain-management clinic; deleting certain requirements for a physician to practice medicine in a pain-management clinic; requiring a physician who works in a pain-management clinic to document the reason a prescription for a certain dosage of a controlled substance is within the proper standard of care; creating a felony of the third-degree for any person to register or attempt to register a pain-management clinic through misrepresentation or fraud; amending s. 458.327, F.S.; providing additional penalties; amending s. 458.331, F.S.; providing additional grounds for disciplinary action by the Board of Medicine; amending s. 459.003, F.S.; defining the term "dispensing physician" as it relates to the practice of osteopathic medicine in this state; amending s. 459.013, F.S.; providing additional penalties; amending s. 459.0137, F.S.; requiring an osteopathic physician who works in a pain-management clinic to document the reason a

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prescription for a certain dosage of a controlled substance is within the proper standard of care; creating a felony of the third-degree for a licensee or other person who serves as the designated physician of a pain-management clinic to register a painmanagement clinic through misrepresentation or fraud; amending s. 459.015, F.S.; providing additional grounds for disciplinary action by the Board of Osteopathic Medicine; amending s. 465.015, F.S.; prohibiting certain persons from knowingly failing to report to the local county sheriff's office and the Department of Law Enforcement the commission of a felony involving a person who acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge under certain conditions; providing penalties; providing requirements for reporting the commission of the felony that involves a person who acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge; providing that a pharmacist, pharmacy intern, or other person employed by or at a pharmacy is not subject to disciplinary action for reporting; amending s. 465.0276, F.S.; requiring a practitioner to register as a dispensing practitioner in order to dispense controlled substances; amending s. 766.101, F.S.; conforming a cross-reference; amending s. 810.02, F.S.; redefining the offense of burglary to include the theft of a controlled

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substance within a dwelling, structure, or conveyance; amending s. 812.014, F.S.; redefining the offense of theft to include the theft of a controlled substance; creating s. 893.021, F.S.; providing conditions in which a drug is considered adulterated; providing that a physician is not prevented from directing or prescribing a change to the recognized manufactured recommendations for use of any controlled substance in a patient under certain circumstances; requiring a prescribing physician to indicate any deviation of the recognized manufacturer's recommended use of a controlled substance on the original prescription; requiring a pharmacist or physician to indicate such deviation on the label of the prescription upon dispensing; amending s. 893.04, F.S.; revising the required information that must appear on the face of a prescription or written record of a controlled substance before it is dispensed by a pharmacist; amending s. 893.055, F.S.; requiring that the prescription drug monitoring program comply with the minimum requirements of the National All Schedules Prescription Electronic Reporting Act; requiring the Department of Health to establish a method to allow corrections to the database of the prescription drug monitoring program; requiring the number of refills ordered and whether the drug was dispensed as a refill or a first-time request to be included in the database of the prescription drug monitoring program; revising the number of days in which a dispensed controlled

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substance must be reported to the department through the prescription drug monitoring program; revising the list of acts of dispensing or administering which are exempt from reporting; requiring a pharmacy, prescriber, practitioner, or dispenser to register with the department by submitting a registering document in order to have access to certain information in the prescription drug monitoring program's database; requiring the department to approve the registering document before granting access to information in the prescription drug monitoring program's database; requiring criminal background screening for those persons who have direct access to the prescription drug monitoring program's database; authorizing the Attorney General to obtain confidential and exempt information for Medicaid fraud cases and Medicaid investigations; requiring certain documentation to be provided to the program manager in order to release confidential and exempt information from the prescription drug monitoring program's database to a patient, legal guardian, or a designated health care surrogate; authorizing the Agency for Health Care Administration to obtain confidential and exempt information from the prescription drug monitoring program's database for Medicaid fraud cases and Medicaid investigations involving controlled substances; deleting the provision that administrative costs of the prescription drug monitoring program are funded through federal grants and private sources;

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requiring the State Surgeon General to enter into reciprocal agreements for the sharing of information in the prescription drug monitoring program with other states that have a similar prescription drug monitoring program; requiring the State Surgeon General to annually review a reciprocal agreement to determine its compatibility; providing requirements for compatibility; prohibiting the sharing of certain information; amending s. 893.0551, F.S.; authorizing the Department of Health to disclose certain confidential and exempt information in the prescription drug monitoring program's database under certain circumstances involving reciprocal agreements with other states; prohibiting the sharing of information from the prescription drug monitoring program's database which is not for the purpose that is statutorily authorized or according to the State Surgeon General's determination of compatibility; amending s. 893.07, F.S.; requiring that a person report to the Department of Law Enforcement and the local sheriff's office the theft or loss of a controlled substance within a specified time; providing penalties; providing legislative intent; amending s. 893.13, F.S.; prohibiting a person from obtaining or attempting to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact; prohibiting a health care provider from

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providing a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact; prohibiting a person from adulterating a controlled substance for certain use without authorization by a prescribing physician; authorizing a law enforcement officer to seize as evidence the adulteration or off-label use of a prescribed controlled substance; providing that such adulterated or off-label use of the controlled substance may be returned to its owner only under certain conditions; providing penalties; prohibiting a prescribing practitioner from writing a prescription for a controlled substance and authorizing or directing the adulteration of the dispensed form of the controlled substance for the purpose of ingestion by means that is not medically necessary; amending s. 893.138, F.S.; providing circumstances in which a pain-management clinic may be declared a public nuisance; providing definitions; requiring the Board of Pharmacy to create a list of opioid analgesic drugs; providing requirements for the list of opioid analgesic drugs; prohibiting a pharmacist from interchanging or substituting an opioid analgesic drug, brand, or generic, for an opioid analgesic drug incorporating a tamper-resistance technology unless certain requirements are met; providing an effective date.



LEGISLATIVE ACTION

Senate House

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

Senate Amendment to Amendment (958050)

Delete lines 285 - 301 and insert:

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- 2. The majority of the physicians who provide services in the clinic primarily provide surgical services or interventional pain procedures of the type routinely billed using surgical codes;
- 3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-thecounter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;

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- 4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- 5. The clinic does not prescribe or dispense controlled substances for the treatment of pain; or
- 6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3).



LEGISLATIVE ACTION

Senate House

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

Senate Amendment to Amendment (958050) (with title amendment)

Delete lines 325 - 327 and insert:

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(c) A physician, an advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical $\frac{1}{4}$ physical examination of a patient on the same day that the physician he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic.

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

management clinic;

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13 And the title is amended as follows: Delete line 1823 14 and insert: 15 practice medicine in a pain-management clinic; 16 17 requiring a physician, an advanced registered nurse practitioner, or a physician assistant to perform an 18 19 appropriate medical examination of a patient on the 20 same day that the physician dispenses or prescribes a controlled substance to the patient at a pain-21



LEGISLATIVE ACTION

Senate House

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

Senate Amendment to Amendment (958050)

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and insert:

of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring three or more times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

(2) Each of the following acts constitutes a misdemeanor of

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the first degree, punishable as provided in s. 775.082 or s. 775.083:

- (g) Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic two times in a 6-month period, or failing to perform a physical examination on two different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.
- (h) Prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring two times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.
- (3) Each of the following acts constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:
- (a) A first offense of failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic.
- (b) A first offense of failing to document in a patient's record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the

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treatment of chronic nonmalignant pain.

Section 9. Subsection (11) is added to section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.-

(11) Notwithstanding subsection (2), upon finding that a physician has prescribed or dispensed, or caused to be prescribed or dispensed, a controlled substance in a painmanagement clinic in a manner that violates the standard of practice as set forth in chapter 458 or rules adopted pursuant to chapter 458, the board shall, at a minimum, suspend the physician's license for at least 6 months and impose a fine of at least \$10,000 per count. Repeated violations shall result in increased penalties.

Section 10. Present subsections (3), (4), and (5) of section 459.003, Florida Statutes, are redesignated as subsections (4), (5), and (6), respectively, and a new subsection (3) is added to that section, to read:

459.003 Definitions.—As used in this chapter:

(3) "Dispensing physician" means an osteopathic physician who is registered as a dispensing practitioner under s. 465.0276.

Section 11. Paragraphs (f) and (g) are added to subsection (1), paragraphs (e) and (f) are added to subsection (2), and paragraphs (d) and (e) are added to subsection (3) of section 459.013, Florida Statutes, to read:

459.013 Penalty for violations.-

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083,



or s. 775.084:

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- (f) Failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic occurring three or more times within a 6-month period, or failing to perform a physical examination on three or more different patients on the same day that the osteopathic physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.
- (q) Prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring three or more times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.
- (2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:
- (e) Failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a painmanagement clinic occurring two times within a 6-month period, or failing to perform a physical examination on two different patients on the same day that the osteopathic physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.
 - (f) Prescribing or dispensing in excess of a 72-hour dose

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of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring two times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

- (3) Each of the following constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:
- (d) A first offense of failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic.
- (e) A first offense of failing to document in a patient's record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic



	LEGISLATIVE ACTION	
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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment to Amendment (958050) (with title amendment)

Delete lines 481 - 484 and insert:

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Section 12. Paragraph (a) of subsection (1) and paragraph (c) of subsection (2) of section 459.0137, Florida Statutes, are amended, and paragraphs (f) and (g) are added to subsection (5) of that section, to read:

459.0137 Pain-management clinics.

(1) REGISTRATION.—

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- (a) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless:
- 1. That clinic is licensed as a facility pursuant to chapter 395;
- 2. The majority of the physicians who provide services in the clinic primarily provide surgical services or interventional pain procedures of the type routinely billed using surgical codes;
- 3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-thecounter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- 4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- 5. The clinic does not prescribe or dispense controlled substances for the treatment of pain; or
- 6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3).

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

Delete line 1837



and insert:

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additional penalties; amending s. 459.0137, F.S.; providing an exemption from the requirement that all privately owned pain-management clinics, facilities, or offices that advertise in any medium for any type of pain-management services, or employ an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the Department of



LEGISLATIVE ACTION

Senate House

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

Senate Amendment to Amendment (958050)

Delete lines 489 - 492 and insert:

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(c) An osteopathic physician, an advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical a physical examination of a patient on the same day that the physician he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes



LEGISLATIVE ACTION

Senate House

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

Senate Amendment (with title amendment)

Delete lines 481 - 483 and insert:

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(c) A physician, an advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical a physical examination of a patient on the same day that the physician he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic.

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



Delete line 42 and insert:

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F.S.; requiring a physician, an advanced registered nurse practitioner, or a physician assistant to perform an appropriate medical examination of a patient on the same day that the physician dispenses or prescribes a controlled substance to a patient at a pain-management clinic; requiring a physician who works in a pain-

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.)

	Prepa	ared By: Tl	ne Professional S	taff of the Criminal	Justice Commit	ttee
BILL:	CS/SB 204					
NTRODUCER:	Criminal J	ustice Co	ommittee and Se	enator Wise		
SUBJECT:	Controlled	Substan	ces			
DATE:	March 11,	2011	REVISED:			
ANAL	YST	STAI	FF DIRECTOR	REFERENCE		ACTION
. Erickson		Cann	on	CJ	Fav/CS	
. Fernandez/O'Callaghan		Stovall		HR	Pre-meetin	ng
				JU		
				BC		
	Please	see S	ection VIII.	for Addition	al Informa	ation:
A	A. COMMITTE	EE SUBST	TITUTE X	Statement of Subs	stantial Change	es
	B. AMENDME			Technical amendr Amendments were	nents were red	commended
				Significant amend	ments were re	commended

I. Summary:

The bill schedules several synthetic cannabinoids or synthetic cannabinoid-mimicking compounds in Schedule I of Florida's controlled substance schedules. The U.S. Drug Enforcement Administration (DEA) recently indicated its intent to temporarily place these substances in Schedule I of the federal controlled substance schedules. The effect of the federal scheduling would be that the substances could no longer be legally sold by retailers and possession and sale of these substances would be a federal crime. The effect of Florida scheduling would be that arrests and prosecutions under Florida law could be made for possession and sale of these substances.

This bill substantially amends sections 893.02 and 893.03, Florida Statutes. This bill reenacts sections 893.13(1), (2), (4), and(5), 893.135(1)(1), and 921.0022(3)(b), (c), and (e), Florida Statutes, to incorporate the amendment to section 893.03, Florida Statutes, in references thereto.

¹ "Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I," Federal Register, Vol. 75, No. 226, November 24, 2010 (http://frwebgate3.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=A2yMds/0/2/0&WAISaction=retrieve) (last accessed on December 23, 2010). All information for this analysis is from this source unless otherwise indicated.

BILL: CS/SB 204 Page 2

II. **Present Situation:**

The DEA has provided the following information regarding synthetic cannabinoids (often referred to by the slang terms "K2" or "Spice"):

Synthetic cannabinoids have been developed over the last 30 years for research purposes to investigate the cannabinoid system. No legitimate non-research uses have been identified for these synthetic cannabinoids. They have not been approved by the U.S. Food and Drug Administration for human consumption. These THC-like synthetic cannabinoids, 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1- naphthoyl)indole (JWH-200), 5-(1,1dimethylheptyl)-2-[(1R,3S)-3- hydroxycyclohexyl]-phenol (CP-47,497), and 5-(1,1dimethyloctyl)-2- [(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue), are so termed for their THC-like pharmacological properties. Though they have similar properties to delta-9- tetrahydrocannabinol (THC) found in marijuana and have been found to be more potent than THC in animal studies. Numerous herbal products have been analyzed and JWH-073, JWH-018, JWH-200, CP-47,497, and cannabicyclohexanol have been identified in varying mixture profiles and amounts spiked on plant material.

The DEA found that these substances have "a high potential for abuse, no currently accepted medical use in treatment in the United States and are not safe for use under medical supervision." Based on the DEA findings, these substances appear to meet the criteria for scheduling under Schedule 1 under both federal and Florida law. The DEA has indicated its intent to temporarily place these substances in Schedule I of the federal controlled substance schedules.³

Currently, these substances are not controlled substances under Florida law and possession and sale offenses are not generally applicable, though it has been reported that the Polk County Sheriff's Office recently arrested several retailers for violation of Florida's imitation controlled substance statute, s. 817.564⁴. It remains to be seen whether convictions will occur under these statutes, and if they do occur, whether they will be upheld if subject to appellate challenge.

The DEA indicated that "[t]he emergence of these synthetic cannabinoids represents a recent phenomenon in the designer drug market." "The popularity of these THC-like synthetic cannabinoids has greatly increased in the United States and they are being abused for their psychoactive properties." The substances are "[p]rimarily found laced on plant material" and "are also being abused alone as self-reported on Internet discussion boards." "The most common route of administration of these synthetic cannabinoids is by smoking, using a pipe, water pipe, or rolling the drug-spiked plant material in cigarette papers."

³ The final order, if issued, will be effective on the date of publication of the order in the Federal Register. It is the DEA's

² See s. 893.03(1), F.S.

intent to issue such a final order as soon as possible after the expiration of thirty days from the date of publication of the notice of scheduling and the date that notification was transmitted to the Assistant Secretary for the U.S. Department of Health and Human Services.

⁴ Curtis, Henry Pierson, "Imitation marijuana: More than dozen arrested in Polk County for selling 'legal weed'," Orlando Sentinel, November 18, 2010 (http://articles.orlandosentinel.com/2010-11-18/news/os-fake-pot-arrests-polk-county-20101118 1 synthetic-marijuana-small-gasoline-stations-legal-weed) (last accessed on January 2, 2011).

BILL: CS/SB 204 Page 3

The DEA stated that "products containing these THC-like synthetic cannabinoids are marketed as 'legal' alternatives to marijuana and are being sold over the Internet and in tobacco and smoke shops, drug paraphernalia shops, and convenience stores." Further, "a number of the products and synthetic cannabinoids appear to originate from foreign sources and are manufactured in the absence of quality controls and devoid of regulatory oversight." "The marketing of products that contain one or more of these synthetic cannabinoids is geared towards teens and young adults." Despite disclaimers that the products are not intended for human consumption, 5 retailers promote that routine urinalysis tests will not typically detect the presence of these synthetic cannabinoids."

The DEA further stated that abuse of these substances or products containing these substances "has been characterized by both acute and long term public health and safety problems":

- These synthetic cannabinoids alone or spiked on plant material have the potential to be extremely harmful due to their method of manufacture and high pharmacological potency. DEA has been made aware that smoking these synthetic cannabinoids for the purpose of achieving intoxication and experiencing the psychoactive effects is identified as a reason for emergency room visits and calls to poison control centers. 6
- "The body appears to recognize the synthetic compounds as a foreign substance and often causes a physiological rejection." Health warnings have been issued by numerous state public health departments and poison control centers describing the adverse health effects associated with these synthetic cannabinoids and their related products including agitation, anxiety, vomiting, tachycardia, elevated blood pressure, seizures, hallucinations and non-responsiveness. Case reports describe psychotic episodes, withdrawal, and dependence associated with use of these synthetic cannabinoids, similar to syndromes observed in cannabis abuse. Emergency room physicians have reported admissions connected to the abuse of these synthetic cannabinoids. Additionally, when responding to incidents involving individuals who have reportedly smoked these synthetic cannabinoids, first responders report that these individuals suffer from intense hallucinations. Detailed chemical analysis by the DEA and other investigators have found these synthetic cannabinoids spiked on plant material in products marketed to the general public. The risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of synthetic cannabinoids(s) spiked on the plant material.

⁵ Labeling these products as "not for human consumption" tends to keep the products out of purview of the Federal Food and Drug Administration (FDA). Additionally, not all the ingredients used in the production of the materials are listed.

⁶ "[T]he American Association of Poison Control Centers (AAPCC) has reported receiving over 1,500 calls as of September 27, 2010, relating to products spiked with these synthetic cannabinoids from 48 states and the District of Columbia." It is unknown how many of those calls were to Florida poison control centers. There have been several media reports of persons having to go to the hospital after use of synthetic cannabinoids. *See e.g.*, Repecki, Tiffany, "Cape teen hospitalized after smoking 'synthetic marijuana'," *Cape Coral Daily Breeze*, November 3, 2010 (http://www.cape-coral-daily-breeze.com/page/content.detail/id/520354.html) (last accessed on January 3, 2011) and Wyazan, Sam, "Teenagers treated after smoking 'K2 Spice' substance," *Tallahassee Democrat* (abstract), June 30, 2010

(http://pqasb.pqarchiver.com/tallahassee/access/2074740741.html?FMT=ABS&date=Jun+30%2C+2010) (last accessed on January 3, 2011).

⁷ Florida Fusion Center Brief: K2 or Spice, The Florida Department of Law Enforcement (June 2010). A copy of this document is on file with the Senate Health Regulation Committee.

BILL: CS/SB 204 Page 4

According to the National Conference of State Legislatures, as of November 23, 2010, "at least 11 state legislatures and another six state agencies have taken action to outlaw the use of these drugs."

III. Effect of Proposed Changes:

The bill amends s. 893.02, F.S., the definitions section of ch. 893, F.S., to define the term "homologue" as "a chemical compound in a series in which each compound differs by one or more alkyl functional groups on an alkyl side chain." The term "homologue" appears in the scheduling nomenclature of one of the substances scheduled by the bill.

The bill also amends. s. 893.03, F.S., to schedule the following synthetic cannabinoids or synthetic cannabinoid-mimicking compounds in Schedule I of Florida's controlled substance schedules:

- 2-[(1R, 3S) -3-hydroxycyclohexyl] -5- (2-methyloctan-2-yl) phenol, also known as CP 47, 497 and its dimethyloctyl (C8) homologue.
- (6aR, 10aR) -9- (hydroxymethyl) -6, 6-dimethyl-3- (2-methyloctan-2-yl) -6a, 7, 10, 10a-tetrahydrobenzo [c] chromen-1-ol, also known as HU-210.
- 1-Pentyl-3- (1-naphthoyl) indole, also known as JWH-018.
- 1-Butyl-3- (1-naphthoyl) indole, also known as JWH-073.
- 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl) indole, also known as JWH-200.

The bill also reenacts ss. 893.13(1), (2), (4), and(5), 893.135(1)(1), and 921.0022(3)(b), (c), and (e), F.S., to incorporate the amendment to s. 893.03, F.S., in references thereto.

The effective date of the bill is July 1, 2011.

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 this 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.

⁸ "Synthetic Cannabinoids (K2)," National Conference of State Legislatures, updated November 23, 2010 (http://www.ncsl.org/?tabid=21398) (last accessed on January 3, 2011).

BILL: CS/SB 204 Page 5

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The scheduling of synthetic cannabinoids as provided in the bill should not impact retailers if the DEA's emergency scheduling of these substances goes into effect before the bill's effective date because federal scheduling would require the removal of these substances and prohibit their sale.

C. Government Sector Impact:

The Criminal Justice Impact Conference (CJIC) estimates that the bill will have a potentially insignificant prison bed impact (small additional number of prison beds projected).⁹

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 Criminal Justice on January 11, 2011:

Adds an additional synthetic cannabinoid (JWH 200) to Schedule I of Florida's controlled substance schedules. This addition is consistent with proposed federal scheduling.

B. Amendments:

None.

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

⁹ Criminal Justice Impact Conference, Office of Economic and Demographic Research (Mar. 2, 2011), available at http://edr.state.fl.us/Content/conferences/criminaljusticeimpact/index.cfm.



LEGISLATIVE ACTION Senate House

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

Senate Amendment (with title amendment)

Between lines 116 and 117 insert:

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Section 3. Subsection (6) of section 893.13, Florida Statutes, is amended to read:

893.13 Prohibited acts; penalties.-

(6)(a) It is 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

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or to be in actual or constructive possession of a controlled substance except as otherwise authorized by this chapter. Any person who violates this provision commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

- (b) If the offense is the possession of not more than 20 grams of cannabis, as defined in this chapter, or 3 grams or less of a controlled substance described in s. 893.03(1)(c)40.-44., the person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For the purposes of this subsection, "cannabis" does not include the resin extracted from the plants of the genus Cannabis, or any compound manufacture, salt, derivative, mixture, or preparation of such resin and a controlled substance described in s. 893.03(1)(c)40.-44. does not include the substance in a powdered form.
- (c) Except as provided in this chapter, it is unlawful to possess in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
- (d) Notwithstanding any provision to the contrary of the laws of this state relating to arrest, a law enforcement officer may arrest without warrant any person who the officer has probable cause to believe is violating the provisions of this chapter relating to possession of cannabis.



42 ======== T I T L E A M E N D M E N T ========= 43 And the title is amended as follows: Delete line 7 44 and insert: 45 list of controlled substances in Schedule I; amending 46 47 s. 893.13, F.S.; providing that it is a misdemeanor of the first degree to be in possession of not more than 48 a specified amount of certain hallucinogenic 49 substances; providing an exception for the powdered 50 form of such substances; 51

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepared B	y: The Professional Sta	aff of the Health Re	egulation Committee		
BILL:	SB 1226					
NTRODUCER:	Senator Joyner					
SUBJECT:	Health Care Fraud					
DATE:	March 11, 201	1 REVISED:				
ANAL	YST	STAFF DIRECTOR	REFERENCE	ACTION		
. Brown		Stovall	HR	Pre-meeting		
			CJ			
			ВС			

I. Summary:

The bill amends Florida Statutes relating to the licensure responsibility and authority of the Department of Health (DOH) over health professions and occupations and 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.

This bill substantially amends the following section of the Florida Statutes: 456.0635.

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 Medicaid fraud, posting sanctioned and terminated Medicaid providers on the Agency for Health Care Administration (AHCA) website, and creating additional criminal felonies for committing health care fraud; among other anti-fraud provisions.¹

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¹ See ch. 2009-223, Laws of Florida.

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 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

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.

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."

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.

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 to an applicant, or person affiliated with that applicant, who 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."

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

The bill expands the current provisions that require 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., or ch. 893, F.S., to include similar felony offenses committed in another state or jurisdiction. The bill 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.
- 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.

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.

For felonies 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 bill prohibits the DOH from approving or denying the application for a license, certificate, or registration until the final resolution of the case.

The bill 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 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 bill deletes reference to "terminated for cause" from the federal Medicare program as grounds for which 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 bill specifies that the prohibitions above relating to examination, licensure, certification, and registration do not apply to applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2010, which was recognized by a board, or by the DOH if there is no applicable board, and who applied for licensure after July 1, 2010.

The bill creates a new statutory subsection relating to licensure *renewal* that requires denial of renewal for the same felony offenses referenced above, except that in order to trigger the renewal prohibition, the conviction or plea must have occurred after July 1, 2010. The bill includes the same provisions for denying licensure renewal as those describe above for examination, licensure, certification, and registration, relative to exclusion from the Medicare program and termination from Medicaid programs in Florida or other states, as well as identical provisions regarding applicants who have entered a pretrial intervention or drug diversion program.

The bill requires the DOH to adopt rules to administer the provisions related to denial of licensure renewal.

Section 2 creates an effective date for the bill of July 1, 2011.

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:

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 rule-making, the costs of which are indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Currently, s. 120.60, F.S., requires the DOH to approve or deny an application within 90 days. The bill tolls the time for persons in a court-approved pretrial intervention or drug diversion program. For renewal applications, renewals that are not approved are classified as delinquent and then become null and void under s. 456.036, F.S. Under the bill, if the DOH is prevented from approving or denying a renewal application until final resolution of the court case, the result would be the same as a denial if the license becomes null and void due to lack of approval.

The bill requires the DOH to adopt rules to administer the bill's provisions related to denial of licensure renewal but not with regard to licensure applications. Rule-making related to denial of licensure renewal appears unnecessary because the renewal standards are explicitly provided in the bill.

The bill 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 ch. 409, 817, or 893, F.S.

Section 456.0635(3), F.S., as created by the bill, refers to a board renewing a license, certification, or registration. However, only the DOH renews licenses – boards do not.

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.

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

	Prepared B	y: The Professional Sta	aff of the Health Re	egulation Committee		
BILL:	SB 1228					
INTRODUCER:	Senator Altman					
SUBJECT:	Military Spouses					
DATE:	March 10, 2011	l revised:				
ANAL	YST.	STAFF DIRECTOR	REFERENCE	ACTION		
O'Callagh	an S	Stovall	HR	Pre-meeting		
			MS			
			BC			

I. Summary:

This bill authorizes the Department of Health (DOH) to issue a temporary professional license, which is valid for 6 months after issuance and is not renewable, to the spouse of an active duty member of the Armed Forces of the United States. To be eligible for licensure, the spouse must submit to the DOH a completed application, application fee, proof of marriage to an active duty service member, proof of a valid license in another state or other jurisdiction, and proof that the applicant and the spouse who is an active duty service member are assigned to a duty station in Florida.

The bill also requires an applicant for a temporary license to submit a complete set of fingerprints to the Florida Department of Law Enforcement (FDLE) to undergo a statewide criminal history check and national criminal history check, which is to be conducted by the Federal Bureau of Investigation. The DOH or the appropriate board may determine whether the applicant meets licensure standards based on the results of the criminal history checks.

The bill requires the applicant to pay the cost of fingerprint processing for criminal history checks and requires the applicant to pay an application fee, which may not exceed the DOH's cost of issuing a license.

This bill substantially amends s. 456.024, F.S.

II. Present Situation:

Background

The United States currently has 1.4 million people serving in the armed forces, over 23 million veterans living in the U.S., and over 200 military installations in 46 states, the District of Columbia, and Puerto Rico. In addition, there are more than 400,000 National Guard members throughout the 50 states, the District of Columbia, and commonwealths and territories. The military operations of the United States touch every state in some manner. ¹

In Florida, there are 22 military bases, over 58,000 active duty military personnel, and over 37,000 Reserve and National Guard personnel.² There are approximately 37,000 military spouses that currently live in Florida.³

Military families often face frequent moves and these moves can add unique financial pressures, as spouses may have to leave their employment due to a military transfer and the families may face a reduction in income.

While the majority of programs and benefits for soldiers and veterans are administered by the federal government, states and state legislatures are playing an increasingly larger role in military issues. With many active duty military members and National Guard and Reservists, and their families, facing multiple deployments, state policymakers are creating benefits and programs designed to assist both the military personnel and their families.⁴

In Florida, in 2009, the Legislature enacted HB 7123, which became ch. 2009-155, Laws of Florida. The Florida Council on Military Base and Mission Support (council) was created with the enactment of this law. The council was created to:

- Support and strengthen all DoD missions and bases located in Florida;
- Know the capabilities of Florida's military installations in order to support future military growth opportunities;
- Support community efforts relating to mission support of a military base by acting as a liaison between the local communities and the Legislature; and
- Enhance Florida's defense economy.⁵

In 2010, the Legislature enacted HB 713, which became ch. 2010-106, Laws of Florida. This law authorizes the Department of Business and Professional Regulation (DBPR) to issue a temporary professional license, which is valid for 6 months after issuance and is not renewable, to the spouse of an active duty member of the Armed Forces of the United States if the spouse applies to the DBPR for the temporary license. The applicant for a temporary license must

¹ National Conference of State Legislatures, *Military Personnel, Veterans and Their Families*, available at: http://www.ncsl.org/default.aspx?TabID=123&tabs=858,137,1160#858 (Last visited on March 10, 2011).

² Telephone interview with Col. Rocky McPherson, USMC, Director of Military and Defense Programs, Enterprise Florida, by professional staff of the Senate Health Regulation Committee on March 10, 2011.

³ Agency for Workforce Innovation, *Military Family Employment Advocacy Program*, available at: http://www.floridajobs.org/workforce/mfea.html (Last visited on March 11, 2011).

⁴ Supra fn. 1.

⁵ Section 288.984(1), F.S.

submit to the DBPR proof of marriage to the military member, proof that he or she holds an active license in another state or jurisdiction, and proof that the military member is assigned to a duty station in Florida. The applicant must also be subject to a criminal history check and is responsible for the cost of the fingerprinting process. The applicant must also pay an application fee.

In Florida, military spouses also enjoy benefits related to education and unemployment compensation. Through federal funding under the Wagner-Peyser Act, the Agency for Workforce Innovation provides services to military spouses and dependents through the Military Family Employment Advocacy Program. The program delivers employment assistance services, including interviewing, assessment, counseling, job search and placement assistance, labor market information, and resume assistance through Military Family Employment Advocates colocated within selected One-Stop Career Centers. Persons eligible for assistance through this program include spouses and dependents of active-duty military personnel, Florida National Guard members, and military reservists.

The Department of Health

Section 20.43, F.S., creates the DOH. The DOH is responsible for the state's public health system, which is designed to promote, protect, and improve the health of all people in the state. The mission of the state's public health system is to foster the conditions in which people can be healthy, by assessing state and community health needs and priorities through data collection, epidemiologic studies, and community participation; by developing comprehensive public health policies and objectives aimed at improving the health status of people in the state; and by ensuring essential health care and an environment which enhances the health of the individual and the community. The State Surgeon General is the State Health Officer and the head of the DOH.

Section 20.43, F.S., creates several divisions under the DOH, including the Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:

- The Board of Acupuncture, created under chapter 457.
- The Board of Medicine, created under chapter 458.
- The Board of Osteopathic Medicine, created under chapter 459.
- The Board of Chiropractic Medicine, created under chapter 460.
- The Board of Podiatric Medicine, created under chapter 461.
- The Board of Optometry, created under chapter 463.
- The Board of Nursing, created under part I of chapter 464.
- The Board of Pharmacy, created under chapter 465.
- The Board of Dentistry, created under chapter 466.
- The Board of Speech-Language Pathology and Audiology, created under part I of chapter 468.

⁶ See ss. 295.01, 1009.21(10), and 443.101(1)(a)1., F.S.

⁷ Agency for Workforce Innovation, *AWI Programs*, available at: http://www.floridajobs.org/workforce/WP_MFEA.html (Last visited on March 10, 2011).

⁸ Section 381.001, F.S.

• The Board of Nursing Home Administrators, created under part II of chapter 468.

- The Board of Occupational Therapy, created under part III of chapter 468.
- The Board of Athletic Training, created under part XIII of chapter 468.
- The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.
- The Board of Massage Therapy, created under chapter 480.
- The Board of Clinical Laboratory Personnel, created under part III of chapter 483.
- The Board of Opticianry, created under part I of chapter 484.
- The Board of Hearing Aid Specialists, created under part II of chapter 484.
- The Board of Physical Therapy Practice, created under chapter 486.
- The Board of Psychology, created under chapter 490.
- The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.

In addition to the professions regulated by the various aforementioned boards, the DOH also regulates the following professions: naturopathy, as provided under chapter 462; nursing assistants, as provided under part II of chapter 464; midwifery, as provided under chapter 467; respiratory therapy, as provided under part V of chapter 468; dietetics and nutrition practice, as provided under part X of chapter 468; electrolysis, as provided under chapter 478; medical physicists, as provided under part IV of chapter 483; and school psychologists, as provided under chapter 490.

Temporary Licensure by the Department of Health

There are several examples of laws that authorize individuals in Florida to obtain temporary permits or licenses from the DOH, typically only if certain conditions are met.

Advanced Registered Nurse Practitioners

Under s. 464.012(1)(b), F.S., the Board of Nursing is authorized to provide by rule for provisional state certification of graduate nurse anesthetists and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification exam.

Clinical Laboratory Personnel

Under s. 483.813, F.S., the DOH may grant a temporary license to any candidate it deems property qualified, for a period not to exceed 1 year.

Dentistry

Under s. 466.025, F.S., the DOH has authority to issue temporary certificates to graduates of accredited dental schools, which are approved by the Board of Dentistry, to practice in state and county government facilities, working under the general supervision of licensed dentists in the state or county facility. The certificate is only valid for such a time as the dentist remains employed by a state or county government facility.

Dietetics/Nutritionists

Under s. 468.511, F.S., the Board of Medicine may issue a temporary permit to an applicant seeking to practice dietetics and nutrition if the applicant files an application, pays a temporary permit fee, submits proof of completion of the required education requirement and is supervised

by a licensed dietitian or nutritionist. The temporary permit expires 1 year from the date of issuance, but one extension may be granted for good cause shown.

Electrolysis

Under s. 478.46, F.S., the DOH is authorized to issue a temporary permit to practice electrolysis if an applicant qualifies for licensure. The temporary permit is valid until the next Board of Medicine meeting at which license applications are to be considered or if the applicant qualifies for licensure but has not taken an exam, the permit is valid until notification of the results of the examination.

Nursing Home Administrators

Under s. 468.1705, F.S., the DOH may issue a one-time temporary license to an applicant who has filed an application for license by endorsement, has paid a fee to take an exam, has filed an application and paid an application fee, has an active license in another state, and has worked as a fully licensed nursing home administrator for 2 years within the 5-year period immediately preceding the application for the temporary license.

Occupational Therapy

Under s. 468.209, F.S., an applicant who qualifies for licensure by endorsement may be issued a temporary permit. Also, an applicant who has not passed an examination, but meets all of the other licensure requirements may be issued a temporary permit by the Board of Occupational Therapy Practice which is valid until the notification of the results of the examination. A person may not practice under the temporary permit unless he or she practices under the supervision of a licensed occupational therapist.

Physician Assistants

Under s. 458.347, F.S., The DOH may grant temporary licensure to an applicant who meets licensure requirements. The temporary license expires 30 days after receipt and notice of scores to the licenseholder from the first available examination following licensure by the DOH. The applicant may be granted one extension of the temporary license.

Radiologic Technologists

Under s. 468.307, F.S., the DOH may issue a temporary certificate to an applicant who has completed an educational program and is awaiting examination for a certificate. However, the applicant must meet all other certification requirements specified in law.

III. Effect of Proposed Changes:

This bill amends s. 456.024, F.S., to authorize the DOH to issue a temporary professional license, which is valid for 6 months after issuance and is not renewable, to the spouse of an active duty member of the Armed Forces of the United States. To be eligible for licensure, the spouse must submit to the DOH:

- A completed application;
- An application fee;
- Proof of marriage to an active duty service member;
- Proof of a valid license in another state, the District of Columbia, a possession or territory of the United States, or a foreign jurisdiction; and

• Proof that the applicant and the spouse who is an active duty service member are assigned to a duty station in Florida.

The bill also requires an applicant for a temporary license to submit a complete set of fingerprints to the FDLE to undergo a statewide criminal history check. The FDLE is required to forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check to be conducted. The DOH or the appropriate board may determine whether the applicant meets licensure standards based on the results of the criminal history checks.

The bill requires the applicant to pay the cost of fingerprint processing for criminal history checks and requires the applicant to pay an application fee, which may not exceed the DOH's cost of issuing a license.

The bill provides that it shall take effect July 1, 2011.

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:

The applicant for a temporary professional license is required to pay an application fee and for the processing of fingerprints for criminal history checks. Statewide and nationwide criminal history checks cost a total of \$54.25.9

B. Private Sector Impact:

Although military spouses may incur costs associated with applying for a temporary license, they may be able to find employment more quickly after transferring to Florida should they be issued a temporary license.

⁹ Florida Department of Law Enforcement, *Criminal History Record Checks/Background Checks Fact Sheet*, January 4, 2011, available at: http://www.fdle.state.fl.us/Content/getdoc/39b8f116-6d8b-4024-9a70-5d8cd2e34aa5/FAQ.aspx (Last visited on March 11, 2011).

C. Government Sector Impact:

The DOH or boards within the DOH may incur costs associated with implementing the bill, which should be off-set by the application fees received for temporary licensure.

VI. Technical Deficiencies:

Typically, the boards within the DOH issue licenses. Therefore, it may be more appropriate in Line 17 of the bill to say, "The board, or the department when there is no board, may issue a temporary professional license..."

Lines 29 through 31 of the bill require the applicant to provide proof that the applicant's spouse is assigned to a duty station in Florida and that the applicant is assigned to a duty station in Florida. This could be interpreted to mean that both the applicant and the applicant's spouse must be in the military and transferred to Florida in order for the applicant to qualify for a temporary license. It is unclear whether it is the intent of the bill to require the applicant to be in the military.

The term "Armed Forces" is not defined in the bill or in ch. 456, F.S. The term "Armed Forces" is defined under s. 250.01(4), F.S., to mean the United States Army, Navy, Air Force, Marine Corps, and Coast Guard, but does not include Reservists or National Guardsmen. It may be appropriate to either define the term "Armed Forces" or cross-reference s. 250.01(4), F.S.

VII. Related Issues:

The DOH may need rulemaking authority to develop and furnish a specific application for the temporary licensure of a person as required under the bill.

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.



LEGISLATIVE ACTION

Senate House

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (3) is added to section 456.024, Florida Statutes, to read:

456.024 Members of Armed Forces in good standing with administrative boards or the department; spouses.-

(3) (a) The board, or the department when there is no board, may issue a temporary professional license to the spouse of an active duty member of the Armed Forces of the United States who submits to the department:

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- 1. A completed application upon a form prepared and furnished by the department in accordance with the board's rules;
 - 2. The required application fee;
- 3. Proof that the applicant is married to a member of the Armed Forces of the United States who is on active duty;
- 4. Proof that the applicant holds a valid license for the profession issued by another state, the District of Columbia, or a possession or territory of the United States, and is not the subject of any disciplinary proceeding in any jurisdiction in which the applicant holds a license to practice a profession regulated by this chapter; and
- 5. Proof that the applicant's spouse is assigned to a duty station in this state pursuant to the member's official active duty military orders.
- (b) The applicant must also submit to the Department of Law Enforcement a complete set of fingerprints. The Department of Law Enforcement shall conduct a statewide criminal history check and forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check.
- (c) The department shall, and the board may, review the results of the state and federal criminal history checks according to the level 2 screening standards in s. 435.04 and shall determine whether the applicant meets the licensure requirements.
- (d) The applicant shall pay the cost of fingerprint processing. If the fingerprints are submitted through an authorized agency or vendor, the agency or vendor shall collect the required processing fees and remit the fees to the

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- (e) The department shall set an application fee, which may not exceed the cost of issuing the license.
- (f) A temporary license expires 6 months after the date of issuance and is not renewable.
- (g) A person issued a temporary license under this subsection is subject to the requirements under s. 456.013(3).

Section 2. Present subsections (1) through (4) of section 458.315, Florida Statutes, are renumbered as subsections (2) through (5), respectively, and a new subsection (1) is added to that section, to read:

458.315 Temporary certificate for practice in areas of critical need.-

- (1) A certificate issued pursuant to this section may be cited as the "Rear Admiral LeRoy Collins, Jr., Temporary Certificate for Practice in Areas of Critical Need."
- Section 3. Present subsections (1) through (4) of section 459.0076, Florida Statutes, are renumbered as subsections (2) through (5), respectively, and a new subsection (1) is added to that section, to read:
- 459.0076 Temporary certificate for practice in areas of critical need.-
- (1) A certificate issued pursuant to this section may be cited as the "Rear Admiral LeRoy Collins, Jr., Temporary Certificate for Practice in Areas of Critical Need."

Section 4. This act shall take effect July 1, 2011.

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

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Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to temporary certificates and licenses for certain health care practitioners; amending s. 456.024, F.S.; providing for issuance of a temporary license to specified health care practitioners who are spouses of active duty members of the Armed Forces under certain circumstances; providing for criminal history checks; providing fees; providing for expiration of a temporary license; requiring a person who is issued a temporary license to be subject to certain general licensing requirements; amending ss. 458.315 and 459.0076, F.S.; naming the temporary certificates issued to physicians who practice in areas of critical need after Rear Admiral LeRoy Collins, Jr.; providing an effective date.