Health Quality Subcommittee

Tuesday, March 19, 2013
9:00 AM - 11:00 AM
306 HOB

Will Weatherford
Speaker

Kenneth L. "Ken" Roberson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Tuesday, March 19, 2013 09:00 am
End Date and Time:	Tuesday, March 19, 2013 11:00 am
Location:	306 HOB
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 605 Workers' Compensation by Hudson
HB 831 Pharmacy & Controlled Substance Prescription by Fasano
HB 847 Temporary Certificates for Visiting Physicians by Peters
HB 1115 Pub. Rec./Dental Workforce Surveys by Williams, A.
HB 1129 Infants Born Alive by Pigman
HB 1205 Sovereign Immunity for Dentists and Dental Hygienists by Magar, Spano

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Monday, March 18, 2013.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, March 18, 2013.

NOTICE FINALIZED on 03/15/2013 16:04 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 605 Workers' Compensation
SPONSOR(S): Hudson
TIED BILLS: **IDEN./SIM. BILLS:** SB 662

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Poche	O'Callaghan
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Florida's workers' compensation law, ch. 440, F.S., requires employers, or employers' insurance carriers, to pay for medically necessary treatment and care for injured employees, including medications. Reimbursement for prescription drugs (generally to dispensing physicians and pharmacies) is the average wholesale price (AWP) plus a $4.18 dispensing fee, or at a contract rate, whichever is lower. AWP is not defined in the worker's compensation law and does not have a universally accepted definition.

Prescription drug repackaging companies are licensed by the Department of Business and Professional Regulation. Drug repackagers purchase pharmaceuticals in bulk from the manufacturer and repackage the drugs into individual prescription sizes. The repackaged drugs are then assigned a different AWP than the manufacturer's suggested AWP, which is often substantially higher than the manufacturer's AWP. As such, the cost for a prescription filled with repackaged drugs in the workers' compensation system is generally much higher than it would have been if the prescription had been filled with the same drug that had not been repackaged. The overwhelming majority of repackaged drugs in Florida's workers' compensation system are dispensed by physicians who are authorized to dispense drugs at their office.

It is estimated that higher reimbursements for repackaged or relabeled drugs add $27.3 million annually to workers' compensation costs, and that providing the same reimbursement for the same prescription drug, regardless of whether the dispensed drug is repackaged, relabeled, or non-repackaged, will decrease system costs by 1.1%. The Office of Insurance Regulation approved a workers' compensation rate filing that provides for an overall 6.1% increase in workers' compensation premiums effective January 1, 2013.

The bill provides the same rate of reimbursement for repackaged or relabeled drugs as for non-repackaged drugs. Specifically, reimbursement for repackaged or relabeled drugs is to be calculated by multiplying the number of units of the drug dispensed by the per-unit AWP set by the original manufacturer of the drug (who may not be the manufacturer of the repackaged or relabeled drug), plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The bill expressly prohibits the price of repackaged or relabeled drugs from exceeding the amount that would otherwise be payable had the drug not been repackaged or relabeled. This reimbursement formula was included in HB 5603 (2010), which was vetoed by Governor Crist.

The bill appears to have a fiscal impact on state and local government.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Workers' Compensation Benefits[1]

Chapter 440, F.S., is Florida's workers' compensation law. For work-related injuries, workers' compensation requires employers, or employers' insurance carriers, to pay for:

- Medically necessary remedial treatment, care, and attendance, including medicines,[2] medical supplies, durable medical equipment, and prosthetics.[3]
- Compensation for disability when the injury causes an employee to miss more than 7 days of work.[4]

The Division of Workers' Compensation (Division) within the Department of Financial Services (DFS) provides regulatory oversight of Florida's workers' compensation system.

Reimbursement for Prescription Drugs in Workers' Compensation

Reimbursement to pharmacies and dispensing physicians for prescription drugs in workers' compensation is provided for in s. 440.13(12)(c), F.S. Under current law, prescription drugs are reimbursed at the average wholesale price (AWP) plus a $4.18 dispensing fee, or at a contract rate, whichever is lower.[5, 6] AWP is not defined in the workers' compensation statute and does not appear to have a universally accepted definition.[7,8]

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[1] Whether an employer is required to have workers' compensation insurance depends upon the employer's industry (construction, non-construction, or agricultural) and the number of employees.

[2] Many workers' compensation insurers have implemented prescription drug programs (sometimes called "first fill" programs) designed to avoid out-of-pocket pharmacy expenses to injured employees for the initial prescription filled at the pharmacy as well as subsequent prescriptions. Under such a program, an injured employee may be given a form or card to show at a pharmacy to avoid out-of-pocket expense.

[3] S. 440.13(2) (a), F.S.

[4] S. 440.12(1), F.S.

[5] Fees for pharmaceuticals and pharmaceutical services must be reimbursable at the applicable fee schedule amount. Where the employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier must reimburse at the scheduled, negotiated, or contract price, whichever is lower. The contract may not rely on a provider that is not reasonably accessible to the employee. S. 440.13(12)(c), F.S.

[6] In response to inquiries received by the Florida Division of Workers' Compensation (Division) as to whether employers/carriers may appropriately deny authorization or reimbursement for prescription medication that is dispensed by a physician instead of a pharmacist, the Florida Department of Financial Services issued Informational Bulletin DFS-02-2009 on August 12, 2009. The bulletin informs, in part, that the Division is unaware of any specific provisions of the workers' compensation law that addresses the issue presented; available at: http://www.myfloridacfo.com/wc/ (last viewed on March 16, 2013).

[7] *See*, for example, "Prescription Benchmarks for Florida, 2nd Edition," a 2011 study by the Workers' Compensation Research Institute (WCRI study) compared with "Impact of Physician-Dispensing of Repackaged Drugs on California Workers' Compensation, Employers Cost, and Workers' Access to Quality Care," a 2006 study conducted by Frank Neuhauser and colleagues for the California Commission on Health and Safety and Workers' Compensation (California study). The WCRI defines average wholesale price as: "Published by First DataBank and Medi-Span ®. The AWP operates as an available price index that represents the most common wholesaler price charged to customers. The AWP does not necessarily represent the actual sales price in any single transaction. The payors may negotiate for lower prices. In workers' compensation systems, however, the AWP is often used as a price benchmark for pharmacy reimbursements of prescription drugs." [Note: On September 28, 2011, First DataBank discontinued publication of the "Blue Book on Average Wholesale Price." *See* http://www.firstdatabank.com/Support/drug-pricing-policy.aspx.] The California study states that: "AWP is probably the most widely quoted pricing benchmark, but the least meaningful.... unlike what the name implies, the price has no relation to a wholesale price, average or otherwise. It is simply a price point established by the

Physician Dispensing of Drugs

The authority for a physician to dispense medicinal drugs is found in s. 465.0276, F.S. To dispense medicinal drugs, a physician must register with the applicable professional licensing board and pay a fee of $100.[9] In addition, the physician must comply with all applicable statutes found in chapter 465, chapter 499, and chapter 893, all applicable rules, and federal laws regarding the dispensing of medicinal drugs.[10] Lastly, a physician must provide the patient with a written prescription and advise him or her, orally or in writing, that there is an option to have the prescription filled at the doctor's office or at a pharmacy.[11] Physician dispensing is regulated by the relevant licensing boards with the Department of Health. Currently, there are 7,187 registered dispensing physicians in Florida.[12]

A physician may not dispense controlled substances listed in Schedule II and Schedule III, as provided in s. 893.03, F.S.[13] However, the following physicians are exempted from the ban on dispensing:

- A physician who dispenses complimentary medications in the normal course of practice without payment or remuneration;
- A physician dispensing a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure, limited to a 14 day supply;
- A physician dispensing a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial;
- A physician dispensing methadone in a methadone clinic licensed under s. 397.427, F.S.; and
- A physician dispensing a controlled substance listed in Schedule II or Schedule III in a hospice care facility licensed under part IV of ch. 400, F.S.[14]

To be eligible for payment under the workers' compensation law, health care providers who treat injured employees, except for emergency treatment, must apply for and be certified by the DFS and receive authorization from the insurer before providing treatment.[15] As of March 2013, there were 36,987 certified health care providers in the workers' compensation system.[16] The number of certified workers' compensation health care providers who are also authorized to dispense drugs is unknown.

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manufacturer, wholesaler, or repackager....The AWP...is typically much higher than the actual amounts that are paid by pharmacies and other wholesale drug purchasers...." Details on the WCRI study are available at http://www.wcrinet.org/. The California study is available at http://www.dir.ca.gov/chswc/search/query.asp?SearchType=0 (last viewed March 16, 2013).

[8] The Florida Division of Workers' Compensation informs that in the event of a reimbursement dispute it would rely on the "Drug Topics Red Book," published by Thomson Reuters (New York) to determine the average wholesale price. The "Red Book" is listed as a reference source in the "Florida Workers' Compensation Health Care Provider Reimbursement Manual, 2008 Edition." The Reimbursement Manual is available at http://www.myfloridacfo.com/wc/ (last viewed March 16, 2013).

[9] S. 465.0276(2)(a), F.S.; Rule 64B8-3.006, F.A.C.; Registration is not required for dispensing complimentary medications in the normal course of practice without payment or remuneration.

[10] S. 465.0276(2)(b), F.S.; chapter 499, F.S., contains the Florida Drug and Cosmetic Act, administered by the DBPR; chapter 893, F.S., contains the Florida Comprehensive Drug Abuse Prevention and Control Act, which was significantly amended during the 2011 Regular Legislative session; *see also* chapter 2011-141, Laws of Fla.

[11] S. 465.0276(2)(c), F.S.

[12] Email correspondence from the Florida Department of Health on file with staff of the Health Quality Subcommittee, dated March 15, 2013.

[13] S. 465.0276(1)(b), F.S.; *see also* s. 15, ch. 2011-141, Laws of Fla.

[14] S. 465.0276(1)(b)1. through 6., F.S.

[15] Section 440.13(3)(a), F.S.; Rule 69L-29.002, F.A.C.

[16] Florida Department of Financial Services, *Division of Workers Compensation Health Care Provider Directory*, available at https://apps.fldfs.com/provider/ (last viewed March 16, 2013).

Relabeled or Repackaged Drugs

The term "repackage", used in the context of distributing drugs in Florida, means to repack or otherwise change the container, wrapping, or labeling to further the distribution of a drug, device, or cosmetic.[17] A "repackager" means a person who repackages a drug, device, or cosmetic, but specifically excludes pharmacies operating in compliance with pharmacy practice standards set out in chapter 465, F.S., and under applicable rules.[18] The term "repackaged" drugs refers to pharmaceuticals that have been purchased in bulk by a repackager from a manufacturer, relabeled, and repackaged into individual prescription sizes that can be dispensed directly by physicians to patients.

Rule 61N-1.001, F.A.C., defines "repackaging or otherwise changing the container, wrapper, or labeling to further the distribution" to mean:

- Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1000 pills to bottles of 100 pills.
- Altering a manufacturer's package for sale under a label different from the manufacturer. For example, a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.
- Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product. This does not include:
    - Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or
    - Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

Repackagers assign an AWP for a repackaged drug that differs from the AWP suggested by the original manufacturer of the drug.[19] Frequently, the AWP assigned by the drug repackager is significantly greater than the AWP suggested by the drug's manufacturer. Thus, the cost of the repackaged drug, in terms of reimbursement paid by an insurer, is often significantly greater than it would have been if the prescription had been filled with the identical non-repackaged drug.

The Florida Department of Business and Professional Regulation (DBPR), which regulates prescription drug repackagers, reports that there are 28 licensed prescription drug repackagers in the state.[20]

The Cost of Repackaged or Relabeled Prescription Drugs to Florida's Workers' Compensation System

The National Council on Compensation Insurance (NCCI) is the designated licensed rating and statistical organization for workers' compensation in Florida. Among its responsibilities, NCCI collects data from workers' compensation insurers in Florida and makes rate filings on the insurers' behalf. The

[17] S. 499.03(49), F.S.
[18] S. 499.003(50), F.S.
[19] United States Government Accountability Office, "Brand-Name Prescription Drug Pricing: Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases" (GAO-10-201, December 2009); available at http://www.gao.gov/products/GAO-10-201 (last viewed March 16, 2013).
[20] Correspondence from the Department of Business and Professional Regulation, dated March 14, 2013 (on file with the Health Quality Subcommittee staff). The DBPR also reports that as of March 2013, there were 275 "out-of-state prescription wholesaler distributor" permits issued. Such distributors are able to repackage drugs. However, the DBPR does not collect information as to whether applicants for such permits repackage drugs, as it does not have legal authority to regulate repackaging outside of the state of Florida.

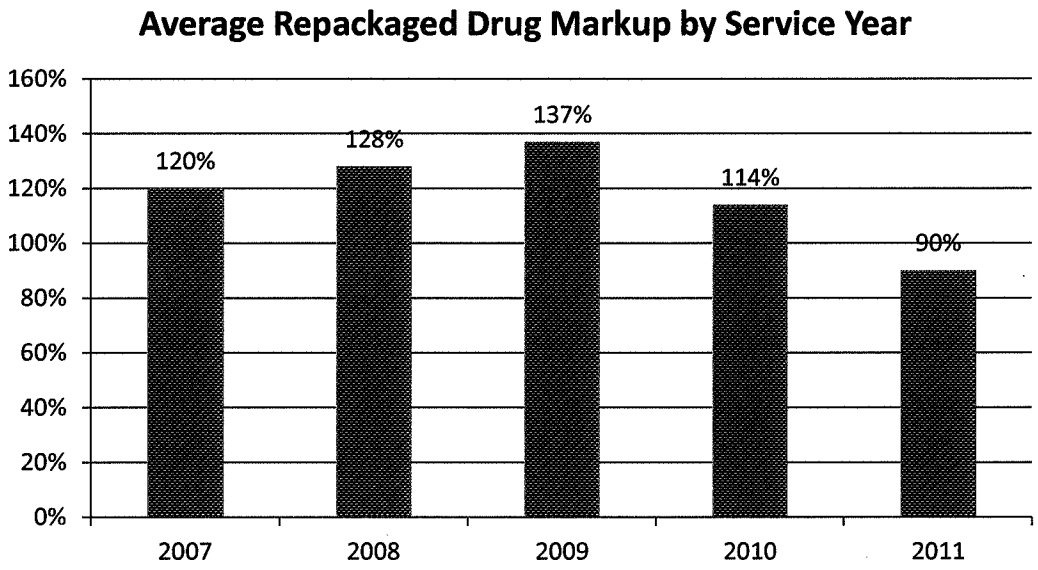
workers' compensation rate filing for 2013 provides for an overall increase in workers' compensation rates of 6.1%.[21]

Using 2011 data from the Division, the NCCI has estimated that reimbursements for repackaged or relabeled prescription drugs add $27.3 million in annual costs to the workers' compensation system, and that elimination of the higher reimbursements available for these drugs, as compared to non-repackaged drugs, would decrease system costs by 1.1%.[22]

Additional findings about Florida's workers' compensation system include the following:

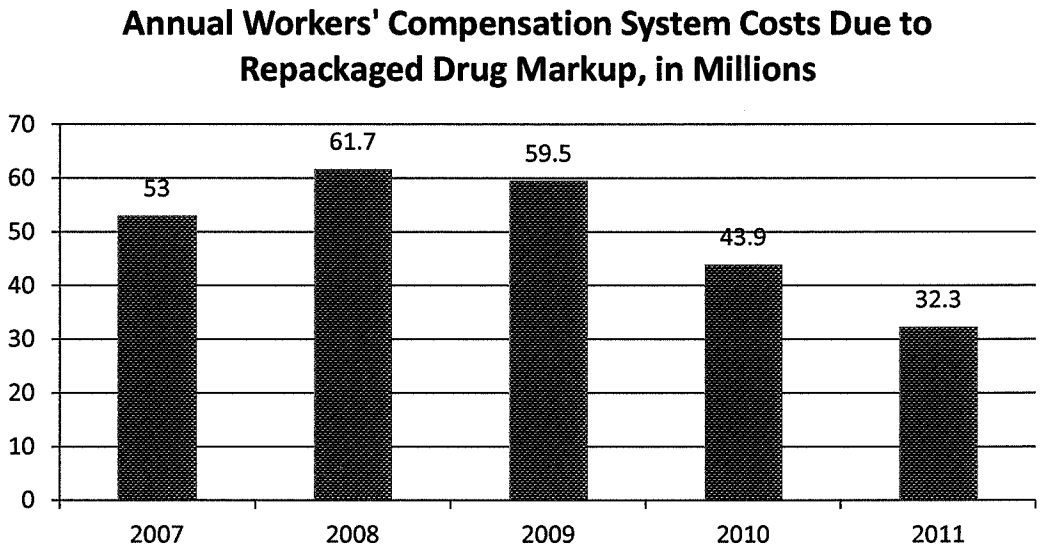
- The 10 most frequently dispensed repackaged drugs have an average markup of 54% to 625%.[23]
- Physician-dispensed drugs account for 62% of all prescription drug dollars; the second highest percentage of the 23 states in one study.[24]
- Physician-dispensed repackaged drugs account for 36% of overall prescription drug costs (by comparison, repackaged drugs dispensed by pharmacies account for approximately 4% of overall drug costs).
- Since 2008, more than 95 percent of reimbursement dollars for repackaged drugs were paid to dispensing physicians.[25] In 2011, 97.9 percent of the reimbursement dollars spent was a result of dispensing physicians.[26]

The following chart illustrates the average markup of repackaged drugs from 2007 through 2011:[27]



[21] Florida Office of Insurance Regulation, Office Statement, *OIR Approves Final Order for Workers' Compensation Rates*, (November 5, 2012), available at http://www.floir.com/PressReleases/index.aspx (last viewed March 14, 2013).
[22] National Council on Compensation Insurance, Moore, Natasha, *Pricing of Workers Compensation Proposals 2013*, page 8 (on file with the Health Quality Subcommittee staff); *see also* National Council on Compensation Insurance, *Analysis of Florida Proposal to Revise Reimbursement for Repackaged or Relabeled Prescription Drugs Effective Upon Adoption*, September 25, 2012, page 1 (on file with the Health Quality Subcommittee staff).
[23] Id. at page 12. The 10 drugs are Meloxicam, Carisoprodol, Lidoderm®, Tramadol HCL, Omeprazole, Gabapentin, Ranitidine HCL, Cyclobenzaprine HCL, Naproxen, and Lyrica.
[24] Workers Compensation Research Institute, Wang, D., *Physician Dispensing in Workers' Compensation*, July 2012, page 8, table A.
[25] Florida Department of Financial Services, Three Member Panel, *2013 Biennial Report*, page 4 (citing Florida Department of Financial Services, Division of Workers' Compensation, *2012 Results and Accomplishments*, page 117); available at www.myfloridacfo.com/wc/pdf/3MP_Report_2013.pdf.
[26] Id.
[27] *See supra*, FN 22 at page 10.

Total workers' compensation system costs as a result of the markup on repackaged drugs were $250 million over the last five years.[28] The following chart shows the annual system costs attributed to the markup of repackaged drugs from 2007 to 2011:[29]



The Three Member Panel (Panel) Biennial Report for 2013 makes the following observation regarding reimbursement to physicians in the workers' compensation system who are repackaging and dispensing medications:

> "...the current statutory benchmark of reimbursing prescription drugs at the Average Wholesale Price has led to a pricing environment that is not conducive to the self-execution of the workers' compensation system and does not provide reimbursement clarity and uniformity, which is a detriment to the payers and payees. The result has been a dramatic increase in the number of petitions for reimbursement dispute filed by physicians in FY 2011/2012 (up 872% over FY 2010/2011 from 1,308 to 12,718, respectively) primarily due to disputes involving physician dispensed medication."

The Panel believes that the Division will continue to see great numbers of petitions for reimbursement dispute being filed until a legislative and/or regulatory solution is achieved.[30]

Findings of the Workers' Compensation Research Institute[31]

In July 2011, the Workers' Compensation Research Institute (WCRI) published "Prescription Benchmarks for Florida, 2nd Edition,"[32] a study that compares the cost, price, and use of pharmaceuticals in workers' compensation in Florida with 16 other states.[33] Among the study's findings on Florida:

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[28] Id. at page 14.
[29] Id.
[30] Id. at page 6.
[31] WCRI is an independent research organization that analyzes workers' compensation systems for states with which it contracts. WCRI provides information through studies and data collection efforts, and does not take positions on the issues it researches.
[32] WCRI study, *supra* note 7.
[33] The 17 states in the WCRI study are California, Florida, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, Pennsylvania, Tennessee, Texas, and Wisconsin.

- For 2007/2008, the average payment per workers' compensation claim for prescription drugs was $536, the second highest cost of the 17 states studied, and 45% higher than the median[34] of the states studied.[35]
- Between 2005/2006 and 2007/2008, the average cost per claim for prescription drugs in Florida increased by 14%, but remained relatively stable in the other study states.
- Higher and growing costs of prescription drugs in Florida were largely due to more frequent and higher-priced physician dispensing.
- Over a four-year period (from 2004/2005 and 2007/2008), the percentage of payments for physician-dispensed prescriptions increased from 17% to 46% of all prescription payments.
- In 2007/2008, for many common drugs, physicians were paid 40% to 80% more than pharmacies for the same prescription.
- 65% of physician-dispensed prescriptions were for pain medications.

Further, the WCRI study identifies and addresses two concerns that have been raised in response to proposals to eliminate higher reimbursements for repackaged drugs, and to provide the same rate of reimbursement for the same drug, whether it is repackaged or non-repackaged. The first concern is that all prescription costs would increase to offset such a change. This position is based on the following assumptions: that physician dispensing would decrease and that physicians dispense generic drugs more frequently than pharmacies. For the most commonly dispensed drugs, the WCRI found that physicians and pharmacies almost always dispense generic drugs, and that physicians are paid much higher prices per pill than pharmacies for the same prescription.

A second concern with providing the same reimbursement for repackaged and non-repackaged drugs is that physicians would stop dispensing drugs, and patients who do not have prescriptions filled by their doctor are less likely to take their medicine as prescribed, which would be detrimental to the patient. For California, the WCRI reports that physician dispensing decreased from 50% to 25% of all prescriptions immediately following enactment of a reform to provide the same reimbursement for repackaged and non-repackaged drugs.[36]

Effect of Proposed Changes

The bill provides the same rate of reimbursement for repackaged or relabeled drugs as for non-repackaged drugs. Specifically, reimbursement for repackaged or relabeled drugs is to be calculated by multiplying the number of units of the drug dispensed by the per-unit AWP set by the original manufacturer of the drug (which may not be the manufacturer of the repackaged or relabeled drug), plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The bill expressly prohibits the price of repackaged or relabeled drugs from exceeding the amount that would otherwise be payable had the drug not been repackaged or relabeled.

B. SECTION DIRECTORY:

Section 1: Amends s. 440.13, F.S., relating to medical services and supplies; penalty for violations; limitations.
Section 2: Provides an effective date of July 1, 2013.

[34] The Merriam-Webster Dictionary online defines median as "a value in an ordered set of values below and above which there is an equal number of values or which is the arithmetic mean of the two middle values if there is no one middle number...." *See* http://www.merriam-webster.com/dictionary.htm.
[35] WCRI study, *supra* note 7, informs that physician dispensing is not generally allowed in three of the states in its study - Massachusetts, New York, and Texas.
[36] Data from the first quarter of 2008. Subsequent dispensing patterns are not addressed in this study.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

To the extent that repackaged drugs are dispensed by physicians to state government employees who suffer a workplace injury, the bill will lower the costs that state government pays for prescription drugs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

To the extent that repackaged drugs are dispensed by physicians to local government employees who suffer a workplace injury, the bill will lower the costs that local governments pay for prescription drugs. Also, for local governments that have procured workers' compensation insurance coverage, there may be a reduction in insurance premiums to reflect system-wide savings of 1.1%, as estimated by the NCCI.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Providing the same rate of reimbursement for repackaged or relabeled drugs as for non-repackaged drugs could save Florida employers $27.3 million annually in workers' compensation costs, a 1.1% system savings.[37]

Physicians that dispense prescription drugs under the workers' compensation system will continue to receive a $4.18 dispensing fee for each prescription they fill, but will no longer derive additional income from current higher reimbursements.

D. FISCAL COMMENTS:

The bill will result in significant savings to state and local governments and lower workers' compensation costs for Florida employers.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

[37] *See supra* at FN 22.

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Financial Services has appropriate rule-making authority, if necessary, to implement the provisions of the bill.[38]

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[38] S. 440.591, F.S.

A bill to be entitled

An act relating to workers' compensation; amending s. 440.13, F.S.; revising requirements for determining the amount of a reimbursement for repackaged or relabeled prescription medication; providing limitations; providing an effective date.

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

Section 1. Paragraph (c) of subsection (12) of section 440.13, Florida Statutes, is amended to read:

440.13 Medical services and supplies; penalty for violations; limitations.—

(12) CREATION OF THREE-MEMBER PANEL; GUIDES OF MAXIMUM REIMBURSEMENT ALLOWANCES.—

(c) As to reimbursement for a prescription medication, regardless of the location from which or the provider from whom the claimant receives the prescription medication, the reimbursement amount ~~for a prescription~~ shall be the average wholesale price plus $4.18 for the dispensing fee, unless ~~except where~~ the carrier has contracted for a lower amount. If the drug has been repackaged or relabeled, the reimbursement amount shall be calculated by multiplying the number of units dispensed times the per-unit average wholesale price set by the original manufacturer of the underlying drug, which may not be the manufacturer of the repackaged or relabeled drug, plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The repackaged or relabeled drug price may not exceed

the amount otherwise payable had the drug not been repackaged or relabeled. Fees for pharmaceuticals and pharmaceutical services shall be reimbursable at the applicable fee schedule amount. If ~~Where~~ the employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier shall reimburse at the schedule, negotiated, or contract price, whichever is lower. ~~No~~ Such contract may not ~~shall~~ rely on a provider that is not reasonably accessible to the employee.

Section 2. This act shall take effect July 1, 2013.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 831 Pharmacy & Controlled Substance Prescription
SPONSOR(S): Fasano
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Poche	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

House Bill 831 revises law regarding physician prescribing of controlled substances, the registration and regulation of pain-management clinics in Florida, and operations of pharmacies under chapter 465, F.S., the Florida Pharmacy Act. The bill specifically does the following:

- Revises criteria for determining when a physician must register as a prescriber of controlled substances and provides exemptions from registering;
- Removes the exemptions from pain-management clinic registration for certain publicly traded corporations and 501(c)(3) corporations;
- Requires a physician or his or her agent to consult the Florida Prescription Drug Monitoring Program (PDMP) database prior to or at the time of a new patient appointment before he or she prescribes a Schedule II or III controlled substance;
- Establishes a definition of "abandoned" to apply to pharmacies that do not commence operations within a certain timeframe after receiving a permit; and
- Establishes procedure for serving notices from the Department of Health on pharmacy permittees.

The bill also permits state funds to be used to operate the PDMP. The bill also removes pharmaceutical companies from the list of "inappropriate sources" of funds that may not be received by the PDMP Foundation for the assistance, funding, and promotional support for the activities of the PDMP.

Lastly, the bill requires the Department of Health, in consultation with certain parties, to develop a model local ordinance, by December 31, 2013, to be used by municipalities and counties for regulation of pain-management clinics. Municipalities and counties may not enact any ordinances regulating pain-management clinics until June 30, 2014. After that date, municipalities or counties may not enact ordinances regulating pain-management clinics that are stricter than the model local ordinance. If a municipal or county ordinance provides for stricter regulation of pain-management clinics than the model local ordinance, the municipal or county ordinance must be amended to comply with the model local ordinance. The bill limits the areas of regulation that may be covered by the model local ordinance.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the different drug schedules are the "potential for abuse"[1] of the substance contained therein and whether there is a currently accepted medical use for the substance. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.[2]

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, peyote, lysergic acid diethylamide (LSD), and cannabis. [3]

Schedule II controlled substances have severely restricted medical uses and a high potential for abuse, which may lead to severe psychological or physical dependence. These drugs include morphine and its derivatives, amphetamines, cocaine, and pentobarbital.[4]

Schedule III controlled substances have lower abuse potential than Schedule II substances and have some accepted medical use, but they may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of dihydrocodeine per dose (such as Tylenol #3), ketamine, and anabolic steroids. [5]

Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan).[6]

Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[7]

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the federal Drug Enforcement Administration (DEA). Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law. Prescribing numbers must be renewed every 3 years.[8]

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[1] S. 893.02(19), F.S.
[2] DEA, Office of Diversion Control, Controlled Substance Schedules, available at: www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited March 18, 2013).
[3] S. 893.03(1), F.S.
[4] S. 893.03(2), F.S.
[5] S. 893.03(3), F.S.
[6] S. 893.03(4), F.S.
[7] S. 893.03 (5), F.S.
[8] U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Questions & Answers-Registration*, available at http://www.deadiversion.usdoj.gov/drugreg/faq.htm#3 (last viewed on March 16, 2013).

Controlled Substance Prescribing

As of January 1, 2012, every physician, podiatrist, or dentist who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain[9] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[10] Before prescribing any controlled substances for the treatment of chronic nonmalignant pain, a practitioner must document certain characteristics about the nature of the pain, success of past treatments, any underlying health problems, and history of alcohol and substance abuse.[11] The practitioner must develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment.[12] Each practitioner must also enter into a controlled substance agreement with their patients; such agreements must include:

- The risks and benefits of controlled substance use, including the risk for addiction or dependence;
- The number and frequency of permitted prescriptions and refills;
- A statement of reasons for discontinuation of therapy, including violation of the agreement; and
- The requirement that a patient's chronic nonmalignant pain only be treated by one practitioner at a time unless otherwise authorized and documented.[13]

Patients treated with controlled substances must been seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.[14] Patients at special risk for drug abuse or diversion may require co-monitoring by an addiction medicine physician or a psychiatrist.[15] Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.[16]

Anesthesiologists, physiatrists, neurologists, and surgeons are exempt from these provisions.[17] Physicians who hold certain credentials relating to pain medicine are also exempt.[18]

Pain-Management Clinics

A pain-management clinic is any facility that advertises pain-management services or where a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.[19] Pain-management clinics are regulated by the practice acts for medical doctors and osteopathic physicians. Until January 1, 2016, all pain-management clinics must register with the Department of Health (DOH) and meet certain provisions concerning staffing, sanitation, recordkeeping, and quality assurance.[20] Clinics are exempt from these provisions if they are:

- Licensed under chapter 395, F.S., as a hospital, ambulatory surgical center, or mobile surgical facility;
- Staffed primarily by surgeons;

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[9] "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. S. 456.44(1)(e), F.S.
[10] S. 456.44(2)(a) and (b), F.S.
[11] S. 456.44(3)(a), F.S.
[12] S. 456.44(3)(b), F.S.
[13] S. 456.44(3)(c)1.-3., F.S.
[14] S. 456.33(3)(d), F.S.
[15] S. 456.44(3)(e), F.S.
[16] S. 456.44(3)(g), F.S.
[17] Id.
[18] Id.
[19] S. 458.3265(1)(a)1.c. and 459.0137(1)(a)1.c., F.S.
[20] S. 458.3265 and 459.0137, F.S.

- Owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;
- Affiliated with an accredited medical school at which training is provided for medical student, residents, or fellows;
- Not involved in prescribing controlled substances for the treatment of pain;
- Owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3); or
- Wholly owned and operated by anesthesiologists, physiatrists, or neurologists, or physicians holding certain credentials in pain medicine.[21]

All clinics must be owned by at least one licensed physician or be licensed as a health care clinic under part X of ch. 400, F.S., to be eligible for registration.[22] DOH is prohibited from registering an entity:

- Not owned by a physician;
- Whose DEA number has ever been revoked;
- Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or
- Who have been convicted of certain drug-related crimes in any jurisdiction.[23]

Pain-management clinics are inspected annually by DOH unless they hold current certification from a DOH-approved national accrediting agency.[24] DOH may suspend or revoke clinic registration or impose administrative fines of up to $5,000 per violation for any offenses against state pain-management clinic provisions or related federal laws and rules.[25]

If the registration for a pain-management clinic is revoked for any reason, the clinic must cease to operate immediately, remove all signs or symbols identifying the facility as a pain-management clinic, and dispose of any medication on the premises.[26] No owner or operator of the clinic may own or operate another pain-management clinic for five years after revocation of registration.[27]

Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F, established the Prescription Drug Monitoring Program (PDMP) in s. 893.055, F.S. The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.[28] Dispensers of certain controlled substances must report specified information to the PDMP database, including the name of the prescriber, the date the prescription was filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed.[29]

Direct access to the PDMP database is presently limited to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.[30] Indirect access to the PDMP database is provided to:

- DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;

[21] S. 458.3265(1)(a)2.a.-h. and 459.0137(1)(a)2.a.-h., F.S.
[22] S. 458.3265(1)(d) and 459.0137(1)(d), F.S.
[23] S. 458.3265(1)(d) and (e) and 459.0137(1)(d) and (e), F.S.
[24] S. 458.3265(3)(a) and 459.0137(3)(a), F.S.
[25] S. 458.3265(5) and 459.0137(5), F.S.
[26] S. 458.3265(1)(h)-(j) and 459.0137(1)(h)-(j), F.S.
[27] S. 458.3265(1)(k) and 459.0137(1)(k), F.S.
[28] S. 893.055(2)(a), F.S.
[29] S. 893.055(3)(a)-(c), F.S.
[30] S. 893.055(7)(b), F.S.

- A law enforcement agency; and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient.[31]

Restrictions on how DOH may fund implementation and operation of the PDMP are also included in statute. DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.[32] Funding for the PDMP comes from three funding sources:[33]

1. Donations procured by the Florida PDMP Foundation, Inc. (Foundation), the direct-support organization authorized by s. 893.055, F.S., to fund the continuing operation of the PDMP. The following amounts have been paid to DOH by the Foundation since the PDMP was established:

FY 2009-2010	$39,108
FY 2010-2011	$201,552
FY 2011-2012	$96,758
FY 2012-2013	$102,654
Total	**$440,072**

2. Federal Grants. The PDMP has been awarded three Harold Rogers Prescription Drug Monitoring Program grants from the U.S. Department of Justice and one additional federal grant. The award date and amount of each grant follows:

   - On May 19, 2010, DOH was awarded an "Implementation" grant of $400,000 to implement the prescription drug monitoring system.
   - On September 19, 2010, DOH was awarded an "Enhancement" grant of $400,000 for system enhancements.
   - On August 21, 2012, DOH was awarded a second "Enhancement" grant of $399,300 to enhance the PDMP.
   - On September 20, 2012, DOH was awarded a grant of $240,105 from the Substance Abuse and Mental Health Services Administration (SAMHSA) to integrate PDMP data into existing clinical workflow and technology and to expand interoperability.

   The total amount of federal grants received is $1,199,300. Of that amount, approximately $566,460 has been expended in operation of the PDMP.

3. Private grants and donations. DOH has been awarded three private grants from the National Association of State Controlled Substance Authorities. These grants, totaling $49,952, were used to create a website, to purchase office equipment, and to purchase promotional items.

Section 893.0551, F.S., provides an exemption from public records for personal information of a patient and certain information concerning health care professionals outlined in the statute.[34] The statute details exceptions for disclosure of information after DOH ensures the legitimacy of the person's request for the information.[35]

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[31] S. 893.055(7)(c)1.-4., F.S.
[32] S. 893.055(10) and (11)(c), F.S.
[33] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), *2011-2012 Prescription Drug Monitoring Program Annual Report*, page 7 (available at www.eforcse.com/docs/2012AnnualReport.pdf) (on file with Health Quality Subcommittee staff); information also came from Florida Department of Health document detailing the funding history of the PDMP, also on file with Health Quality Subcommittee staff.
[34] S. 893.0551(2)(a)-(h), F.S.
[35] S. 893.0551(3)(a)-(g), F.S.

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[36] Health care practitioners began accessing the PDMP on October 17, 2011.[37] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[38]

Between 2011 and 2012, physicians and pharmacists used the PDMP database at least 2.6 million times.[39] Nearly 5,000 pharmacists entered 56 million prescriptions into the database.[40] Law enforcement queried the PDMP database more than 20,000 times in conjunction with active criminal investigations.[41]

The PDMP is currently funded through fiscal year 2012-2013.[42]

City and County Ordinances Regulating Pain-Management Clinics

In an effort to combat the proliferation of illegitimate pain-management clinics within their communities, cities and counties throughout Florida have enacted local ordinances to impose zoning requirements, building codes, certificate or use requirements, and other regulations designed to adversely impact the operation of illegitimate pain-management clinics and prevent the establishment of new clinics. As a result, there are many local ordinances covering all points along the spectrum of regulation, some of which go beyond the areas of regulation traditionally within the purview of cities and counties and begin to regulate the practice of medicine, which is within the purview of the state.

Section 893.138, F.S., permits a municipality or county to declare a pain-management clinic a public nuisance and abate such nuisance if the pain-management clinic has been used on more than two occasions in a six month period as the site of a violation of state statute relating to:

- Assault and battery;[43]
- Burglary;[44]
- Dealing in theft;[45]
- Robbery by sudden snatching;[46] or
- Unlawful distribution of controlled substances.[47]

Any county or municipality may, by ordinance, create an administrative board (board) to hear complaints regarding the public nuisance.[48] If the board declares a pain-management clinic to be a public nuisance, it may enter an order requiring the owner of such place or premises to adopt a procedure considered to be appropriate under the circumstances to abate any such nuisance or it may enter an order immediately prohibiting:

- The maintaining of the nuisance;
- The operating or maintaining of the place or premises, including the closure of the place or premises or any part thereof; or

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[36] Supra FN 37 at page 4.
[37] Id.
[38] Id.
[39] Id. at page 1.
[40] Id.
[41] Id.
[42] Florida Department of Health, *Florida's Prescription Drug Monitoring Program*, Presentation to the Senate Health Policy Committee, January 23, 2013, slide 5 (on file with Health Quality Subcommittee staff).
[43] SS. 784.011, 784.021, 784.03, or 784.045, F.S.
[44] S. 810.02, F.S.
[45] S. 812.014, F.S.
[46] S. 812.131, F.S.
[47] S. 893.13, F.S.
[48] S. 893.138(4), F.S.

- The conduct, operation, or maintenance of any business or activity on the premises which is conducive to such nuisance.[49]

An order expires after 1 year, or earlier if stated in the order.[50] The order may be enforced pursuant to the procedures contained in s. 120.69, F.S.[51],[52] The board may also bring a complaint under s. 60.05, F.S., seeking temporary and permanent injunctive relief against any nuisance.[53] Nothing contained within s. 893.138, F.S., prohibits a county or municipality from proceeding against a public nuisance by any other means.[54]
Section 893.138(11), F.S., provides that the provisions outlined above may be supplemented by a county or municipal ordinance, which may include, but is not limited to, provisions that establish additional penalties for public nuisances that:

- Include fines not to exceed $250 per day;[55]
- Provide for the payment of reasonable costs, including reasonable attorney fees associated with investigations of and hearings on public nuisances;
- Provide for continuing jurisdiction for a period of 1 year over any place or premise that has been or is declared to be a public nuisance;
- Establish penalties, including fines not to exceed $500 per day for recurring public nuisances;[56]
- Provide for the recording of orders on public nuisances so that notice must be given to subsequent purchasers, successors in interest, or assigns of the real property that is the subject of the order;
- Provide that recorded orders on public nuisances may become liens against the real property that is the subject of the order;[57] and
- Provide for the foreclosure of property subject to a lien and the recovery of all costs, including reasonable attorney fees, associated with the recording of orders and foreclosure.

Effect of Proposed Changes

Controlled Substance Prescribing by Physicians

The bill revises application of the provisions of s. 456.44(2), F.S., which requires a prescriber of controlled substances to comply with certain registration requirements. Current law requires any licensed physician who prescribes controlled substances for the treatment of chronic nonmalignant pain to comply with registration requirements. The bill narrows applicability to only those licensed physicians who prescribe more than a 30-day supply of Schedule II, III, or IV controlled substances over a six month period to any one patient.

The bill requires physicians licensed under chapter 458, F.S., to consult the PDMP database, either prior to a new patient visit or at the time of a new patient visit, before prescribing Schedule II or III controlled substances to a new patient. The physician may designate an agent to consult the PDMP database. The bill requires the applicable board to adopt a penalty for failure to consult the PDMP database as required. The bill exempts the following physicians from the PDMP database consultation requirement:

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[49] S. 893.138(5), F.S.
[50] S. 893.138(6), F.S.
[51] S. 120.69, F.S., relates to enforcement of agency action. This section provides that an agency may seek enforcement of an action by filing a petition for enforcement in the circuit court where the subject matter of the enforcement is located.
[52] S. 893.138(7), F.S.
[53] S. 893.138(8), F.S.
[54] S. 893.138(9), F.S.
[55] S. 893.138(11), F.S., provides that the total fines imposed pursuant to the authority of this section shall not exceed $15,000.
[56] Id.
[57] S. 893.138(11), F.S., provides that no lien created pursuant to the provisions of this section may be foreclosed on real property which is a homestead under s. 4, Art. X of the State Constitution.

- A physician who prescribes a medically necessary controlled substance to a resident of a nursing home; and
- A physician who writes less than 50 prescriptions for controlled substances to all of his or her patients over a one-year period.

Registration of Pain-Management Clinics

The bill removes the exemption from registration requirements in chapters 458 and 459, F.S., for pain-management clinics that:

- Are owned by a publicly traded corporation with assets exceeding $50 million; or
- Are owned by a tax-exempt corporate entity under 26 U.S.C. 501(c)(3).[58]

The bill also requires DOH to deny registration to a pain-management clinic that is not a licensed health care clinic under part I of chapter 400, F.S., fully-owned by a physician or group of physicians.

Model Local Ordinance for Pain-Management Clinics

The bill requires DOH, in conjunction with the Florida Association of Counties, the Florida Medical Association, the Florida Osteopathic Medical Association, and appropriate specialty societies of the associations, to develop a local model ordinance to be used by municipalities and counties to regulate pain-management clinics registered under chapter 458 and 459, F.S. The model local ordinance must not infringe on the state's power to regulate the practice of medicine and can only address the following areas:

- Zoning;
- Certificate of Use;
- Permitting;
- Building codes;
- General business facility regulations, including design, operation, and maintenance; and
- Penalties for violation of the ordinance.

The bill places a moratorium on municipalities and counties prohibiting the passage of any local ordinance related to pain-management clinics until June 30, 2014. After that date, municipalities and counties may not adopt ordinances that are stricter than the model local ordinance drafted by the group. If a municipality or county does adopt a stricter ordinance, the bill requires the ordinance to be amended to match the requirements of the model local ordinance.

The model local ordinance must be completed by October 1, 2013. A report containing the ordinance must be issued to the Governor, the President of the Senate, and the Speaker of the House of Representatives on or before that date.

Pharmacy Regulations

The bill adds the definition of "abandoned" to the Florida Pharmacy Act (Act), chapter 465, F.S., meaning a person has failed to commence pharmacy operations within 180 days of receiving a permit

[58] Tax- exempt entities pursuant to 26 U.S.C. 501(c)(3) include the following: corporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation (except as otherwise provided in subsection (h)), and which does not participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.

to do so or a person has failed to follow pharmacy closure procedures as set out by the Board of Pharmacy.

The bill adds the following to the list of acts that are grounds for denial of a license or disciplinary action under the Act:

- Violation of the rules adopted under chapter 893, F.S., relating to drug abuse prevention and control, including but not limited to chapter 64K-1, F.A.C., relating to the PDMP, rule 64B-3.005, F.A.C., relating to the transfer of prescription orders, and rule 64B16-27.1003, F.A.C., relating to oral prescriptions and copies.
- Misappropriating drugs, supplies, or equipment from a pharmacy permittee.

The bill requires all notices from DOH relating to provisions of the Act be in writing and be either personally delivered to a pharmacy permittee by an agent of DOH or delivered to the pharmacy permittee by certified mail. If the permittee refuses to accept service, evades service, or service cannot be accomplished after due diligence by the agent for DOH, notices may be posted in a conspicuous place at the pharmacy.

Under the provisions of the bill, a pharmacy permittee is required to begin pharmacy operations within 180 days of receiving a permit to do so. If pharmacy operations have not begun within the established timeframe, a pharmacy permittee must show good cause to DOH for the failure to initiate operations. The Board of Pharmacy is given authority to promulgate rules to establish what constitutes commencement of pharmacy operations, but the bill specifies that acts within the scope of the Act and ordering and receiving drugs satisfy the commencement of pharmacy operations standard.

The bill also requires a pharmacy permittee to be supervised by a prescription department manager[59] or consultant pharmacist[60] of record at all times.

Prescription Drug Monitoring Program (PDMP)

The bill deletes obsolete language that triggered the development of rules relating to the operation of PDMP. The obsolete language established funding benchmarks to be met before rule development began for the PDMP. The funding benchmarks have long since been met, rules have been developed, and the PDMP is in operation. Deletion of the language is appropriate.

The bill also deletes obsolete contingency language relating the operation of the PDMP. The language that is proposed for deletion made the establishment and implementation of the PDMP contingent on the receipt of non-state funding. Again, sufficient funding has been received and the PDMP is operational without the use of non-state funding. Deletion of the language is appropriate.

Current law only allows DOH to operate the PDMP with federal grants or private funding. The bill would allow DOH to also use state funds to operate the PDMP. Lastly, the bill clarifies that pharmaceutical companies are not included in the list of inappropriate sources, contained in s. 893.055(11)(c), F.S., from which the PDMP direct-support organization may not receive funds for the operation of the PDMP. As a result, funds from both the state and pharmaceutical companies may be obtained and used to operate the PDMP.

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[59] S. 465.018(2), F.S., requires a licensed pharmacist to be designated as the prescription department manager before a permit to operate a community pharmacy can be issued.

[60] A "consultant pharmacist" is licensed under s. 465.0125, F.S. and "...shall be responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities."; *see also* Rule 64B16-26.300, F.A.C. (consultant pharmacist licensure).

Conforming Changes and Cross References

The bill makes conforming changes and cross references to ss. 409.9201, 458.331, 459.015, 465.014, 465.015, 465.0156, 465.0197, 465.022, 465.023, 465.1901, 499.003, and 893.02, F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.44, F.S., relating to controlled substance prescribing.
Section 2: Amends s. 458.326, F.S., relating to intractable pain; authorized treatment.
Section 3: Amends s. 458.3265, F.S., relating to pain-management clinics.
Section 4: Amends s. 459.0137, F.S., relating to pain-management clinics.
Section 5: Creates an unnumbered section of law relating to the development of a model local ordinance for pain-management clinics.
Section 6: Amends s. 465.003, F.S., relating to definitions.
Section 7: Amends s. 465.016, F.S., relating to disciplinary actions.
Section 8: Creates s. 465.0065, F.S., relating to notices; forms and service.
Section 9: Amends s. 465.022, F.S., relating to pharmacies; general requirements; fees.
Section 10: Amends s. 465.023, F.S., relating to pharmacy permittee; disciplinary action.
Section 11: Amends s. 893.055, F.S., relating to prescription drug monitoring program.
Section 12: Amends s. 409.9201, F.S., relating to Medicaid fraud.
Section 13: Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 14: Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 15: Amends s. 465.014, F.S., relating to pharmacy technician.
Section 16: Amends s. 465.015, F.S., relating to violations and penalties.
Section 17: Amends s. 465.0156, F.S., relating to registration of nonresident pharmacies.
Section 18: Amends s. 465.0197, F.S., relating to Internet pharmacy permits.
Section 19: Amends s. 465.022, F.S., relating to pharmacies; general requirements; fees.
Section 20: Amends s. 465.023, F.S., relating to pharmacy permittee; disciplinary action.
Section 21: Amends s. 465.1901, F.S., relating to practice of orthotics and pedorthics.
Section 22: Amends s. 499.003, F.S., relating to definitions of terms used in this part.
Section 23: Amends s. 893.02, F.S., relating to definitions.
Section 24: Creates an unnumbered section of law providing directions to the Division of Law Revision and Information.
Section 25: Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill removes an exemption from registration as a pain-management clinic for certain entities. DOH may realize additional registration fees from these previously exempt entities if they choose to continue to operate as pain-management clinics. The number of physicians registering with DOH as a prescribing practitioner for chronic nonmalignant pain may decrease, because the bill exempts certain physicians from the registration requirement.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill requires a pharmacy permittee to be supervised by a pharmacy department manager or consultant pharmacists at all times. Some pharmacies may realize additional administrative costs to employ a pharmacy department manager or consultant pharmacist in a supervisory capacity at all times.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH and relevant boards have sufficient rule-making authority to implement most of the provisions of the bill. Other provisions of the bill, for which DOH and relevant boards may or may not have rule-making authority to implement, grant appropriate rule-making authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On line 470, the bill does not define "supplies" or "equipment" in relation to misappropriation of those items from a pharmacy permittee constituting grounds for license denial or disciplinary action. To avoid a challenge to the statute being brought by a licensed pharmacist or a pharmacist seeking licensure based on lack of specificity, it is suggested that the terms "supplies" and "equipment" be defined in

either s. 465.003, F.S., which contains the definitions applicable to the chapter, or proposed s. 465.016(1)(u), F.S., which established the violation for misappropriation of these items.

On line 480, the term "conspicuous place" is not sufficiently explained. In order to complete service of a notice on a pharmacy permittee and encourage consistency, it is suggested that the statute specify a particular location within a pharmacy where the notice may be posted if service cannot be achieved. If the agent of DOH is unable to gain access to the pharmacy, the statute may provide for posting of the notice on the front door of the pharmacy. This will ensure that notice will be posted in a limited number of places and avoid any challenge on the basis of whether the area where a particular notice was posted satisfied the conspicuousness requirement.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy and controlled substance prescription; amending s. 456.44, F.S.; limiting the application of requirements for prescribing controlled substances; requiring physicians to consult the prescription drug monitoring program database before prescribing certain controlled substances; authorizing the board to adopt a penalty for failure to consult the database; exempting nursing home residents and certain physicians from requirements regarding prescription of controlled substance; amending s. 458.326, F.S.; requiring physicians to consult the prescription drug monitoring program database or designate an agent to consult the database before prescribing certain controlled substances; authorizing the board to adopt a penalty for failure to consult the database; amending ss. 458.3265 and 459.0137, F.S.; requiring that owners of pain-management clinics be licensed physicians; removing language regarding nonphysician-owned pain-management clinics; prohibiting municipalities and counties from enacting ordinances related to pain-management clinics until a specified date; providing for development of a model local ordinance; prohibiting adoption of a local ordinance after a specified date with restrictions on pain-management clinics stricter than those in the model local ordinance; amending s. 465.003, F.S.; defining a term; conforming a cross-reference;

amending s. 465.016, F.S.; providing additional grounds for disciplinary action; creating s. 465.0065, F.S.; providing notice requirements for inspection of a pharmacy; amending s. 465.022, F.S.; requiring a pharmacy permittee to commence operations within 180 days after permit issuance or show good cause why operations were not commenced; authorizing the board to establish rules; requiring a pharmacy permittee to be supervised by a prescription department manager or consultant pharmacist of record; amending s. 465.023, F.S.; providing additional grounds for disciplinary action; amending s. 893.055, F.S.; deleting an obsolete provision; authorizing the prescription drug monitoring program to be funded by state funds and pharmaceutical company donations; amending ss. 409.9201, 458.331, 459.015, 465.014, 465.015, 465.0156, 465.0197, 465.022, 465.023, 465.1901, 499.003, and 893.02, F.S.; correcting cross-references; providing a directive to the Division of Law Revision and Information; providing an effective date.

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

Section 1. Subsections (2) and (3) of section 456.44, Florida Statutes, are amended to read:

456.44 Controlled substance prescribing.—

(2) REGISTRATION.—~~Effective January 1, 2012,~~ A physician

licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes more than a 30-day supply of any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, over a 6-month period to any one patient for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each

registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Pursuant to s. 458.326, before prescribing a controlled substance listed in Schedule II or Schedule III, as provided in s. 893.03, a physician shall consult the prescription drug monitoring program database, as provided in s. 893.055(2)(a), before seeing a new patient or during a new patient visit. A physician may designate an agent under his or her supervision to consult the database. The board shall adopt rules to establish a penalty for a physician that does not comply with this subsection.

(c) ~~(b)~~ Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(d) ~~(c)~~ The physician shall discuss the risks and benefits

of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(e) ~~(d)~~ The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and

indications of substance abuse or diversion at a minimum of 3-month intervals.

(f) ~~(e)~~ The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(g) ~~(f)~~ A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.
2. Diagnostic, therapeutic, and laboratory results.
3. Evaluations and consultations.
4. Treatment objectives.
5. Discussion of risks and benefits.
6. Treatments.
7. Medications, including date, type, dosage, and quantity prescribed.
8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The physician's full name presented in a legible manner.

(h) ~~(g)~~ Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395 or to a resident in a facility licensed under part II of chapter 400. This subsection does not apply to any physician licensed under chapter 458 or chapter 459 who writes fewer than 50 prescriptions for a controlled substance for all of his or her patients during a 1-year period.

Section 2. Subsection (3) of section 458.326, Florida Statutes, is amended to read:

458.326 Intractable pain; authorized treatment.—

(3)(a) Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in s. 893.03, to a person

for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

(b) Before prescribing a controlled substance listed in Schedule II or Schedule III, as provided in s. 893.03, a physician shall consult the prescription drug monitoring program database, as provided in s. 893.055(2)(a), before seeing a new patient or during a new patient visit. A physician may designate an agent under his or her supervision to consult the database. The board shall adopt rules to establish a penalty for a physician who does not comply with this paragraph.

Section 3. Paragraphs (a) and (d) of subsection (1) of section 458.3265, Florida Statutes, are amended, subsections (5) and (6) of that section are renumbered as subsections (6) and (7), respectively, and a new subsection (5) is added to that section, to read:

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

(a)1. As used in this section, the term:

a. "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

b. "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the

injury that is the cause of the pain or more than 90 days after surgery.

c. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department unless:

a. That clinic is licensed as a facility pursuant to chapter 395;

b. The majority of the physicians who provide services in the clinic primarily provide surgical services;

~~c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;~~

c.~~d.~~ The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

d.~~e.~~ The clinic does not prescribe controlled substances for the treatment of pain;

~~f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);~~

e.~~g.~~ The clinic is wholly owned and operated by one or more board-eligible or board-certified anesthesiologists,

physiatrists, rheumatologists, or neurologists; or

f.~~h.~~ The clinic is wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education, or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians, each of whom is licensed under this chapter or chapter 459; or that is not a health care clinic licensed under part X of chapter 400 that is fully owned by such physician or group of physicians.

(5) LOCAL ORDINANCES.—

(a) The Legislature finds that it is necessary to promote uniformity throughout the state in the fight against prescription drug abuse. Municipalities and counties are prohibited from enacting further ordinances related to pain-management clinics until June 30, 2014.

(b) After June 30, 2014, a municipality or county that chooses to regulate pain-management clinics may not adopt regulations stricter than those identified in the model local ordinance developed under section 5 of this act. If an existing

local ordinance exceeds the scope of the model local ordinance, the local government shall amend its ordinance to bring it into conformity with the model local ordinance.

Section 4. Paragraphs (a) and (d) of subsection (1) of section 459.0137, Florida Statutes, are amended, subsections (5) and (6) of that section are renumbered as subsections (6) and (7), respectively, and a new subsection (5) is added to that section, to read:

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

(a)1. As used in this section, the term:

a. "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

b. "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

c. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department unless:

a. That clinic is licensed as a facility pursuant to chapter 395;

b. The majority of the physicians who provide services in the clinic primarily provide surgical services;

~~c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;~~

c.~~d.~~ The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

d.~~e.~~ The clinic does not prescribe controlled substances for the treatment of pain;

~~f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);~~

e.~~g.~~ The clinic is wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or

f.~~h.~~ The clinic is wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical

Specialties, the American Association of Physician Specialists, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under chapter 458 or this chapter or a group of physicians, each of whom is licensed under chapter 458 or this chapter; or that is not a health care clinic licensed under part X of chapter 400 that is fully owned by such physician or group of physicians.

(5) LOCAL ORDINANCES.—

(a) The Legislature finds that it is necessary to promote uniformity throughout the state in the fight against prescription drug abuse. Municipalities and counties are prohibited from enacting further ordinances related to pain-management clinics until June 30, 2014.

(b) After June 30, 2014, a municipality or county that chooses to regulate pain-management clinics may not adopt regulations stricter than those identified in the model local ordinance developed under section 5 of this act. If an existing local ordinance exceeds the scope of the model local ordinance, the local government shall amend its ordinance to bring it into conformity with the model local ordinance.

Section 5. In an effort to stop the proliferation of prescription drug abuse, promote uniformity in the law, and protect the bona fide practice of medicine, the Florida Department of Health in conjunction with the Florida Association of Counties, the Florida League of Cities, the Florida Medical

Association, the Florida Osteopathic Medical Association, and the appropriate specialty societies of those associations shall develop a model local ordinance for pain-management clinics that register with the state under s. 458.3265 or s. 459.0137, Florida Statutes. The agencies and entities specified in this section shall complete the model local ordinance by October 1, 2013, and shall issue a report containing the model local ordinance to the Governor, the President of the Senate, and the Speaker of the House of Representatives on or before that date. In drafting the model local ordinance, the agencies and entities specified in this section shall ensure that the local regulation of pain-management clinics does not intrude on the state's power to regulate the practice of medicine. The model local ordinance shall only address the following areas of local concern:

(1) Zoning.

(2) Certificates of use.

(3) Permitting.

(4) Building codes.

(5) General business facility regulations, including design, operation, and maintenance.

(6) Appropriate penalties for ordinance violations.

Section 6. Subsections (1) through (17) of section 465.003, Florida Statutes, are renumbered as subsections (2) through (18), respectively, paragraph (a) of present subsection (11) of that section is amended, and a new subsection (1) is added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:

(1) "Abandoned" means when a person who is issued a

pharmacy permit fails to commence pharmacy operations within 180 days after issuance of the pharmacy permit without good cause or fails to follow pharmacy closure requirements as set by the board.

(12) ~~(11)~~ (a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate

with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in this section ~~subsection (13)~~.

Section 7. Paragraphs (e) and (s) of subsection (1) of section 465.016, Florida Statutes, are amended, and paragraph (u) is added to subsection (1) of that section, to read:

465.016 Disciplinary actions.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893 or rules adopted thereunder.

(s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003~~(14)~~ or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

(u) Misappropriating drugs, supplies, or equipment from a pharmacy permittee.

Section 8. Section 465.0065, Florida Statutes, is created to read:

465.0065 Notices; form and service.—Each notice served by the department pursuant to this chapter must be in writing and must be delivered personally by an agent of the department or by

certified mail to the pharmacy permittee. If the pharmacy permittee refuses to accept service, evades service, or the agent is otherwise unable to effect service after due diligence, the department may post such notice in a conspicuous place at the pharmacy.

Section 9. Subsections (10) through (14) of section 465.022, Florida Statutes, are renumbered as subsections (11) through (15), respectively, present subsection (10) of that section is amended, and a new subsection (10) is added to that section, to read:

465.022 Pharmacies; general requirements; fees.—

(10) The permittee shall commence pharmacy operations within 180 days after issuance of the permit, or show good cause to the department why pharmacy operations were not commenced. Commencement of pharmacy operations includes, but is not limited to, acts within the scope of the practice of pharmacy, ordering or receiving drugs, and other similar activities. The board shall establish rules regarding commencement of pharmacy operations.

(11) ~~(10)~~ A pharmacy permittee shall be supervised by a prescription department manager or consultant pharmacist of record at all times. A permittee must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record.

Section 10. Paragraph (c) of subsection (1) of section 465.023, Florida Statutes, is amended to read:

465.023 Pharmacy permittee; disciplinary action.—

(1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:

(c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893 or rules adopted thereunder;

Section 11. Paragraph (b) of subsection (2), subsection (10), and paragraph (c) of subsection (11) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(2)

(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,~~ 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 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 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.

(10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through state funds, 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 state funds, 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 costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation 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. Funds provided, directly

or indirectly, by prescription drug manufacturers may not be used to implement the program.

(11) 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.

(c) The State Surgeon General shall appoint a board of directors for the direct-support organization. Members of the board shall serve at the pleasure of the State Surgeon General. The State Surgeon General 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, excluding pharmaceutical companies, that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

Section 12. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. 465.003~~(8)~~, s. 499.003(46) or (53) or s. 499.007(13).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 13. Paragraph (pp) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

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

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(pp) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United

States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003~~(14)~~ or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(2).

Section 14. Paragraph (rr) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

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

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(rr) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or

nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003~~(14)~~ or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(2).

Section 15. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003~~(13)~~. All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines

adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

Section 16. Paragraph (c) of subsection (2) of section 465.015, Florida Statutes, is amended to read:

465.015 Violations and penalties.—

(2) It is unlawful for any person:

(c) To sell or dispense drugs as defined in s. 465.003~~(8)~~ without first being furnished with a prescription.

Section 17. Subsection (8) of section 465.0156, Florida Statutes, is amended to read:

465.0156 Registration of nonresident pharmacies.—

(8) Notwithstanding s. 465.003~~(10)~~, for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 18. Subsection (4) of section 465.0197, Florida Statutes, is amended to read:

465.0197 Internet pharmacy permits.—

(4) Notwithstanding s. 465.003~~(10)~~, for purposes of this section, the Internet pharmacy and the pharmacist designated by the Internet pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 19. Paragraph (j) of subsection (5) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.—

(5) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003~~(14)~~ or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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 department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

Section 20. Paragraph (h) of subsection (1) of section 465.023, Florida Statutes, is amended to read:

465.023 Pharmacy permittee; disciplinary action.—

(1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director,

or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:

(h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003~~(14)~~ or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

Section 21. Section 465.1901, Florida Statutes, is amended to read:

465.1901 Practice of orthotics and pedorthics.—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003~~(13)~~, and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice

pending adoption of these rules.

Section 22. Subsection (43) of section 499.003, Florida Statutes, is amended to read:

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

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003~~(8)~~, s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

Section 23. Subsection (22) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(22) "Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of

s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003~~(8)~~, which does not fall within the definition of a controlled substance as defined in this act.

Section 24. The Division of Law Revision and Information is directed to replace the phrase "this act" wherever it occurs in sections 458.3265 and 459.0137, Florida Statutes, as amended by this act, with the assigned chapter number of this act.

Section 25. This act shall take effect July 1, 2013.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Fasano offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (tt) is added to subsection (1) of section 458.331, Florida Statutes, to read:

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

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(tt) Failing to review a patient's controlled substance prescription history prior to prescribing a controlled substance, as required under s. 893.055.

Section 2. Paragraph (vv) is added to subsection (1) of section 459.015, Florida Statutes, to read:

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

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(vv) Failing to review a patient's controlled substance prescription history prior to prescribing a controlled substance, as required under s. 893.055.

Section 3. Paragraph (dd) is added to subsection (1) of section 461.013, Florida Statutes, to read:

461.013 Grounds for disciplinary action; action by the board; investigations by department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(dd) Failing to review a patient's controlled substance prescription history prior to prescribing a controlled substance, as required under s. 893.055.

Section 4. Paragraph (ff) is added to subsection (1) of section 462.14, Florida Statutes, to read:

462.14 Grounds for disciplinary action; action by the department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(ff) Failing to review a patient's controlled substance prescription history prior to prescribing a controlled substance, as required under s. 893.055.

Section 5. Paragraph (nn) is added to subsection (1) of section 466.028, Florida Statutes, to read:

466.028 Grounds for disciplinary action; action by the board.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(nn) Failing to review a patient's controlled substance prescription history prior to prescribing a controlled substance, as required under s. 893.055.

Section 6. Subsections (4), (9), (10), and (12) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 2 ~~7~~ 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.

(9)(a) Any prescriber who willfully and knowingly fails to access the electronic database, as required under subsection (12), may be disciplined pursuant to the practice act under which the prescriber is licensed.

(b) 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 costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation 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. ~~Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.~~

(12) A prescriber must access the electronic database established under this section to review the controlled substance prescription history of the prescriber's patient prior to prescribing a controlled substance to that patient. ~~or~~ A dispenser may have access to the electronic database established ~~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 substance ~~drug~~ prescription history of the dispenser's patient. 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 required to access or dispenser authorized to access information under this subsection for accessing or failing to access such information.

Section 7. This act shall take effect July 1, 2013.

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

Remove everything before the enacting clause and insert: An act relating to controlled substance prescription; amending ss. 458.331, 459.015, 461.013, 462.14, and 466.028, F.S.; providing for disciplinary actions under the relevant practice acts for failing to review a patient's controlled substance prescription history prior to prescribing a controlled substance; amending s. 893.055, F.S.; reducing the number of days within which a dispenser must report to the Department of Health that a controlled substance has been dispensed; providing that a prescriber of controlled substances, who willfully and knowingly fails to access an electronic database to review a patient's controlled substance prescription history prior to prescribing a controlled substance, may be administratively

disciplined; removing a prohibition of funding by prescription drug manufacturers to implement the prescription drug monitoring program; requiring a prescriber to access the electronic database established by the prescription drug monitoring program prior to prescribing a controlled substance to a patient; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 847 Temporary Certificates for Visiting Physicians
SPONSOR(S): Peters
TIED BILLS: **IDEN./SIM. BILLS:** SB 1302

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		McElroy	O'Callaghan
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Currently, s. 458.3137, F.S., authorizes the issuance of temporary medical certificates only to visiting plastic surgeons who are participating in certain plastic surgery training programs and plastic surgery educational symposiums. This bill amends the scope of the statute and extends eligibility for the issuance of temporary medical certificates to visiting physicians who are participating in medical and surgical training and educational symposiums. The bill also expands the duration of the temporary certificates from 3 days to 5 days. Finally, the bill expands the number of temporary certificates which can be issued from 6 per year to 12 per symposium.

The bill appears to have an indeterminate positive fiscal impact on state government.

The bill does not appear to have a fiscal impact on local government.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Physician Shortage

There is currently a physician workforce shortage in the United States.[1] This shortage is predicted to continue into the foreseeable future and will likely worsen in light of recent healthcare reforms.[2] Specifically, as more individuals qualify for healthcare benefits there will necessarily be a greater need for more physicians to provide these services. As the physician shortage worsens, states will likely seek physicians from neighboring states to improve their situation.

Florida is not immune to the national problem and is facing an imminent physician shortage itself.[3] Of Florida's 44,804 physicians, 5,810 (12.97%) will retire in the next five years and 11,650 (27%) are over 60 years old.[4] Additionally, 1,767 (3.94%) intend to move their practice to another state within the next five years.[5] Of the physicians stating where they intended to relocate, 85 were relocating to Georgia, 130 to North Carolina and 153 to Texas.[6]

License to Practice Medicine

Chapter 458, F.S., provides for the regulation of the practice of Medicine by the Board of Medicine. Any person who wishes to practice as a medical physician must be licensed and meet specified criteria which include: being at least 21 years of age; being of good moral character; not having committed any act or offenses in Florida or another jurisdiction which would constitute the basis for disciplining a Florida-licensed physician; meeting specified educational requirements, including residency; and successfully passing a national medical licensing examination.

Section 458.3145(6), F.S., provides requirements for a distinguished scholar to be issued a temporary medical faculty certificate to teach for a time-limited period at a medical school or teaching hospital. The certificate may be issued to a physician who is requested by the dean of an accredited medical school or the medical director of a teaching hospital within the state to practice only within that facility or its affiliated clinical facilities. The certificate holder must demonstrate financial responsibility by either having medical malpractice insurance, holding an escrow account or a letter of credit in the specified amounts required by s. 458.320, F.S., or be exempt from the financial responsibility requirements as an officer, employee, or agent of the federal or state government. From 2007 to present there have been 11(10 were issued in 2012-2013) temporary certificates issued under this provision.[7] No applications for temporary medical certificates were denied during this time period.[8]

Section 458.3135, F.S., provides a mechanism for the issuance of temporary certificates to visiting international physicians who may practice in board-approved cancer centers. Such visiting physicians are training under the direct supervision of a physician employed by or under contract with an approved

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[1] Center for Workforce Studies Association of American Medical Colleges, *Recent Studies and Reports on Physician Shortages in the US*, October 2012. www.doh.state.fl.us/.../Articles/PhysicianShortages_AAMC_5-2011.pdf (last viewed on March 16, 2013).
[2] Id.
[3] Id.
[4] Florida Department of Health, *Physician Workforce Annual Report 2012*. www.doh.state.fl.us/.../PhysicianWorkforceAnnualReport2012.pdf (last viewed on March 16, 2013).
[5] Id.
[6] Id.
[7] Excel spreadsheet on the issuance of temporary medical certificates, provided by the Department of Health and on file with the Health and Human Services Committee staff, March 16, 2013.
[8] Id.

cancer center for a period of no more than 1 year. To be issued a temporary certificate the visiting physician must: pay an application fee; be a graduate of an accredited medical school; hold a valid unencumbered license to practice medicine in another country; have not completed any act in Florida or any other jurisdiction that would constitute the basis for disciplining a physician under s. 456.072 (general regulatory provisions) or s. 458.331, F.S., (medical practice act); meet the financial responsibility requirements for Florida-licensed physicians; and have been accepted for a course of training by a cancer center approved by the Florida Board of Medicine. The temporary certificate allows the recipient to practice for the duration of the course of training at the approved cancer center so long as the duration of the course does not exceed 1 year. A visiting physician who holds a temporary certificate is exempt from the practitioner profiling requirements, but all other provisions of Ch. 456 or Ch. 458, F.S., apply. The maximum number of temporary certificates that may be issued by the board may not exceed 10 at each approved cancer center. From 2007 to present there have been 2 temporary certificates issued under this provision.[9] No applications for temporary medical certificates were denied during this time period.[10]

Section 458.3137, F.S., authorizes the issuance of a temporary certificate, without examination, for visiting physicians to obtain limited medical privileges for instructional purposes in conjunction with certain plastic surgery training programs and plastic surgery educational symposiums. The temporary certificates are valid for no more than three days and no more than 6 may be issued in any given year. From 2007 to present there have been 9 temporary certificates issued under this provision.[11] No applications for temporary medical certificates were denied during this time period.[12]

Effects of the Bill

This bill amends s. 458.3137, F.S., to provide for the issuance of a temporary certificate, without examination, for visiting physicians to obtain limited medical practice privileges for instructional purposes in conjunction with medical and surgical training programs and educational symposiums. Currently, s. 458.3137, F.S., authorizes the issuance of temporary medical certificates only to visiting plastic surgeons who are participating in certain plastic surgery training programs and plastic surgery educational symposiums.

The bill provides that an applicant may be issued a temporary certificate if he or she is invited either by:

- A medical or surgical program that is affiliated with a medical school within this state that is accredited by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or that is part of a teaching hospital as defined in s. 408.07, F.S.; or
- Any medical or surgical society in conjunction with one of the aforementioned medical schools or teaching hospitals.

The physician must meet all of the following requirements:

- Is a graduate of an accredited medical school or its equivalent or is a graduate of a foreign medical school listed with the World Health Organization;
- Holds a valid and unencumbered license to practice medicine in another state or country;
- Is a recognized expert in a specific area of plastic surgery or other field of medicine or surgery as demonstrated by peer-review publications, invited lectureships, and academic affiliations;
- Has completed an application form adopted by the Board of Medicine and pays a nonrefundable application fee not to exceed $300;
- Has not committed an act in this or any other jurisdiction that would constitute a basis for disciplining a physician under s. 456.072, F.S., or s. 458.331, F.S.;

[9] Id.
[10] Id.
[11] Id.
[12] Id.

- Meets the financial responsibility requirements of s. 458.320(1) or (2), F.S.; and
- Is applying only in connection with a symposium.

No more than 12 temporary certificates for any one symposium may be granted under this provision. This is an expansion of the statute which currently limits temporary certificates to 6 per calendar year.

A temporary certificate issued under this section is valid for no more than 5 days. This is an expansion of the statute which currently limits a temporary certificate's duration to no more than 3 days.

The statute currently requires the sponsoring organization to obtain a surety bond or line of credit of at least $250,000 to ensure malpractice insurance coverage for a foreign physician. This bill allows the sponsoring organization to provide documentation that the physician is covered by the malpractice coverage maintained by the teaching hospital in lieu of posting the bond. The requirement to obtain a surety bond, or alternatively, documentation proving the physician has malpractice coverage seems to apply only to foreign physicians who are seeking a temporary certificate. It does not appear that a visiting physician from another state would need to meet this requirement.

B. SECTION DIRECTORY:

Section 1. Creates s. 458.3137, F.S., relating to temporary certificates for visiting physicians to obtain medical privileges for instructional purposes in conjunction with medical and surgical training and educational symposiums.
Section 2. The bill provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Indeterminate.

   However, there is a $300 application fee and a limit of no more than 12 temporary certificates to be issued for any one symposium. Thus, it appears that revenue will be generated.

2. Expenditures:

   Indeterminate.

   The Department of Health implemented the original bill in 2003. While this bill expands the number of certificates that could be issued per year, the DOH's fiscal analysis indicates that impact is indeterminate as the number of applications that could be received is unknown.[13]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   There does not appear to be any fiscal impact on the revenues of local governments.

2. Expenditures:

   There does not appear to be any fiscal impact on the expenditures of local governments.

[13] Florida Department of Health, *SB 1302 Bill Analysis* (Mar. 5, 2013) (on file with House of Rep., Health Quality Subcommittee staff) (SB 1302 is similar to HB 847).

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Indeterminate.

Under certain circumstances, the organization sponsoring the educational symposium must either obtain a surety bond, certificate of deposit, or guaranteed letter of credit in an amount not less than $250,000. The exact cost for this expense cannot be determined at this time.

By expanding the temporary certificates to other medical and surgical training programs, additional educational symposiums may choose Florida as their location for their next conference. The exact benefit of additional symposiums cannot be determined at this time.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill authorizes the issuance of temporary certificates for training programs affiliated with a medical school that is accredited by the American Osteopathic Association; however, only Ch. 458, F.S., related to the allopathic medical act, is included in the bill. Additionally, references to disciplinary action and financial responsibility only include Ch. 458, F.S. Osteopathic physicians are specifically regulated under Ch. 459, F.S.

Section 458.3137, F.S., authorizes the issuance of a temporary certificate, without examination, for visiting physicians to obtain limited medical privileges for instructional purposes in conjunction with certain plastic surgery training programs and plastic surgery educational symposiums. Thus, temporary certificates can be issued for training programs *and* educational symposiums. The bill, in its proposed s. 458.3137(4) states, "the department shall not issue more than 12 temporary certificates under this section for any one symposium." (lines 71-73). This language appears to preclude the issuance of temporary certificates for the purpose of training programs.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to temporary certificates for visiting physicians; amending s. 458.3137, F.S.; expanding authorization to issue a temporary certificate for a visiting physician to obtain medical privileges for instructional purposes; revising requirements for issuing temporary certificates; providing an effective date.

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

Section 1. Section 458.3137, Florida Statutes, is amended to read:

458.3137 Temporary certificate for visiting physicians to obtain medical privileges for instructional purposes in conjunction with certain plastic surgery training programs, ~~and~~ plastic surgery educational symposiums, and other medical and surgical training and educational symposiums.—

(1) Any physician who has been invited by ~~both~~:

(a) A plastic surgery training program or other medical or surgical training program that is affiliated with a medical school within this state that is accredited by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or that is part of a teaching hospital as defined in s. 408.07; or ~~and~~

(b) An educational symposium cosponsored by the American Society of Plastic Surgeons, the Plastic Surgery Educational Foundation, ~~or~~ the American Society for Aesthetic Plastic

Surgery, or any other medical or surgical society in conjunction with a medical school or teaching hospital as provided in paragraph (a)

may be issued a temporary certificate for limited privileges solely for purposes of providing educational training in plastic surgery or other medical or surgical procedures in accordance with the restrictions set forth in this section.

(2) A temporary certificate to practice medicine for educational purposes to help teach plastic surgery residents or other medical or surgical residents of a medical school within this state, in conjunction with a nationally sponsored educational symposium or a symposium held by a medical school or teaching hospital, may be issued without examination, upon verification by the board that the individual meets all of the following requirements:

(a) Is a graduate of an accredited medical school or its equivalent or is a graduate of a foreign medical school listed with the World Health Organization.

(b) Holds a valid and unencumbered license to practice medicine in another state or country.

(c) Is a recognized expert in a specific area of plastic surgery or other field of medicine or surgery as demonstrated by peer-reviewed publications, invited lectureships, and academic affiliations.

(d) Has completed an application form adopted by the board and remitted a nonrefundable application fee not to exceed $300.

(e) Has not committed an act in this or any other

jurisdiction that would constitute a basis for disciplining a physician under s. 456.072 or s. 458.331.

(f) Meets the financial responsibility requirements of s. 458.320(1) or (2).

(g) Is applying only in connection with a symposium as provided in paragraph (1)(b) ~~both a medical school within this state that is accredited by the Accreditation Council for Graduate Medical Education and an educational symposium sponsored by the American Society of Plastic Surgeons, the Plastic Surgery Educational Foundation, or the American Society for Aesthetic Plastic Surgery~~.

(3) A temporary certificate issued under this section is valid for no more than 5 ~~3~~ days per year, and such certificate expires 1 year after issuance.

(4) The department shall not issue more than 12 ~~six~~ temporary certificates under this section for any one symposium ~~per calendar year~~.

(5) In order for a physician who is a graduate of a foreign medical school and holds a valid and unencumbered license to practice medicine in another country but does not hold a license to practice medicine in this or another state to obtain a temporary certificate under this section, the organization sponsoring the educational symposium must pay for any medical judgments incurred by that physician by obtaining a surety bond issued by a surety company authorized to do business in this state or establishing a certificate of deposit or a guaranteed letter of credit with a licensed and insured bank or savings institution located in the state or provide

documentation that the physician is covered by the malpractice coverage maintained by the teaching hospital. The amount of the bond, certificate of deposit, or guaranteed letter of credit shall be an amount not less than $250,000.

(6) A physician applying under this section is exempt from the requirements of ss. 456.039-456.046. All other provisions of chapter 456 and this chapter apply.

(7) The board shall not issue a temporary certificate for practice to any physician who is under investigation in another jurisdiction for an act that would constitute a violation of this chapter or chapter 456 until such time as the investigation is complete and the physician is found innocent of all charges.

Section 2. This act shall take effect July 1, 2013.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Peters offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 458.3137, Florida Statutes, is amended to read:

458.3137 Temporary certificate for visiting physicians to obtain medical privileges for instructional purposes in conjunction with certain plastic surgery or other medical or surgical training programs and ~~plastic surgery~~ educational symposiums.—

(1) A ~~Any~~ physician who has been invited by ~~both~~:

(a) A plastic surgery or other medical or surgical training program ~~that is~~ affiliated with a medical school in ~~within~~ this state which ~~that~~ is accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or which is part of a teaching hospital as defined in s. 408.07; or ~~and~~

(b) An educational symposium cosponsored by the American Society of Plastic Surgeons, the Plastic Surgery Educational Foundation, ~~or~~ the American Society for Aesthetic Plastic Surgery, or any other medical or surgical society in conjunction with a medical school or teaching hospital as defined in s. 408.07,

may be issued a temporary certificate for limited privileges solely for purposes of providing educational training in plastic surgery or other medical or surgical procedures, as appropriate, in accordance with the restrictions set forth in this section.

(2) A temporary certificate to practice medicine for educational purposes to help teach plastic surgery or other medical or surgical procedures to residents in a training program affiliated with a medical school that is accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or that is part of a teaching hospital, or to residents of a medical school within this state in conjunction with a nationally sponsored educational symposium or an educational symposium held by a state medical school or teaching hospital, may be issued without examination, upon verification by the board that the individual ~~meets all of the following requirements~~:

(a) Is a graduate of an accredited medical school or its equivalent or is a graduate of a foreign medical school listed with the World Health Organization.

(b) Holds a valid and unencumbered license to practice medicine in another state or country.

(c) Is a recognized expert in a specific area of plastic surgery or another field of medicine or surgery, as demonstrated by peer-reviewed publications, invited lectureships, and academic affiliations.

(d) Has completed an application form adopted by the board and remitted a nonrefundable application fee not to exceed $300.

(e) Has not committed an act in this or any other jurisdiction that would constitute a basis for disciplining a physician under s. 456.072 or s. 458.331.

(f) Meets the financial responsibility requirements of s. 458.320(1) or (2).

(g) Is applying only in connection with a training program or an educational symposium as described in subsection (1)~~both a medical school within this state that is accredited by the Accreditation Council for Graduate Medical Education and an educational symposium sponsored by the American Society of Plastic Surgeons, the Plastic Surgery Educational Foundation, or the American Society for Aesthetic Plastic Surgery~~.

(3) A temporary certificate issued under this section is valid for up to 5 ~~no more than 3~~ days per year~~,~~ and ~~such certificate~~ expires 1 year after issuance.

(4) The department may ~~shall~~ not issue more than 12 ~~six~~ temporary certificates for any single educational symposium or single training program under this section ~~per calendar year~~.

(5) In order for a physician who is a graduate of a foreign medical school and holds a valid and unencumbered license to practice medicine in another country but does not hold a license to practice medicine in this or another state to

obtain a temporary certificate under this section, the organization sponsoring the educational symposium must pay for any medical judgments incurred by that physician by obtaining a surety bond issued by a surety company authorized to do business in this state, by ~~or~~ establishing a certificate of deposit or a guaranteed letter of credit with a licensed and insured bank or savings institution located in the state, or by providing proof that the physician is covered under a teaching hospital's or medical school's medical malpractice insurance. The amount of the bond, certificate of deposit, or guaranteed letter of credit must ~~shall~~ be at least ~~an amount not less than~~ $250,000.

(6) A physician applying under this section is exempt from the requirements of ss. 456.039-456.046. All other provisions of chapter 456 and this chapter apply.

(7) The board may ~~shall~~ not issue a temporary certificate for practice to any physician who is under investigation in another jurisdiction for an act that would constitute a violation of this chapter or chapter 456 until such time as the investigation is complete and the physician is found innocent of all charges.

Section 2. This act shall take effect July 1, 2013.

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

Remove everything before the enacting clause and insert:

An act relating to temporary certificates for visiting physicians; amending s. 458.3137, F.S.; providing that a physician who has been invited by certain medical or surgical training programs or educational symposiums may be issued a temporary certificate for limited privileges solely to provide educational training; modifying criteria; revising the requirements for proof of medical malpractice insurance; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1115 Pub. Rec./Dental Workforce Surveys
SPONSOR(S): Williams
TIED BILLS: **IDEN./SIM. BILLS:** SB 1066

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Holt	O'Callaghan
2) Government Operations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill creates a public record exemption for all personal identifying information contained in records provided by dentists or dental hygienists in response to dental workforce surveys and held by the Department of Health. Such information must be disclosed:

- With the express written consent of the individual, to whom the information pertains, or the individual's legally authorized representative.
- By court order upon a showing of good cause.
- To a research entity, provided certain requirements are met.

The bill provides for repeal of the exemption on October 2, 2018, unless reviewed and saved from repeal by the Legislature. It also provides a statement of public necessity as required by the State Constitution, and provides an effective date of upon becoming a law.

Article I, s. 24(c) of the State Constitution, requires a two-thirds vote of the members present and voting for final passage of a newly created public record or public meeting exemption. The bill creates a new public record exemption; thus, it requires a two-thirds vote for final passage.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Public Records Law

Article I, s. 24(a) of the State Constitution sets forth the state's public policy regarding access to government records. The section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of Article I, s. 24(a) of the State Constitution. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.[1]

Public policy regarding access to government records is addressed further in the Florida Statutes. Section 119.07(1), F.S., guarantees every person a right to inspect and copy any state, county, or municipal record. Furthermore, the Open Government Sunset Review Act[2] provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. In addition, it may be no broader than is necessary to meet one of the following purposes:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption.
- Protects sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision.
- Protects trade or business secrets.

Workforce Surveys

Current law does not provide for a dental workforce survey as part of the licensure renewal process for dentists and dental hygienists. In 2009, however, the Department of Health (DOH) developed a workforce survey for dentists and dental hygienists to complete on a voluntary basis in conjunction with the biennial renewal of dental licenses.[3] Of the 11,272 dentists who renewed an active license by June 23, 2010, 89 percent responded to the voluntary survey.[4]

Responses to the survey are self-reported. The survey was designed to obtain information unavailable elsewhere on key workforce characteristics in order to better inform and shape public healthcare policy. Specifically, the survey consists of 25 core questions on demographics, education and training, practice characteristics and status, specialties, retention, and access to oral healthcare in Florida.[5]

Unlike dentists and dental hygienists, physicians are statutorily required to respond to physician workforce surveys as a condition of license renewal.[6] All personal identifying information contained in records provided by physicians in response to these workforce surveys is confidential and exempt

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[1] Section 24(c), Art. I of the State Constitution.
[2] Section 119.15, F.S.
[3] Section 466.013(2), F.S., authorizes DOH to adopt rules for the biennial renewal of licenses.
[4] Florida Department of Health , *Report on the 2009-2010 Workforce Survey of Dentists*, March 2011, at 11, http://www.doh.state.fl.us/Family/dental/OralHealthcareWorkforce/2009_2010_Workforce_Survey_Dentists_Report.pdf (last visited March 15, 2013).
[5] *Id.*
[6] Section 381.4018, F.S. Language requiring the submission of physician workforce surveys for license renewal can be found in s. 458.3191, F.S., for allopathic physicians and s. 459.0081, F.S., for osteopathic physicians.

under s. 458.3193, F.S., concerning allopathic physicians, and s. 459.0083, F.S., concerning osteopathic physicians.

Effect of Bill

The bill provides that all personal identifying information contained in records provided by dentists or dental hygienists licensed under ch. 466, F.S., in response to dental workforce surveys and held by DOH is confidential and exempt[7] from public records requirements. Such information must be disclosed:

- With the express written consent of the individual, to whom the information pertains, or the individual's legally authorized representative.
- By court order upon a showing of good cause.

In addition, such information must be disclosed to a research entity, if the entity seeks the record or data pursuant to a research protocol approved by DOH. The research entity must maintain the records or data in accordance with the approved research protocol, and enter into a purchase and data-use agreement with DOH. The agreement must restrict the release of information that would identify individuals, limit the use of records or data to the approved research protocol, and prohibit any other use of the records or data. Copies of records or data remain the property of DOH.

DOH is authorized to deny a research entity's request if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit.

The bill provides for repeal of the exemption on October 2, 2018, unless reviewed and saved from repeal by the Legislature. It also provides a statement of public necessity as required by the State Constitution.[8]

B. SECTION DIRECTORY:

Section 1. Creates an unnumbered section of law that creates a public record exemption for personal identifying information of dentists or dental hygienists contained in a response to a dental workforce survey.
Section 2. Provides a public necessity statement.
Section 3. Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

[7] There is a difference between records the Legislature designates as exempt from public record requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. (*See WFTV, Inc. v. The School Board of Seminole*, 874 So.2d 48, 53 (Fla. 5th DCA 2004), review denied 892 So.2d 1015 (Fla. 2004); *City of Riviera Beach v. Barfield*, 642 So.2d 1135 (Fla. 4th DCA 1994); *Williams v. City of Minneola*, 575 So.2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released, by the custodian of public records, to anyone other than the persons or entities specifically designated in the statutory exemption. (*See* Attorney General Opinion 85-62, August 1, 1985).

[8] Section 24(c), Art. I of the State Constitution.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

Vote Requirement
Article I, s. 24(c) of the State Constitution, requires a two-thirds vote of the members present and voting for final passage of a newly created public record or public meeting exemption. The bill creates a new public record exemption; thus, it requires a two-thirds vote for final passage.

Public Necessity Statement
Article I, s. 24(c) of the State Constitution, requires a public necessity statement for a newly created or expanded public record or public meeting exemption. The bill creates a new public record exemption; thus, it includes a public necessity statement.

B. RULE-MAKING AUTHORITY:

The bill does not appear to create a need for rulemaking or rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Other Comments: Voluntary Survey
The Department of Health developed a workforce survey for dentists and dental hygienists to complete on a voluntary basis in conjunction with the biennial renewal of dental licenses. However, there does not appear to be any statutory authority for the creation of such survey.

Other Comments: Retroactive Application
The Supreme Court of Florida ruled that a public record exemption is not to be applied retroactively unless the legislation clearly expresses intent that such exemption is to be applied retroactively.[9] The bill does not contain a provision requiring retroactive application. As such, the public record exemption would only apply prospectively to survey information collected.

[9] *Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation*, 729 So.2d. 373 (Fla. 2001).

Other Comments: Public Necessity

It is unclear whether a public necessity exists. Because the survey is voluntary, if a dentist or dental hygienist is uncomfortable with their personal identifying information being disclosed, he or she may refrain from responding to the survey.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to public records; providing an exemption from public records requirements for information contained in dental workforce surveys submitted by dentists or dental hygienists to the Department of Health; providing exceptions to the exemption; providing for future legislative review and repeal of the exemption under the Open Government Sunset Review Act; providing a statement of public necessity; providing an effective date.

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

Section 1. Confidentiality of certain information contained in dental workforce surveys.—

(1) All personal identifying information contained in records provided by dentists or dental hygienists licensed under chapter 466, Florida Statutes, in response to dental workforce surveys and held by the Department of Health is confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution, except such information shall be disclosed:

(a) With the express written consent of the individual to whom the information pertains or the individual's legally authorized representative.

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

(c) To a research entity, if the entity seeks the records or data pursuant to a research protocol approved by the

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

(2) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15, Florida Statutes, and shall stand repealed on October 2, 2018, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that personal identifying information concerning a dentist or dental hygienist licensed under chapter 466, Florida Statutes, who responds to a dental workforce survey be made confidential and exempt from disclosure. Candid and honest responses by licensed dentists or dental hygienists to the workforce survey will ensure that timely and accurate information is available to the Department of Health. The Legislature finds that the failure to maintain the confidentiality of such personal identifying information would

prevent the resolution of important state interests to ensure the availability of dentists or dental hygienists in this state.

Section 3. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1129 Infants Born Alive
SPONSOR(S): Pigman and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1636

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		McElroy	O'Callaghan
2) Civil Justice Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill amends ss. 390.011 and 390.0111, F.S., which relate to the termination of pregnancies, to define the term "born alive" and provide that all infants born alive are entitled to the same rights, powers, and privileges as any child born in the course of natural birth. The bill also provides that any infant born alive must be transported and admitted to a hospital, at which time the child will be presumed to have been surrendered.

The bill also creates a mandatory reporting requirement for certain individuals who have knowledge that specified violations have been committed. Specifically, health care practitioners, as well as employees of hospitals, physicians' offices and abortion clinics, must report all known violations to the Department of Health. Failure to report a known violation is a first degree misdemeanor.

The bill appears to have an indeterminate negative fiscal impact on state government.

The bill does not appear to have a fiscal impact on local government.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Case Law on Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*, was decided by the U.S. Supreme Court.[1] Using strict scrutiny, the Court determined that a woman's right to termination is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution.[2] Further, the Court reasoned that state regulation limiting the exercise of this right must be justified by a compelling state interest, and must be narrowly drawn.[3] The Court established the trimester framework for the regulation of termination – holding that in the third trimester, a state could prohibit termination to the extent that the woman's life or health was not at risk.[4]

In *Planned Parenthood v. Casey*, the U.S. Supreme Court, while upholding the fundamental holding of *Roe,* recognized that medical advancement could shift determinations of fetal viability away from the trimester framework.[5]

Article I, Section 23 of the Florida Constitution provides an express right to privacy. The Florida Supreme Court has recognized the Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[6]

In *In re T.W.*, the Florida Supreme Court, determined that:

> [p]rior to the end of the first trimester, the abortion decision must be left to the woman and may not be significantly restricted by the state. Following this point, the state may impose significant restrictions only in the least intrusive manner designed to safeguard the health of the mother. Insignificant burdens during either period must substantially further important state interests....Under our Florida Constitution, the state's interest becomes compelling upon viability....Viability under Florida law occurs at that point in time when the fetus becomes capable of meaningful life outside the womb through standard medical procedures.

The court recognized that after viability, the state can regulate termination in the interest of the unborn child so long as the mother's health is not in jeopardy.[7]

Florida's Abortion Laws

In Florida, abortion is defined as the termination of a human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.[8] A termination of pregnancy must be performed by a physician[9] licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.[10]

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[1] 410 U.S. 113 (1973).
[2] Id.
[3] Id.
[4] Id.
[5] 505 U.S. 833 (1992).
[6] *See In re T.W.*, 551 So.2d 1186, 1192 (Fla. 1989)(holding that a parental consent statute was unconstitutional because it intrudes on a minor's right to privacy).
[7] Id.
[8] s. 390.011(1), F.S.
[9] s. 390.0111(2), F.S.
[10] s. 390.011(7), F.S.

In Florida, a termination of pregnancy may not be performed in the third trimester unless there is a medical emergency.[11] Florida law defines the third trimester to mean the weeks of pregnancy after the 24th.[12] Medical emergency is a situation in which:

- To a reasonable degree of medical certainty, the termination of pregnancy is necessary to save the life or preserve the health of the pregnant woman,[13] and is a condition that, on the basis of a physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death; or

- The good faith clinical judgment of the physician, that a delay in the termination of her pregnancy will create serious risk of substantial and irreversible impairment of a major bodily function.[14]

In 2011, the Department of Health (DOH) reported that there were 213,237 live births in the state of Florida.[15] For the same time period, the Agency for Health Care Administration (AHCA) reported that there were 77,166 termination procedures performed in the state.[16]

Born Alive

The federal Born Alive Infants Protection Act (BAIPA) of 2002 states that in determining the meaning of any Act of Congress or of any ruling, regulation, or interpretation of the various federal administrative bureaus and agencies, the words "person", "human being", "child" and "individual" shall include every infant member of the species homo sapiens who is born alive at any stage of development.[17] The Act defined "born alive" as:

> the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section or induced abortion.[18]

The BAIPA was initially viewed as a symbolic act which did not alter the treatment that physicians already provided to extremely premature infants.[19] A change occurred in 2005 when the U.S. Department of Health and Human Services (HHS) issued a Program Instruction to state and territorial agencies administering or supervising the administration of the federal Child Abuse Prevention and Treatment Act (CAPTA) Program. The Program Instruction stated that regulations affected by the BAIPA were to be enforced under CAPTA.[20] Specifically, states must ensure that implementation of section 106(b)(2)(B) of CAPTA, which requires states to have procedures for responding to reports of medical neglect (including the withholding of medically indicated treatment from disabled infants with life-threatening conditions), applies to born-alive infants.[21] This created an obligation to provide medical

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[11] s. 390.0111(1), F.S.
[12] s. 390.011(7), F.S.
[13] s. 390.0111(1)(a), F.S.
[14] s. 390.01114(2)(d), F.S.
[15] Florida Department of Health, *Florida Vital Statistics Annual Reports- Births.* http://www.flpublichealth.com/VSBOOK/VSBOOK.aspx (last visited on March 16, 2013).
[16] Email from AHCA on file with the Health and Human Services Committee Staff, March 16, 2013.
[17] 1U.S.C. 8(a).
[18] 1U.S.C. 8(b).
[19] Am. Acad. of Ped. Neonatal Resuscitation Prog. Steering Comm., *Born-Alive Infants Protection Act of 2001, Public Law No. 107-207*, 111 PEDIATRICS 680 (Mar. 2003).
[20] U.S. Department of Health and Human Services, Administration of Children, Youth and Families- Program Instruction; Log No- ACYF-CB-PI-05-01; Issuance Date- April 22, 2005.
[21] Id.

services to a born alive infant, as well as, an obligation to report when such treatment was withheld.[22] Thus, the failure to provide medical services to a born-alive infant may subject a physician to criminal neglect and abuse charges under applicable state law.[23]

The federal Emergency Medical Treatment and Labor Act (EMTALA) places potential provider obligations on hospitals and physicians when presented with an individual who may have an emergency medical condition, irrespective of that individual's ability to pay.[24] The Centers for Medicare and Medicaid Services (CMS), a subunit of the HHS, issued its "Guidance on the interaction of the BAIPA and the EMTALA" in 2005. According to the CMS, born alive infants as "individuals" were entitled to protection under the EMTALA.[25] Thus, individuals who failed to provide stabilizing treatment to a born alive infant may be subject to penalties under the EMTALA.[26]

Currently, twenty-eight states have statutory provisions which define and/or offer protections for born-alive infants. In at least one of these states a born-alive infant is deemed to be a surrendered newborn.[27] Other states allow evidence of the abortion procedure to be utilized as evidence in a petition for termination of parental rights.[28]

Florida does not have a statutory provision for born-alive infants.

Voluntary Surrender of Infants

Florida law provides for the treatment and protection of a surrendered newborn.[29] Under Florida law a "newborn infant" means a child who a licensed physician reasonably believes is approximately 7 days old or younger at the time the child is left at a hospital, emergency medical services (EMS) station or a fire station.[30] Hospitals are authorized to admit and provide all necessary services and care to a surrendered new born infant.[31] Likewise, EMS technicians, paramedics and firefighters are also authorized to render EMS to a newborn infant.[32] However, EMS technicians, paramedics and firefighters have a secondary obligation of arranging for the immediate transport of the newborn infant to a hospital for admittance.[33]

Termination of Parental Rights

In Florida, termination of parental rights is initiated by the filing of a petition which alleges the basis for the termination, that the termination is in the manifest best interests of the child, and that the termination is the least restrictive means of protecting the child from harm.[34] Parental rights will not be terminated until the court has adjudicated the petition.

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[22] Conway, Craig, *What Will Become of the Born-Alive Infants Protection Act?* www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20BAIPA.pdf (last visited on March , 2013).

[23] Hermer, Laura, *The "Born-Alive Infants Protection Act" and its Potential Impact on Medical Care and Practice.* www.law.uh.edu/healthlaw/perspectives/2006/(LH)BAIPA.pdf (last visited on March , 2013).

[24] *See* Sadath A. Sayeed, *Baby Doe Redux? The Department of Health and Human Services and the Born-Alive Infants Protection Act of 2002: A Cautionary Note on Normative Neonatal Practice*, 116:4 PEDIATRICS e576 (Oct. 2005). http://pediatrics.aappublications.org/content/116/4/e576.full.pdf+html (last visited on March , 2013).

[25] Id.

[26] Hermer, Laura, *The "Born-Alive Infants Protection Act" and its Potential Impact on Medical Care and Practice.* www.law.uh.edu/healthlaw/perspectives/2006/(LH)BAIPA.pdf (last visited on March , 2013).

[27] 1939 PA288, MCL s. 712.3(a born-alive infant who is in a hospital setting or transferred to a hospital is a newborn surrendered.).

[28] See South Dakota Codified Laws s. 34-23A-18 and Tex. Bus. & Com. Code s. 161.006.

[29] s. 383.50, F.S.

[30] s. 383.50(1), F.S.

[31] s. 383.50(4), F.S

[32] s. 383.50(3)(a), F.S.

[33] s. 383.50(3)(b), F.S

[34] s. 39.802(4), F.S.

Under Florida law parents of surrendered newborn infants are presumed to have consented to the termination of their parental rights.[35] However, this is a rebuttable presumption and a parent of a surrendered newborn infant may claim a newborn infant up until the time the court enters a judgment terminating his or her parental rights.[36]

Effects of the Bill

The bill amends s. 390.011, F.S., to define the term "born alive" to mean-:

> the complete expulsion or extraction from the mother of a human infant, at any stage of development, who, after such expulsion or extraction, breathes or has a beating heart, or definite and voluntary movement of muscles, regardless of whether the umbilical cord has been cut and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, Cesarean section, induced abortion, or other method.

This is almost identical to the definition of born alive contained within the BAIPA of 2002.

The bill provides that an infant born alive during or immediately after an attempted abortion is entitled to the same rights, powers and privileges as any other child born in the course of a natural birth.

The bill provides that an infant born alive must be immediately transported and admitted to a hospital. Upon admittance to the hospital the infant is presumed surrendered and must receive medical care and be provided social services.

The BAIPA does not expressly contain a requirement to treat or hospitalize a born alive infant. However, it is the position of CMS that a physician or hospital who fails to render stabilizing treatment may be subject to fines under the EMTALA.

The bill provides that a health care practitioner or any employee of a hospital, physician's office, or abortion clinic who has knowledge of a violation of the requirements pertaining to an infant born alive must report the violation to the DOH. Failure to report is a first degree misdemeanor (maximum imprisonment of 1 year and maximum fine of $1,000).

The BAIPA does not expressly contain a reporting requirement for violations of its provisions. However, it is the position of the HHS that the withholding of medical treatment to a born alive infant must be reported under the CAPTA.

B. SECTION DIRECTORY:

Section 1. Amends s. 390.011, F.S., relating to definitions.

Section 2. Amends s. 390.0111, F.S., relating to termination of pregnancies.

Section 3. Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

[35] s. 383.50(2), F.S. (there is a presumption that the parent who leaves a newborn infant at a hospital, emergency medical services (EMS) station or a fire station intended to leave the newborn infant and consented to termination of parental rights).
[36] s. 383.50(6), F.S.

There does not appear to be any fiscal impact on the revenues of state government.

2. Expenditures:

The bill appears to have an indeterminate negative fiscal impact on the expenditures of state government (see "Fiscal Comments" below).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

There does not appear to be any fiscal impact on the revenues of local governments.

2. Expenditures:

Because this bill creates a first degree misdemeanor, it may have an indeterminate jail bed impact on local governments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There does not appear to be any fiscal impact on the private sector.

D. FISCAL COMMENTS:

Born alive infants could potentially create a negative fiscal impact on state government. Upon admittance to a hospital born alive infants are surrendered to the care of the state. Thus, any medical expenses and social services expenses would be partially borne by the state. This creates an indeterminate impact as there are no reliable statistics for born alive infants in the United States. However, from all available information it appears that born alive infants comprise an exceedingly small percentage of the total number of births per year.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to infants born alive; amending s. 390.011, F.S.; defining the term "born alive"; amending s. 390.0111, F.S.; providing that an infant born alive during or immediately after an attempted abortion is entitled to the same rights, powers, and privileges as any other child born alive in the course of natural birth; requiring health care practitioners to preserve the life and health of such an infant born alive, if possible; providing for the transport and admittance of an infant born alive to a hospital; providing a presumption that the infant has been surrendered; providing for certain medical and social services for the infant; requiring a health care practitioner or certain employees who have knowledge of any violations with respect to infants born alive after an attempted abortion to report those violations to the Department of Health; providing a penalty; providing an effective date.

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

Section 1. Subsections (4) through (8) of section 390.011, Florida Statutes, are renumbered as subsections (5) through (9), respectively, and a new subsection (4) is added to that section to read:

390.011 Definitions.—As used in this chapter, the term:

(4) "Born alive" means the complete expulsion or

extraction from the mother of a human infant, at any stage of development, who, after such expulsion or extraction, breathes or has a beating heart, or definite and voluntary movement of muscles, regardless of whether the umbilical cord has been cut and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, Cesarean section, induced abortion, or other method.

Section 2. Subsections (12) and (13) of section 390.0111, Florida Statutes, are renumbered as subsections (13) and (14), respectively, subsection (10) is amended, and a new subsection (12) is added to that section to read:

390.0111 Termination of pregnancies.—

(10) PENALTIES FOR VIOLATION.—Except as provided in subsections (3), ~~and~~ (7), and (12):

(a) Any person who willfully performs, or actively participates in, a termination of pregnancy procedure in violation of the requirements of this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) Any person who performs, or actively participates in, a termination of pregnancy procedure in violation of the provisions of this section which results in the death of the woman commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(12) INFANTS BORN ALIVE.—

(a) An infant born alive during or immediately after an attempted abortion is entitled to the same rights, powers, and privileges as are granted by the laws of this state to any other

child born alive in the course of natural birth.

(b) If an infant is born alive during or immediately after an attempted abortion, any health care practitioner present at the time shall humanely exercise the same degree of professional skill, care, and diligence to preserve the life and health of the infant as a reasonably diligent and conscientious health care practitioner would render to an infant born alive in the course of natural birth.

(c) An infant born alive during or immediately after an attempted abortion must be immediately transported and admitted to a hospital pursuant to s. 390.012(3)(c) or rules adopted thereunder. Upon such hospital admittance, the infant is presumed to be surrendered under s. 383.50(2) and must receive the medical care and social services provided under s. 383.50(4), (7), and (8).

(d) A health care practitioner or any employee of a hospital, a physician's office, or an abortion clinic who has knowledge of a violation of this subsection must report the violation to the department.

(e) A person who violates this subsection commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 3. This act shall take effect July 1, 2013.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 1129 (2013)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION		
ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	_____	

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Pigman offered the following:

Amendment (with title amendment)

Between lines 78 and 79, insert:

Section 1. Subsection (1) of section 390.0112, Florida Statutes, is amended to read:

390.0112 Termination of pregnancies; reporting.—

(1) The director of any medical facility in which any pregnancy is terminated shall submit a monthly report to the agency which contains the number of procedures performed, the reason for same, ~~and~~ the period of gestation at the time such procedures were performed, and the number of infants born alive during or immediately after an attempted abortion ~~to the agency~~. The agency shall be responsible for keeping such reports in a central place from which statistical data and analysis can be made.

Amendment No.

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

Remove line 19 and insert:

amending s. 390.0112, F.S.; revising a reporting requirement; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1205 Sovereign Immunity for Dentists and Dental Hygienists
SPONSOR(S): Magar and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1016

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Holt	O'Callaghan
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill amends s. 766.1115, F.S., the Access to Health Care Act (Act), to allow patients receiving services performed by a dentist or dental hygienist to voluntarily contribute to the health care provider the cost of dental laboratory expenses, without compromising the health care provider's sovereign immunity. Currently, the Act provides certain health care providers, under contract as agents of the state, immunity from negligence liability for providing free medical services to underserved populations within the state.

The bill defines "uncompensated services" within the Act as services voluntarily provided under a contract in which a dentist or dental hygienist licensed under ch. 466, F.S., does not receive compensation from the governmental contractor and may not bill or accept compensation from a recipient or any public or private third-party payor for specific services provided to a low-income recipient covered by the contract. Additionally, if a patient or a parent or a guardian of the recipient chooses to contribute to the dental laboratory expenses associated with the care of the recipient, this contribution is not considered compensation for services.

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

The bill takes effect on July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Access to Health Care Act

Section 766.1115, F.S., is entitled the "Access to Health Care Act" (Act). The Act was enacted in 1992 to encourage health care providers to provide care to low-income persons.[1] The Act extends sovereign immunity to health care providers who execute a contract with a governmental contractor and who provide volunteer, uncompensated health care services to low-income individuals as an agent of the state. Health care providers are considered agents of the state under s. 768.28(9), F.S., for purposes of extending sovereign immunity while acting within the scope of duties required under the Act.

A governmental contractor is defined to mean the Department of Health (DOH), county health departments, a special taxing district with health care responsibilities, or a hospital owned and operated by a governmental entity.[2]

Health care providers are defined to include a dentist or dental hygienist licensed under ch. 466, F.S., and the following:[3]

- A birth center licensed under ch. 383, F.S.
- An ambulatory surgical center licensed under ch. 395, F.S.
- A hospital licensed under ch. 395, F.S.
- A physician or physician assistant licensed under ch. 458, F.S.
- An osteopathic physician or osteopathic physician assistant licensed under ch. 459, F.S.
- A chiropractic physician licensed under ch. 460, F.S.
- A podiatric physician licensed under ch. 461, F.S.
- A registered nurse, nurse midwife, licensed practical nurse, or advanced registered nurse practitioner licensed or registered under part I of ch. 464, F.S.
- Any facility which employs nurses licensed or registered under part I of ch. 464, F.S., to supply all or part of the care delivered under the Act.
- A midwife licensed under ch. 467, F.S.
- A health maintenance organization certified under part I of ch. 641, F.S.
- A health care professional association and its employees or a corporate medical group and its employees.
- Any other medical facility, the primary purpose of which is to deliver human medical diagnostic services or which delivers nonsurgical human medical treatment, and which includes an office maintained by a provider.
- A free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.
- Any other health care professional, practitioner, provider, or facility under contract with a governmental contractor, including a student enrolled in an accredited program that prepares the student for licensure in any one of the health care professions listed above.
- Any nonprofit corporation qualified as exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c) of the Internal Revenue Code, which

[1] Low-income persons are defined in the Act as a person who is Medicaid-eligible, a person who is without health insurance and whose family income does not exceed 200 percent of the federal poverty level, or any eligible client of DOH who voluntarily chooses to participate in a program offered or approved by DOH. *See* s. 766.1115(3)(e), F.S.

[2] Section 766.1115(3)(c), F.S.

[3] Section 766.1115(3)(d), F.S.

delivers health care services provided by the listed licensed professionals, any federally funded community health center, and any volunteer corporation or volunteer health care provider that delivers health care services.

Contract Requirements

Section 766.1115(3)(a), F.S., provides that the contract must be for volunteer, uncompensated services. For services to qualify as volunteer, uncompensated services the health care provider must receive no compensation from the governmental contractor for any services provided under the contract and may not bill or accept compensation from the recipient, or any public or private third-party payor, for the specific services provided to the low-income recipients covered by the contract.[4]

The Act further stipulates that:[5]

- The governmental contractor retains the right of dismissal or termination of any health care provider delivering services under the contract.
- The governmental contractor has access to the patient records of any health care provider delivering services under the contract.
- The health care provider must report adverse incidents and information on treatment outcomes.
- The governmental contractor must make patient selection and initial referrals.
- The health care provider must accept all referred patients; however, the contract may specify limits on the number of patients to be referred.
- Patient care, including any follow-up or hospital care is subject to approval by the governmental contractor.
- The health care provider is subject to supervision and regular inspection by the governmental contractor.

The governmental contractor must provide written notice to each patient, or the patient's legal representative, receipt of which must be acknowledged in writing, that the provider is covered under s. 768.28, F.S., for purposes of actions related to medical negligence.[6]

The individual accepting services through this contracted provider may not have medical or dental care coverage for the illness, injury, or condition in which medical or dental care is sought.[7] The services not covered under this program include experimental procedures and clinically unproven procedures.[8] The governmental contractor has the authority to determine whether or not a procedure is covered.[9]

Additionally, the health care provider may not subcontract for the provision of services under the Act.[10]

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.

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[4] Section 766.1115(3)(a), F.S.
[5] Section 766.1115(4), F.S.
[6] Section 768.28, F.S., provides a waiver of sovereign immunity in tort actions and sets limitations on recovery, attorney fees, and a statute of limitations.
[7] Rule 64I-2.002, F.A.C.
[8] Rule 64I-2.006, F.A.C.
[9] *Id.*
[10] *Supra* fn 5.

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 for a 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. Section 768.28(5), F.S., limits the recovery of any one person to $200,000 for one incident and limits all recovery related to one incident to a total of $300,000. The sovereign immunity recovery caps do not prevent a plaintiff from obtaining a judgment in excess of the caps but the plaintiff cannot recover the excess damages without action by the Legislature.[11]

Whether sovereign immunity applies turns on the degree of control of the agent of the state retained by the state.[12] In *Stoll v. Noel*, the Florida Supreme Court explained that independent contractor physicians may be agents of the state for purposes of sovereign immunity:

> One who contracts on behalf of another and subject to the other's control except with respect to his physical conduct is an agent and also independent contractor.[13]

The court examined the employment contract between the physicians and the state to determine whether the state's right to control was sufficient to create an agency relationship and held that it did.[14]

Effects of Proposed Changes

The bill amends s. 766.1115, F.S., of the Act to allow patients receiving services performed by a dentist or dental hygienist (health care provider) to contribute to the cost of dental laboratory expenses without compromising the health care provider's sovereign immunity.

The bill defines "uncompensated services" within the Act as services voluntarily provided under a contract in which a licensed dentist or dental hygienist[15] does not receive compensation from the governmental contractor and may not bill or accept compensation from a recipient or any public or private third-party payor for the specific services provided to a recipient covered by the contract. Additionally, if a patient or a parent or a guardian of the recipient chooses to contribute to the dental laboratory expenses associated with the care of the recipient, this contribution is not considered compensation for services. The effect of this definition is unclear, since the definition specifies that the care is provided under contract. The definition of "contract" provided in s. 766.1115 (3)(a), F.S., specifically states that the provider must not receive compensation for any services provided and may not bill or accept compensation from the recipient.

Additionally, the bill amends the contract requirements to expressly state that a licensed dentist or dental hygienist while acting within the scope of duties under contract as an agent of the governmental contractor may accept a voluntary monetary contribution for dental laboratory services related to the services provided to the patient. The contribution may not exceed the actual cost of the dental laboratory charges. The effect of this change would be to keep the blanket of sovereign immunity intact, despite the voluntary compensation for services.

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[11] Section 768.28(5), F.S.
[12] *Stoll v. Noel*, 694 So. 2d 701, 703(Fla. 1997).
[13] *Stoll v. Noel*, 694 So. 2d 701, 703(Fla. 1997) (quoting The Restatement of Agency).
[14] *Supra* fn 11.
[15] Chapter 466, F.S., governs the practice of Dentistry and Dental Hygienists.

B. SECTION DIRECTORY:

Section 1. Amends s. 766.1115, F.S., relating to health care providers; and the creation of agency relationships with governmental contractors.

Section 2. Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A small number of health care providers may be compensated for dental laboratory work.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The DOH has sufficient authority to promulgate rules to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Drafting Issues:

The bill creates a new definition of "uncompensated services," which includes the use of the current definition of "contract." The definition of "contract" specifically states that the provider must receive no compensation for any services provided under the contract, and may not bill or accept compensation

from the recipient, which conflicts with the intent, to allow a recipient to contribute to dental laboratory expenses.

Because the term "uncompensated services" is used to preclude all health care providers under the Act from being compensated for services provided under the contract, changing the definition of "uncompensated services" to mean specifically uncompensated services provided by dentists or dental hygienists may have unintended consequences. It is not clear whether this change would affect the sovereign immunity conditions for other health care providers under contract with DOH.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to sovereign immunity for dentists and dental hygienists; amending s. 766.1115, F.S.; revising a definition; defining the term "uncompensated services" as it relates to the liability of health care providers licensed under ch. 466, F.S., who are agents of governmental contractors; providing that the contribution to the dental laboratory expenses associated with the care of a patient is not considered compensation for the services; requiring a contract with a governmental contractor for health care services to include a provision for a health care provider licensed under ch. 466, F.S., as an agent of the governmental contractor, to allow a patient or a parent or guardian of the patient to voluntarily contribute a fee to cover costs of dental laboratory work related to the services provided to the patient without forfeiting sovereign immunity; prohibiting the contribution from exceeding the actual amount of the dental laboratory charges; providing an effective date.

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

Section 1. Paragraph (a) of subsection (3) of section 766.1115, Florida Statutes, is amended, paragraph (f) is added to that subsection, and paragraph (h) is added to subsection (4) of that section, to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

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

(a) "Contract" means an agreement executed in compliance with this section between a health care provider and a governmental contractor which allows~~. This contract shall allow~~ the health care provider to deliver health care services to low-income recipients as an agent of the governmental contractor. The contract must be for volunteer, uncompensated services. For services to qualify as volunteer, uncompensated services under this section, the health care provider must receive no compensation from the governmental contractor for ~~any~~ services provided under the contract and must not bill or accept compensation from the recipient, or a ~~any~~ public or private third-party payor, for the specific services provided to the low-income recipients covered by the contract.

(f) "Uncompensated services" means services voluntarily provided under a contract in which a health care provider licensed under chapter 466 does not receive compensation from the governmental contractor and may not bill or accept compensation from the recipient or any public or private third-party payor for the specific services provided to a low-income recipient covered by the contract. If a patient or a parent or guardian of the patient chooses to contribute to the dental laboratory expenses associated with the care of the patient, this contribution is not considered compensation for the services.

(4) CONTRACT REQUIREMENTS.—A health care provider that

executes a contract with a governmental contractor to deliver health care services on or after April 17, 1992, as an agent of the governmental contractor is an agent for purposes of s. 768.28(9), while acting within the scope of duties under the contract, if the contract complies with the requirements of this section and regardless of whether the individual treated is later found to be ineligible. A health care provider under contract with the state may not be named as a defendant in any action arising out of medical care or treatment provided on or after April 17, 1992, under contracts entered into under this section. The contract must provide that:

(h) As an agent of the governmental contractor for purposes of s. 768.28(9), while acting within the scope of duties under the contract, a health care provider licensed under chapter 466 may allow a patient or a parent or guardian of the patient to voluntarily contribute a fee to cover costs of dental laboratory work related to the services provided to the patient. This contribution may not exceed the actual cost of the dental laboratory charges.

A governmental contractor that is also a health care provider is not required to enter into a contract under this section with respect to the health care services delivered by its employees.

Section 2. This act shall take effect July 1, 2013.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Magar offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (a) of subsection (3) of section 766.1115, Florida Statutes, is amended, and paragraph (h) is added to subsection (4) of that section, to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

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

(a) "Contract" means an agreement executed in compliance with this section between a health care provider and a governmental contractor which allows~~. This contract shall allow~~ the health care provider to deliver health care services to low-income recipients as an agent of the governmental contractor. The contract must be for volunteer, uncompensated services. For services to qualify as volunteer, uncompensated services under

this section, the health care provider must receive no compensation from the governmental contractor for ~~any~~ services provided under the contract and must not bill or accept compensation from the recipient, or a ~~any~~ public or private third-party payor, for the specific services provided to the low-income recipients covered by the contract.

(4) CONTRACT REQUIREMENTS.—A health care provider that executes a contract with a governmental contractor to deliver health care services on or after April 17, 1992, as an agent of the governmental contractor is an agent for purposes of s. 768.28(9), while acting within the scope of duties under the contract, if the contract complies with the requirements of this section and regardless of whether the individual treated is later found to be ineligible. A health care provider under contract with the state may not be named as a defendant in any action arising out of medical care or treatment provided on or after April 17, 1992, under contracts entered into under this section. The contract must provide that:

(h) Notwithstanding subsection (3), as an agent of the governmental contractor for purposes of s. 768.28(9), while acting within the scope of duties under the contract, a health care provider licensed under chapter 466 may allow a patient or a parent or guardian of the patient to voluntarily contribute a fee to cover costs of dental laboratory work related to the services provided to the patient. This contribution may not exceed the actual cost of the dental laboratory charges and is deemed in compliance with this section.

A governmental contractor that is also a health care provider is not required to enter into a contract under this section with respect to the health care services delivered by its employees.

Section 2. This act shall take effect July 1, 2013.

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

Remove everything before the enacting clause and insert:

An act relating to sovereign immunity for dentists and dental hygienists; amending s. 766.1115, F.S.; revising a definition; requiring a contract with a governmental contractor for health care services to include a provision for a health care provider licensed under ch. 466, F.S., as an agent of the governmental contractor, to allow a patient or a parent or guardian of the patient to voluntarily contribute a fee to cover costs of dental laboratory work related to the services provided to the patient without forfeiting sovereign immunity; prohibiting the contribution from exceeding the actual amount of the dental laboratory charges; providing that the contribution complies with the requirements of s. 766.1115, F.S.; providing an effective date.