The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, January 14, 2014
TIME: 2:00 —4:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Sobel, Vice Chair; Senators Brandes, Braynon, Flores, Galvano, Garcia, Grimsley, and Joyner

TAB	OFFICE and APPOINTMENT (HOME CITY)	FOR TERM ENDING	COMMITTEE ACTION
	Senate Confirmation Hearing: A public hearing will be held for consideration of the below-named executive appointment to the office indicated.		
	State Surgeon General		
1	Armstrong, John H. (Ocala)	Pleasure of Governor	Recommend Confirm Yeas 9 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	Consideration of proposed committee bill:		
2	**SPB 7008**	Nonresident Pharmacies; Deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; requiring registered nonresident pharmacies to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; authorizing the department to inspect registered nonresident pharmacies, etc.	Submitted as Committee Bill Yeas 9 Nays 0
	Consideration of proposed committee bill:		
3	**SPB 7010**	Health Access Dental Licenses; Deleting the requirement that a license applicant or renewing licensee not have been reported to the National Practitioner Data Bank; authorizing the Board of Dentistry to deny licensure to an applicant or renewing licensee who has committed or is under investigation or prosecution for certain violations; repealing provisions relating to the future repeal of provisions authorizing the health access dental license, etc.	Submitted as Committee Bill Yeas 9 Nays 0
	Consideration of proposed committee bill:		

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SPB 7014**	OGSR/Department of Health; Amending provisions which make confidential and exempt certain information of a patient or patient's agent, health care practitioner, and others held by the Department of Health; specifying that the Attorney General, health care regulatory boards, and law enforcement agencies may disclose certain confidential and exempt information to certain entities only if such information is relevant to an active investigation that prompted the request for the information, etc.	Temporarily Postponed
	Consideration of proposed committee bill:		
5	**SPB 7016**	Prescription Drug Monitoring; Revising provisions relating to the comprehensive electronic database system and prescription drug monitoring program maintained by the Department of Health; requiring a law enforcement agency to submit a subpoena as a condition of direct access to information in the program; authorizing the department to provide relevant information that does not contain personal identifying information if the program manager determines a specified pattern exists, etc.	Temporarily Postponed
6	**Workshop** - Discussion and testimony only on the following (no vote to be taken): Telemedicine		
	Telemedicine		Discussed
	Other Related Meeting Documents		

RICK SCOTT
GOVERNOR

May 17, 2013

The Honorable Kenneth W. Detzner
Secretary of State
State of Florida
R. A. Gray Building, Room 316
500 South Bronough Street
Tallahassee, Florida 32399-0250

Dear Secretary Detzner:

Please be advised I have made the following reappointment under the provisions of Section 1001.71, Florida Statutes:

Dr. John H. Armstrong
688 Southeast 47th Loop
Ocala, Florida 34480

as State Surgeon General of the Department of Health, subject to confirmation by the Senate. This appointment is effective May 16, 2013, for a term ending at the pleasure of the Governor.

Sincerely,

Rick Scott
Governor

RS/vh

THE CAPITOL
TALLAHASSEE, FLORIDA 32399 • (850) 488-2272 • FAX (850) 922-4292

QUESTIONNAIRE FOR SENATE CONFIRMATION

The information from this questionnaire will be used by the Florida Senate in considering action on your confirmation. The questionnaire MUST BE COMPLETED IN FULL. Answer "none" or "not applicable" where appropriate.
Please type or print in blue or black ink.

June 5, 2013
Date Completed

1. Name: Dr. | Armstrong | John | Hulse
Mr./Mrs./Ms. | Last | First | Middle/Maiden

2. Business Address: 4052 Bald Cypress Way, Bin-A00 | Tallahassee
Street | Office # | City
FL | 32399 | 850-245-4210
Post Office Box | State | Zip Code | Area Code/Phone Number

3. Residence Address: 688 SE 47th Loop | Ocala | Marion
Street | City | County
FL | 34480 | 786-255-4820
Post Office Box | State | Zip Code | Area Code/Phone Number

Specify the preferred mailing address: Business ☒ Residence ☐ Fax # _____ (optional)

4. A. List all your places of residence for the last five (5) years.

Address	City & State	From	To
688 SE 47th Loop	Ocala, FL	8/06	Present
B. (continued from below)			
5070 Likini St, #1609	Honolulu, HI	7/89	6/90
1539 Epukane St	Honolulu, HI	7/88	7/89

B. List all your former and current residences outside of Florida that you have maintained at any time during adulthood.

Address	City & State	From	To
115 E. Hermosa Drive	San Antonio, TX	7/01	7/04
2108 Sabrina Drive	Vienna, VA	7/98	7/01
6229 N. London Ave, Apt G	Kansas City, MO	7/97	7/98
920 Neal Drive	Alexandria, VA	6/93	6/95
418 C Halawa View Loop	Honolulu, HI	7/90	6/93

5. Date of Birth: May 10, 1963 Place of Birth: Malta, MT

6. Social Security Number: _____

7. Driver License Number: _____ Issuing State: FL

8. Have you ever used or been known by any other legal name? Yes ☐ No ☒ If "Yes" Explain

9. Are you a United States citizen? Yes ■ No ☐ If "No" explain:

If you are a naturalized citizen, date of naturalization:

10. Since what year have you been a continuous resident of Florida? 2003

11. Are you a registered Florida voter? Yes ■ No ☐ If "Yes" list:

A. County of Registration: Marion B. Current Party Affiliation: Republican

12. Education

A. High School: West Springfield High School, Springfield, VA (Name and Location) Year Graduated: 1980

B. List all postsecondary educational institutions attended:

Name & Location	Dates Attended	Certificates/Degrees Received
Princeton University, Princeton, NJ	9/5/1980 to 6/6/1984	BA, Economics
University of Virginia School of Medicine, Charlottesville, VA	8/22/1984 to 5/22/1988	MD
US Army Command & General Staff College, Fort Leavenworth, KS	7/11/1997 to 6/6/1998	Graduate

13. Are you or have you ever been a member of the armed forces of the United States? Yes ■ No ☐ If "Yes" list:

A. Dates of Service: 6/17/1988 to 11/22/2005

B. Branch or Component: US Army

C. Date & type of discharge: Honorable, 11/22/2005

14. Have you ever been arrested, charged, or indicted for violation of any federal, state, county, or municipal law, regulation, or ordinance? (Exclude traffic violations for which a fine or civil penalty of $150 or less was paid.) Yes ☐ No ■ If Yes" give details:

Date	Place	Nature	Disposition

15. Concerning your current employer and for all of your employment during the last five years, list your employer's name, business address, type of business, occupation or job title, and period(s) of employment.

Employer's Name & Address	Type of Business	Occupation/Job Title	Period of Employment
Florida Department of Health, 4052 Bald Cypress Way, Bin-A00, Tallahassee, FL 32399-1708	State Surgeon General		5/23/2012 to present
USF Morsani College of Medicine, Dept of Surgery, 2 Tampa General Cir, Tampa, FL	Associate Professor of Surgery, Chief Medical Officer CAMLS,		12/1/2010 to 5/22/2012
John H. Armstrong, MD, FACS, 688 SE 47th Loop, Ocala, FL 34480	Consultant		10/30/2010 to 11/30/2010
Univ of Florida College of Medicine, UF HSC, Box 100108, 1600 SW Archer Road, Gainesville, FL 32610-0286	Assistant Professor of Surgery, TMD		4/24/2006 to 10/29/2012

16. Have you ever been employed by any state, district, or local governmental agency in Florida? Yes ■ No ☐
If "Yes", identify the position(s), the name(s) of the employing agency, and the period(s) of employment:

Position	Employing Agency	Period of Employment
State Surgeon General	Florida Department of Health	5/23/2012 to present

17. A. State your experiences and interests or elements of your personal history that qualify you for this appointment.

For 21 years (13 in Florida), I have been a caring surgeon, surgical educator, and patient advocate. I have managed a diversity of personnel, clinics, services, centers, and systems across health care delivery in military and civilian sectors, and have served on Florida Department of Health Trauma System committees and Centers for Disease Control panels. Particular areas of interest include public health preparedness, team performance, health system development, and health policy. Communication skills have been honed in media (print, radio, and television), audiovisual presentations, speeches, and legislative testimony.

B. Have you received any degree(s), professional certification(s), or designations(s) related to the subject matter of this appointment? Yes ■ No ☐ If "Yes", list:

MD; US Army Command & General Staff College; University of Florida College of Medicine Master Educator in Medical Education; Certified, American Board of Surgery in Surgery and Surgical Critical Care; Fellow, American College of Surgeons; Fellow, American College of Chest Physicians.

C. Have you received any awards or recognitions relating to the subject matter of this appointment? Yes ■ No ☐ If "Yes", list:

2013: Ray Alexander Award, Florida Chapter, American College of Surgeons: 2011, Senior Visiting Trauma Surgeon, Landstuhl Regional Medical Center, Germany; American Association for the Surgery of Trauma/American College of Surgeons Health Policy Scholarship; Exemplary Teacher, University of Florida College of Medicine; 2008 & 2009: Award of Excellence, Florida Department of Health; 2005: US Army Meritorious Service Medal, 4th Oak Leaf Cluster; US Navy Commendation Medal; 2003: US Army Surgeon General's Physician Recognition Award for Lieutenant Colonel; Surgeon General's A-designator for General Surgery.

D. Identify all association memberships and association offices held by you that relate to this appointment:

Florida Medical Association; American Medical Association (former Young Physician Trustee, Secretary); American College of Surgeons (Governor from Florida; AMA Delegation Chair; former ACSPA-Surgeons PAC Chair); American College of Physician Executives; American College of Chest Physicians; Association of Military Surgeons of the United States; American Association for the Surgery of Trauma.

18. Do you currently hold an office or position (appointive, civil service, or other) with the federal or any foreign government? Yes ☐ No ■ If "Yes", list:

19. A. Have you ever been elected or appointed to any public office in this state? Yes ■ No ☐ If "Yes", state the office title, date of election or appointment, term of office, and level of government (city, county, district, state, federal):

Office Title	Date of Election or Appointment	Term of Office	Level of Government
State Surgeon General	5/23/2012	One year	State

B. If your service was on an appointed board(s), committee(s), or council(s):

(1) How frequently were meetings scheduled: _____

(2) If you missed any of the regularly scheduled meetings, state the number of meetings you attended, the number you missed, and the reasons(s) for your absence(s).

Meetings Attended	Meetings Missed	Reason for Absence

20. Has probable cause ever been found that you were in violation of Part III, Chapter 112, F.S., the Code of Ethics for Public Officers and Employees? Yes ☐ No ■ If "Yes", give details:

Date	Nature of Violation	Disposition

21. Have you ever been suspended from any office by the Governor of the State of Florida? Yes ☐ No ■ If "Yes", list:

A. Title of office: _____ C. Reason for suspension: _____

B. Date of suspension: _____ D. Result: Reinstated ☐ Removed ☐ Resigned ☐

22. Have you previously been appointed to any office that required confirmation by the Florida Senate? Yes ■ No ☐ If "Yes", list:

A. Title of Office: State Surgeon General

B. Term of Appointment: One year

C. Confirmation results: Recommended for confirmation by Senate Health Policy Committee

23. Have you ever been refused a fidelity, surety, performance, or other bond? Yes ☐ No ■ If "Yes", explain:

24. Have you held or do you hold an occupational or professional license or certificate in the State of Florida? Yes ■ No ☐ If "Yes", provide the title and number, original issue date, and issuing authority. If any disciplinary action (fine, probation, suspension, revocation, disbarment) has ever been taken against you by the issuing authority, state the type and date of the action taken:

License/Certificate Title & Number	Original Issue Date	Issuing Authority	Disciplinary Action/Date
ME69442	10/12/1995	DOH MQA	N/A

25. A. Have you, or businesses of which you have been and owner, officer, or employee, held any contractual or other direct dealings during the last four (4) years with any state or local governmental agency in Florida, including the office or agency to which you have been appointed or are seeking appointment? Yes ☐ No ■ If "Yes", explain:

Name of Business	Your Relationship to Business	Business' Relationship to Agency

B. Have members of your immediate family (spouse, child, parents(s), siblings(s)), or businesses of which members of your immediate family have been owners, officers, or employees, held any contractual or other direct dealings during the last four (4) years with any state or local governmental agency in Florida, including the office or agency to which you have been appointed or are seeking appointment? Yes ☐ No ■ If "Yes", explain:

Name of Business	Family Member's Relationship to You	Family Member's Relationship to Business	Business' Relationship to Agency

26. Have you ever been a registered lobbyist or have you lobbied at any level of government at any time during the past five (5) years? Yes ■ No ☐

A. Did you receive any compensation other than reimbursement for expenses? Yes ☐ No ■

B. Name of agency or entity you lobbied and the principal(s) you represented:

Agency Lobbied	Principal Represented
Florida Legislature	Florida Department of Health
US Congress	American College of Surgeons

27. List three persons who have known you well within the past five (5) years. Include a current, complete address and telephone number. Exclude your relatives and members of the Florida Senate.

Name	Mailing Address	Zip Code	Area Code/Phone Number
Mary E. Maniscalco-Theberge, MD			
Richard B. Reiling, MD			
Cecil B. Wilson, MD			

AMSUS, 9320 Old Georgetown Road, Bethesda, MD 20184, 1993 to present; AAST, 633 N. St. Clair St, Chicago, IL 60611, 2010 to present

28. Name any business, professional, occupational, civic, or fraternal organizations(s) of which you are now a member, or of which you have been a member during the past five (5) years, the organization address(es), and date(s) of your membership(s).

Name	Mailing Address	Office(s) Held & Term	Date(s) of Membership
Florida Medical Association	1430 Piedmont Dr E, Tallahassee, FL 32308		2003 to present
American Medical Association	515 N. State St, Chicago, IL 60610	Young Physician Trustee, Secretary, 2002-6	1988 to present
American College of Surgeons	633 N. St. Clair St, Chicago, IL 60611	Governor (current), AMA Delegation Chair (current), ACSPA SurgeonsPAC Chair, 2009-12)	2000 to present
American College of Physician Executives	400 N. Ashley Drive, Suite 400, Tampa, FL 33602		1995 to present
American College of Chest Physicians	3300 Dundee Rd, Northbrook, IL 60062-2348		2000 to present

29. Do you know of any reason why you will not be able to attend fully to the duties of the office or position to which you have been or will be appointed? Yes ☐ No ■ If "Yes", explain:

30. If required by law or administrative rule, will you file financial disclosure statements? Yes ■ No ☐

CERTIFICATION

STATE OF FLORIDA
COUNTY OF Leon

Before me, the undersigned Notary Public of Florida, personally appeared John Hulse Armstrong, who, after being duty sworn, say: (1) that he/she has carefully and personally prepared or read the answers to the foregoing questions; (2) that the information contained in said answers is complete and true; and (3) that he/she will, as an appointee, fully support the Constitutions of the United States and of the State of Florida.

John H Armstrong
Signature of Applicant-Affiant

Sworn to and subscribed before me this 12 day of June, 2013.

Margaret H Medina
Signature of Notary Public-State of Florida

Margaret H. Medina
(Print, Type, or Stamp Commissioned Name of Notary Public)

My commission expires: _____

Personally Known [X] **OR** Produced Identification [ ]

Type of Identification Produced _____

RECEIVED
DEPARTMENT OF STATE
2013 JUN 14 AM 9:17
DIVISION OF ELECTIONS
TALLAHASSEE, FL

MARGARET HARVARD MEDINA
Commission # FF 008844
Expires April 23, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

(seal)

1030

STATE OF FLORIDA
DEPARTMENT OF STATE
Division of Elections

I, Ken Detzner, Secretary of State,
do hereby certify that

John H. Armstrong

is duly appointed

State Surgeon General,
Department of Health

for a term beginning on the
Sixteenth day of May, A.D., 2013,
to serve at the pleasure of the Governor
and is subject to be confirmed by the Senate
during the next regular session of the Legislature.

Given under my hand and the Great Seal of the State of Florida, at Tallahassee, the Capital, this the Nineteenth day of June, A.D., 2013.

Ken Detzner

Secretary of State

DSDE 99 (3/03)

OATH OF OFFICE

(Art. II. § 5(b), Fla. Const.)

2013 JUN 14 AM 9:17

STATE OF FLORIDA

County of Leon County

I do solemnly swear (or affirm) that I will support, protect, and defend the Constitution and Government of the United States and of the State of Florida; that I am duly qualified to hold office under the Constitution of the State, and that I will well and faithfully perform the duties of

State Surgeon General & Secretary of Health

(Title of Office)

on which I am now about to enter, so help me God.

[NOTE: If you affirm, you may omit the words "so help me God." *See* § 92.52, Fla. Stat.]

John H. Armstrong

Signature

Sworn to and subscribed before me this 5th *day of* June, 2013.

Signature of Officer Administering Oath or of Notary Public

Print, Type, or Stamp Commissioned Name of Notary Public

MARGARET HARVARD MEDINA
Commission # FF 008844
Expires April 23, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

Personally Known [X] ***OR*** *Produced Identification* [ ]

Type of Identification Produced _____

ACCEPTANCE

I accept the office listed in the above Oath of Office.

Mailing Address: [☑] Home [☐] Office

688 SE 47th Loop
Street or Post Office Box

Ocala, FL 34480
City, State, Zip Code

John H. Armstrong, MD, FACS
Print name as you desire commission issued

John H. Armstrong
Signature

DS-DE 56 (Rev. 02/10)

The Florida Senate

Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of

John H. Armstrong

State Surgeon General

NOTICE OF HEARING

TO: Dr. John H. Armstrong

YOU ARE HEREBY NOTIFIED that the Committee on Health Policy of the Florida Senate will conduct a hearing on your executive appointment on Tuesday, January 14, 2014, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 2:00 p.m., pursuant to Rule 12.7(1) of the Rules of the Florida Senate.

Please be present at the time of the hearing.
DATED this the 6th day of January, 2014

Committee on Health Policy

Senator Aaron Bean
As Chair and by authority of the committee

cc: Members, Committee on Health Policy
Office of the Sergeant at Arms

The Florida Senate

COMMITTEE RECOMMENDATION ON EXECUTIVE APPOINTMENT

COMMITTEE: Committee on Health Policy
MEETING DATE: Tuesday, January 14, 2014
TIME: 2:00 —4:00 p.m.
PLACE: Pat Thomas Committee Room, 412 Knott Building

TO: The Honorable Don Gaetz, President

FROM: Committee on Health Policy

The committee was referred the following executive appointment subject to confirmation by the Senate:

Office: State Surgeon General

Appointee: Armstrong, John H.

Term: 5/16/2013-Pleasure of Governor

After inquiry and due consideration, the committee recommends that the Senate **confirm** the aforesaid executive appointment made by the Governor.

THE FLORIDA SENATE

COMMITTEE WITNESS OATH

CHAIR:

Please raise your right hand and be sworn in as a witness.

Do you swear or affirm that the evidence you are about to give will be the truth, the whole truth, and nothing but the truth?

WITNESS'S NAME: John H. Armstrong, M.D.

ANSWER: I do.

Pursuant to §90.605(1), *Florida Statutes*: "The witness's answer shall be noted in the record."

COMMITTEE NAME: Health Policy

DATE: 1/14/14

File 1 copy with the Secretary of the Senate (303 Capitol) S-002 (10/2004)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SPB 7008
INTRODUCER:	For consideration by the Health Policy Committee
SUBJECT:	Nonresident Pharmacies
DATE:	December 23, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall		

I. Summary:

SPB 7008 requires a pharmacy located in another state (nonresident pharmacy) to obtain a nonresident pharmacy compounded sterile products permit prior to shipping, mailing, delivering, or dispensing a compounded sterile product into Florida. Any sterile compounded product that is sent into Florida must have been compounded in a manner that meets or exceeds the standards for sterile compounding.

The proposed bill authorizes the Department of Health (department) or its agents to inspect any nonresident pharmacy that is registered with the department. The nonresident pharmacy is responsible for the cost of this inspection. The department is also authorized to take regulatory action against a nonresident pharmacy immediately, without waiting 180 days for the pharmacy's home state to act on alleged conduct that causes or could cause serious injury to a human or animal in this state.

II. Present Situation:

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) found in ch. 465, F.S.[1] The Board of Pharmacy (the board) is created within the department to adopt rules to implement provisions of the Act and take other actions according to duties conferred on it in the Act.[2]

Several pharmacy types are specified in law and are required to be permitted or registered under the Act:

- Community pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

[1] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.
[2] Section 465.005, F.S.

- Institutional pharmacy – a location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medical drugs are compounded, dispensed, stored, or sold. The Act further classifies institutional pharmacies according to the type of facility or activities with respect to the handling of drugs within the facility.
- Nuclear pharmacy – a location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, excluding hospitals or the nuclear medicine facilities of such hospitals.
- Internet pharmacy – a location not otherwise permitted under the Act, whether within or outside the state, which uses the internet to communicate with or obtain information from consumers in this state in order to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.
- Non-resident pharmacy – a location outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state.
- Special pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold if such location is not otherwise defined which provides miscellaneous specialized pharmacy service functions. Seven special pharmacy permits are established in rule.[3]

Nonresident pharmacy

Any pharmacy located outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is required to be registered with the board as a nonresident pharmacy.[4,5] In order to register in this state, a nonresident pharmacy must submit an application fee of $255 and a certified application[6] that documents:

- That the pharmacy maintains a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the drugs are dispensed,
- The identity of the principal corporate officers and the pharmacist who serves as the prescription department manager as well as the criminal and disciplinary history of each,
- That the pharmacy complies with lawful directions and requests for information from applicable regulatory bodies,
- The pharmacy department manager's licensure status,
- The most recent pharmacy inspection report, and
- The availability of the pharmacist and patient records for a minimum of 40 hours per week, 6 days a week.

The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for:

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[3] Rule 64B16-28.800, F.A.C., establishes the following special permits: Special-Parenteral and Enteral, Special-Closed System Pharmacy, Special-Non Resident (Mail Service), Special-End Stage Renal Disease, Special-Parenteral/Enteral Extended Scope, Special-ALF, and Special Sterile Compounding.
[4] Section 465.0156, F.S.
[5] However, the board may grant an exemption from the registration requirements to any nonresident pharmacy which confines its dispensing activity to isolated transactions. *See* s. 465.0156(2), F.S.
[6] The complete application packet may be found at: http://www.floridaspharmacy.gov/Applications/app-non-resident-parmacy.pdf (last visited Dec. 16, 2013).

- Failure to comply with Florida's drug substitution provisions in s. 465.025, F.S.,
- Failure to comply with the registration requirements,
- Advertising the services of a nonresident pharmacy which has not registered knowing the advertisement will likely induce members of the public in this state to use the pharmacy to fill prescriptions, or
- Conduct which causes serious bodily injury or serious psychological injury to a resident of Florida if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to act within 180 days of the referral.

Pharmaceutical Compounding

Compounding is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating prescription or non-prescription ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent.[7]

Historically and continuing today, a practitioner might prescribe a compounded preparation when a patient requires a different dosage form, such as turning a pill into a liquid for a patient who cannot swallow pills or into a lollipop or flavored medication for children; a different dosage strength, such as for an infant; or allergen-free medication. Compounding and dispensing in this manner is typically patient-specific. More recently, the practice of compounding medications has evolved and expanded to include compounding for office use. "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.[8] Typically a drug compounded for office use is not prepared, labeled, and dispensed for a specific patient.

Under the board's rules, compounding includes:

- The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
- The preparation pursuant to a prescription of drugs or devices which are not commercially available.
- The preparation of commercially available products[9] from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

[7] *See* Rule 64B16-27.700, F.A.C.
[8] *See* Rule 64B16-27.700, F.A.C.
[9] The term "commercially available product" means any medicinal product that is legally distributed in Florida by a drug manufacturer or wholesaler. *See* Rule 64B16-27.700, F.A.C.

Compounded Products

Compounded products may be either sterile or non-sterile. A sterile preparation is defined in the board's rule[10] as any dosage form devoid of viable microorganisms, but does not include commercially manufactured products that do not require compounding prior to dispensing. Compounded sterile preparations include, but are not limited, to the following:

- Injectables;
- Parenterals, including Total Parenteral Nutrition (TPN) solutions, parenteral analgesic drugs, parenteral antibiotics, parenteral antineoplastic agents, parenteral electrolytes, and parenteral vitamins;
- Irrigating fluids;
- Ophthalmic preparations; and
- Aqueous inhalant solutions for respiratory treatments.

A non-sterile compounded product is a compounded preparation that is not a sterile compounded preparation.

The United States Pharmacopeia and the National Formulary (USP–NF) is a book containing standards for chemical and biological drug substances, dosage forms, and compounded preparations, excipients, medical devices, and dietary supplements. The federal Food Drug and Cosmetic Act (FDCA) designates the USP–NF as the official compendium for drugs marketed in the United States. A drug product in the U.S. market must conform to the USP–NF standards for strength, quality, purity, packaging, and labeling of medications to avoid possible charges of adulteration and misbranding.[11] The USP–NF has five chapters specifically related to pharmaceutical compounding, two of which are USP Chapter 795, which addresses compounding for non-sterile preparations, and USP Chapter 797, which addresses compounding for sterile preparations. In addition, USP Chapter 797 requires the use of other general chapters as well.

Safety concerns of compounded drugs

Compounded drugs can pose both direct and indirect health risks. Compounded drugs may be unsafe and pose direct health risks because of the use of poor quality compounding practices. They may be sub- or super-potent, contaminated, or otherwise adulterated. Indirect health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective. Some pharmacists are well-trained and well-equipped to compound certain medications safely. But not all pharmacists have the same level of skills and equipment, and some drugs may be inappropriate for compounding. In some cases, compounders may lack sufficient controls (e.g., equipment, training, testing, or facilities) to ensure product quality or to compound complex drugs like sterile or extended-release drugs.

[10] Rule 64B16-27.797, F.A.C.
[11] For additional information on the USP-NP *see* http://www.usp.org/usp-nf (last visited Dec. 17, 2013).

In 2012, the federal Centers for Disease Control and Prevention (CDC), in collaboration with state and local health departments and the Food and Drug Administration (FDA), began investigating a multistate outbreak of fungal meningitis and other infections among patients who received contaminated preservative-free methylprednisolone acetate (MPA) steroid injections from the New England Compounding Center (NECC).[12] As of October 23, 2013, 751 cases were reported nationwide, with 64 deaths attributed to contaminated injectables compounded in the Massachusetts pharmacy.[13] Florida reported 25 cases, with 7 deaths related to persons receiving the medications from the contaminated lots.

The FDA continues to inform the public about recalls, inspections, and regulatory enforcement action related to compounded medications.[14]

State and Federal Oversight of Compounded Medications

Until recently, the regulation of compounded medications was murky, without clear guidelines and oversight responsibility by the FDA or state agencies.[15,16] The FDA traditionally regulated the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. State boards of pharmacy historically have regulated the compounding of medications by a pharmacy under the practice of pharmacy.[17] However, compounding standards, inspector competency, and inspectional frequency and resources in the states, if existent, vary considerably.[18]

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA),[19] legislation to enhance the oversight of the compounding of human drugs. This law creates a new section 503B in the FDCA. Under section 503B, a compounder can become an "outsourcing facility." An outsourcing facility is not required to also be a state-licensed pharmacy. An

[12] The Centers for Disease Control and Prevention Multistate Fungal Meningitis Outbreak Investigation, available at: http://www.cdc.gov/hai/outbreaks/meningitis.html (last visited Dec. 27, 2013).
[13] The Centers for Disease Control and Prevention Multistate Fungal Meningitis Outbreak Investigation, available at: http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table (last visited Dec. 27, 2013).
[14] *See* the FDA website at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm (last visited Dec. 27, 2013).
[15] The U.S. Supreme Court had found certain provisions relating to the advertising and promotion of certain human compounded drugs in section 503A of the FDCA to be unconstitutional in 2002 and struck the entire section of law dealing with the remaining provisions related to compliance with current good manufacturing practices, labeling, and FDA approval prior to marketing. In subsequent opinions, lower courts split on whether the remaining provisions remained intact and enforceable.
[16] In some instances, the FDA was refused admittance to conduct an inspection of compounders, which necessitated obtaining an administrative warrant to gain access to the firm and make copies of the firm's records. *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm (last visited Dec. 27, 2013).
[17] *See generally* U.S. Food and Drug Administration, Regulatory Guidance for Compounded Drugs, available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited Dec, 27, 2013).
[18] House Democrats Release Report on Flawed Compounding Pharmacy Oversight, April 15, 2013, available at: http://dingell.house.gov/press-release/house-democrats-release-report-flawed-compounding-pharmacy-oversight (last visited Dec. 27, 2013).
[19] H.R. 3204, 113th Congress.

outsourcing facility will be able to qualify for exemptions from the FDA approval requirements for new drugs and the requirement to label products with adequate directions for use. Outsourcing facilities:

- Must comply with current good manufacturing practices (CGMP) requirements,
- Will be inspected by FDA according to a risk-based schedule, and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

This law provides the framework such that if compounders register with the FDA as outsourcing facilities, hospitals and other health care providers can lawfully provide their patients with drugs that were compounded in outsourcing facilities that are subject to CGMP requirements and federal oversight.

A compounder that chooses not to register as an outsourcing facility and qualify for the exemptions under section 503B, may qualify for the exemptions under section 503A of the FDCA relating to traditional compounding for patient-specific medications. Otherwise, the compounder is subject to all of the requirements in the FDCA applicable to conventional manufacturers.

The FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding. The FDA has also indicated it intends to continue to cooperate with state authorities to address pharmacy compounding activities that may be violative of the FDCA.[20]

With the nationwide fungal meningitis outbreak caused by contaminated compounded products, the Florida Board of Pharmacy adopted Emergency Rule 64B16ER12-1, Florida Administrative Code. This Emergency Rule required all Florida licensed pharmacy permit holders, including non-residents, to complete a mandatory survey to inform the board of their compounding activities. The goal of this mandatory survey was to determine the scope of sterile and non-sterile compounding within Florida licensed pharmacies –whether physically located in or out-of-state. Of the 8,981 permitted pharmacies, 8,294 (92 percent) responded. The board published the compounding survey results in January 2013.[21]

Key results relating to non-sterile compounding:

- 55 percent (4,494) compound non-sterile products; 9 percent (382) of these are nonresident pharmacies.
- 54 percent (4,380) compound non-sterile products pursuant to a patient-specific prescription; 9 percent (373) of these are nonresident pharmacies.
- 6 percent (459) compound non-sterile products in bulk; 81 percent (373) of these are nonresident pharmacies.

[20] *Supra*, 16.
[21] Florida Board of Pharmacy compounding Survey Report, January 23, 2013 is available at: http://www.floridaspharmacy.gov/Forms/info-compounding-survey-report.pdf, (last visited Dec. 27, 2013).

- 1 percent (119) compound non-sterile products in bulk for office use; 50 percent (59) of these are nonresident pharmacies.
- 5 percent (382) ship compounded non-sterile products to other states; 80 percent (307) of these are nonresident pharmacies.

Key results relating to sterile compounding:

- 12 percent (946) compound sterile products; 32 percent (301) of these are nonresident pharmacies. Some of these in-state pharmacies may hold other permit types as well, such as an institutional permit or a special permit that authorizes compounding.
- 11 percent (913) compound sterile products pursuant to a patient-specific prescription; 32 percent (289) of these are nonresident pharmacies.
- 4 percent (348) compound sterile products in bulk and/or in bulk for office use; 45 percent (155) of these are nonresident pharmacies. Eighty-three of these 348 pharmacies (22 in-state and 61 nonresident) compound greater than 100 doses from a single batch.
- 4 percent (307) ship compounded sterile products to other states; 177 of these are nonresident pharmacies that ship sterile compounded products to Florida.

Effective September 23, 2013, the board adopted a rule requiring most pharmacies that engage or intend to engage in the preparation of sterile compounded products within the state to obtain a Special Sterile Compounding permit.[22] Pharmacies required to obtain this permit must compound sterile products in strict compliance with the standards set forth in board rules.[23] These rules address, among other things, compounding for office use, including the quantity of product that may be safely compounded for office use, execution of an agreement between the pharmacist and practitioner outlining responsibilities of the practitioner, and labeling. Compliance with additional standards based on the risk level for contamination in the practice of compounding sterile preparations is also required. The rule addressing standards of practice for compounding sterile preparations was first adopted in 2008 and amended in January of 2010. These standards apply to all sterile pharmaceuticals, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or doctor's office.[24]

There is no statutory authority to require nonresident pharmacies to register or obtain a separate sterile compounding permit in Florida.

Compounding Pharmacy Accreditation

The Pharmacy Compounding Accreditation Board (PCAB) is a nationally recognized organization that issues a voluntary quality accreditation designation for the compounding industry. Founders of the organization include the American College of Apothecaries, National Community Pharmacists Association, American Pharmacists Association, National Alliance of State Pharmacy Associations, International Academy of Compounding Pharmacists, National Association of Boards of Pharmacy, National Home Infusion Association, and United States Pharmacopeia.

[22] Rule 64B16-28.100(8), F.A.C.
[23] Rules 64B16-27.797 and 64B16-27.700, F.A.C.
[24] Rule 64B16-27.700, F.A.C.

The PCAB accreditation means the pharmacy has independent, outside validation that it meets nationally accepted quality assurance, quality control, and quality improvement standards. In order to demonstrate compliance with PCAB standards and earn PCAB accreditation, pharmacies participate in an off-site and on-site evaluation process that includes:[25]

- Verification by PCAB that the pharmacy is not on probation for issues related to compounding quality, public safety or controlled substances.
- Verification that the pharmacy is properly licensed in each state it does business in.
- An extensive on-site evaluation by a PCAB surveyor, all of whom are compounding pharmacists trained in evaluating compliance with PCAB's quality standards. For example, this evaluation includes:
  - An assessment of the pharmacy's system for assuring and maintaining staff competency.
  - A review of facilities and equipment.
  - Review of records and procedures required to prepare quality compounded medications.
  - Verification that the pharmacy uses ingredients from FDA registered and or licensed sources.
  - Review of the pharmacy's program for testing compounded preparations.

Currently, 187 pharmacies hold PCAB accreditation, 15 of which are located in Florida.[26]

III. Effect of Proposed Changes:

Section 1 amends s. 465.0156, F.S., to authorize the department to take regulatory action against a nonresident pharmacy immediately, without waiting 180 days for the pharmacy's home state to act on alleged conduct that causes or could cause serious injury to a human or animal in this state. Authorized regulatory action is expanded to include conduct that could cause serious injury, without demonstrating that the conduct actually injured a person. Regulatory enforcement action may also occur for conduct that causes or could cause serious bodily injury to an animal in this state or for noncompliance with the requirements of the newly established nonresident pharmacy compounded sterile products permit.

Section 2 creates s. 465.0158, F.S., to establish the nonresident pharmacy compounded sterile products permit. A pharmacy located in another state is required to obtain a nonresident pharmacy compounded sterile products permit prior to shipping, mailing, delivering, or dispensing a compounded sterile product into Florida. This permit is a supplemental permit to registration as a nonresident pharmacy.

The proposed bill allows a registered nonresident pharmacy until January 31, 2015 to become permitted, while continuing to send compounded sterile products into this state, if the products meet or exceed the standards required in the proposed bill. However, if a nonresident pharmacy is not registered by July 1, 2014, it must seek registration and obtain the nonresident pharmacy compounded sterile products permit prior to sending compounded sterile products to Florida.

[25] Pharmacy Compounding Accreditation Board, http://www.pcab.org/prescribers, (last visited Dec. 27, 2013).
[26] *See* http://www.pcab.org/pharmacy, (last visited Dec. 27, 2013.

Any sterile compounded product that is sent into this state must have been compounded in a manner that meets or exceeds the standards for sterile compounding in Florida. The owners, officers, and prescription department manager or pharmacist in charge must attest that he or she understands Florida's laws and rules governing sterile compounding and that any compounded sterile products sent into this state will comply with those standards, unless the board has granted an exemption due to conflicting standards where the nonresident pharmacy is located.

The department is required to notify the permittee when Florida's laws or rules for sterile compounding change. However, if notification does not occur, the permittee remains obligated to comply with Florida's standards.

The department is directed to schedule the biennial permit renewal concurrent with the nonresident pharmacy's biennial registration. The board is authorized to adopt in rule a permit fee that will not exceed $250.

Section 3 amends s. 465.017, F.S., to authorize the department or its agents to inspect any nonresident pharmacy that is registered with the department. The nonresident pharmacy is responsible for the actual costs incurred by the department for this inspection. Grammatical changes are also made to this section.

Section 4 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

A biennial permit fee in an amount not to exceed $250 is authorized. According to the board's compounding survey results, 177 nonresident pharmacies ship sterile compounded products to Florida. Assuming all 177 nonresident pharmacies seek a permit to continue shipping sterile compounded products to Florida, the biennial revenue from the permit, plus the $5 unlicensed activity fee,[27] is estimated at $45,135.

[27] The $5 unlicensed activity fee is required by s. 456.065(3), F.S.

B. Private Sector Impact:

SPB 7008 enhances the regulation of pharmacies that are located in other states and provide medication to persons in this state. These pharmacies that compound sterile products for patients in Florida may experience increased costs related to additional permit fees as discussed above and compliance with greater compounding practice standards, if the pharmacy is located in a state with lesser practice standards. All registered nonresident pharmacies may experience on-site inspections and regulatory enforcement for non-compliance with Florida-specific practice requirements.

Patients receiving compounded sterile products from other states might experience increased medication costs to offset any costs of compliance with safer compounding standards. The overall health care market might experience reduced utilization to the extent that adverse health consequences are minimized from safer compounded medications. The fiscal impact of these factors is indeterminate.

C. Government Sector Impact:

The department will incur additional costs related to rule adoption, permitting activities, and regulatory enforcement actions. An analysis from the department was not available; however, frequently the department indicates these costs can be absorbed within existing resources. Costs incurred for inspections of nonresident pharmacies will be reimbursed by the nonresident pharmacy.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 465.0156 and 465.017.

This bill creates the following section of the Florida Statutes: 465.0158.

IX. Additional Information:

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

None.

B. Amendments:

None.

634504

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
01/14/2014	.	
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	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment

Delete line 83
and insert:
the state in which the nonresident pharmacy is located; or

724630

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
01/14/2014	.	
	.	
	.	
	.	

The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Delete line 110
and insert:
this section.
(9) This section shall stand repealed on October 1, 2018 unless reenacted by the Legislature.

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

724630

And the title is amended as follows:

Delete line 18

and insert:

authorizing the Board of Pharmacy to adopt rules;

providing for the future repeal of s. 465.0158;

FOR CONSIDERATION By the Committee on Health Policy

588-00653A-14 20147008__

A bill to be entitled

An act relating to nonresident pharmacies; amending s. 465.0156, F.S.; conforming provisions to changes made by the act; deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; creating s. 465.0158, F.S.; requiring registered nonresident pharmacies to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; requiring submission of an application and a nonrefundable fee; specifying requirements; requiring the Department of Health to inform permittees of any law or rule changes; authorizing the board to deny, revoke, or suspend a permit for certain actions; providing dates by which certain registered and unregistered nonresident pharmacies must obtain a permit; authorizing the Board of Pharmacy to adopt rules; amending s. 465.017, F.S.; authorizing the department to inspect registered nonresident pharmacies; requiring nonresident pharmacies to pay for the costs of such inspections; providing an effective date.

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

Section 1. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended to read:

465.0156 Registration of nonresident pharmacies.—

(4) The board may deny, revoke, or suspend registration of,

or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, s. 465.0158, or ~~with~~ any requirement of this section in accordance with ~~the provisions of~~ this chapter.

(5) In addition to the prohibitions of subsection (4), the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with ~~the provisions of~~ this chapter for conduct that ~~which~~ causes or could cause serious bodily injury or serious psychological injury to a human or animal in ~~resident of~~ this state ~~if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral~~.

Section 2. Section 465.0158, Florida Statutes, is created to read:

465.0158 Nonresident pharmacy compounded sterile products permit.—A nonresident pharmacy registered under s. 465.0156 must also hold a compounded sterile products permit issued under this section in order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.

(1) Application for a permit shall be submitted on a form furnished by the board, together with a nonrefundable permit fee as provided under s. 465.022(14). The board may require such information as it deems reasonably necessary to carry out the purposes of this section, including information pertaining to registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services.

(2) As a condition of initial permitting and permit renewal, the owners, officers, and prescription department

manager or pharmacist in charge of the nonresident pharmacy must attest in writing that they have read and understand the laws and rules governing sterile compounding in this state and that any compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding.

(a) The department shall notify all compounded sterile products permittees when state laws or rules affecting the standards for sterile compounding in this state are adopted or revised, along with the effective date of the law or rule.

(b) If the department fails to notify a permittee of a change in state laws or rules, or the permittee does not receive notification of applicable rules, the permittee remains legally obligated to meet or exceed this state's standards with respect to any compounded sterile product shipped, mailed, delivered, or dispensed into this state. The board may provide an exception to this requirement by rule if the sterile compounding laws and rules of the state in which the nonresident pharmacy is located directly conflict with a board rule for sterile compounding in this state but provide a comparable standard of product safety and integrity.

(3) A nonresident pharmacy may not ship, mail, deliver, or dispense any compounded sterile product into this state which:

(a) Was compounded in violation of the laws and rules of the state in which the nonresident pharmacy is located; and

(b) Does not meet or exceed this state's sterile compounding standards as provided in subsection (2).

(4) To the extent feasible, biennial permit renewal shall be timed to coincide with nonresident pharmacies' registration

renewal under s. 465.0156.

(5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of, or fine or reprimand, a nonresident pharmacy for:

(a) Failure to comply with the requirements of this section; or

(b) Conduct that causes or could cause serious bodily injury or serious psychological injury to a human or animal in this state.

(6) A registered nonresident pharmacy that is currently shipping, mailing, delivering, or dispensing compounded sterile products into this state may continue to do so if such products meet or exceed the standards for sterile compounding in this state and the pharmacy is issued a nonresident pharmacy compounded sterile products permit on or before January 31, 2015.

(7) A nonresident pharmacy seeking registration in this state under s. 465.0156 on or after July 1, 2014, may not ship, mail, deliver, or dispense a compounded sterile product into this state until it has received the sterile compounded products permit required under this section.

(8) The board shall adopt rules necessary to administer this section.

Section 3. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(1) Duly authorized agents and employees of the department may ~~shall have the power to~~ inspect in a lawful manner at all reasonable hours any pharmacy, including a nonresident pharmacy

registered under s. 465.0156, and any~~,~~ hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a) Determining if any provision ~~of the provisions~~ of this chapter or any rule adopted ~~promulgated~~ under its authority is being violated;

(b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c) Securing such other evidence as may be needed for prosecution under this chapter.

(2) The cost for inspecting a nonresident pharmacy shall be reimbursed by the pharmacy. The cost to the pharmacy is limited to the actual costs incurred by the department.

(3)~~(2)(a)~~ Except as permitted by this chapter~~,~~ and chapters 406, 409, 456, 499, and 893 or upon the written authorization of the patient, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs may ~~shall not~~ be furnished only ~~to any person other than~~ to the patient for whom the drugs were dispensed, or her or his legal representative, ~~or~~ to the department pursuant to existing law, or if~~, in the event that~~ the patient is incapacitated or unable to request such ~~said~~ records, her or his spouse ~~except upon the written authorization of such patient~~.

(a) Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her

or his legal representative by the party seeking such records.

(b) The board shall adopt rules <u>establishing</u> ~~to establish~~ practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules <u>must</u> ~~shall~~ be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

Section 4. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/14/2014
Meeting Date

Topic NON RESIDENT PHARMACIES

Bill Number SPB 7008 *(if applicable)*

Name MICHAEL JACKSON

Amendment Barcode _____ *(if applicable)*

Job Title EVP & CEO

Address 610 N. ADAMS ST
Street
TALLAHASSEE FL 32301
City *State* *Zip*

Phone (850) 222-2400

E-mail MJACKSON@PHARMVIEW.COM

Speaking: ☒ For ☐ Against ☐ Information

Representing FLORIDA PHARMACY ASSOC

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SPB 7010
INTRODUCER:	For consideration by the Health Policy Committee
SUBJECT:	Health Access Dental Licenses
DATE:	December 19, 2013 REVISED: 1/14/14

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall		**HP Submitted as Committee Bill**

I. Summary:

SPB 7010 changes the requirements for obtaining a health access dental license. A health access license authorizes out-of-state dentists to practice in designated facilities that serve patients who otherwise would not have access to care. The bill removes language that would render an applicant ineligible based on a report to the National Practitioner Data Bank (NPDB). Instead, the Board of Dentistry (Board) is given authority to deny licensure if the applicant has violated or is being investigated for a violation of chapter 466, Florida Statutes., the dental practice act, or other licensing requirements. The bill also extends the sunset date of the program to January 1, 2020.

II. Present Situation:

The Importance of Oral Health Care

Mouth and throat diseases, which range from cavities to cancer, cause pain and disability for millions of Americans each year. Ninety-six percent of adults aged 50-64 years have had dental caries (tooth decay, cavities). In children, cavities are the most common form of chronic disease, which often begins at an early age. More than one-fourth of U.S. children aged 2-5 years and half of children aged 12-15 years have been affected by tooth decay. Children and adolescents from low-income families are hardest hit: about two-thirds of those aged 12-19 years have had caries, and one in four has untreated caries. Untreated tooth decay can cause pain, dysfunction, and absence from school, and poor appearance — problems that can greatly affect a child's quality of life.[1]

[1] Centers for Disease Control and Prevention and Nat'l Center for Chronic Disease Prevention and Health Promotion, *Oral Health Program Strategic Plan for 2011-2014*, 5 (March 2011) *available at* http://www.cdc.gov/OralHealth/pdfs/oral_health_strategic_plan.pdf (last visited Nov. 25, 2013).

While progress has been made over the last 40 years, the Healthy People 2010 Final Review[2] noted that during the period from 1988-94 to 1999-2004, there were several instances where caries was increasing. Dental caries and untreated caries increased among children aged 2-4 years. Untreated caries also increased for children aged 6-8 years and for adults aged 35-44 years.[3] Caries remains a problem for the increasing number of older adults who have retained most of their teeth. One-fourth of adults older than age 65 years have lost all of their teeth because of tooth decay and advanced gum disease. Tooth loss can affect a person's self-esteem and may contribute to nutrition problems by limiting the types of food that a person can eat.[4]

Disparities exist in the prevalence of caries across populations. The greatest racial and ethnic disparity among children aged 2-4 years and aged 6-8 years is seen in Mexican American and black, non-Hispanic children. Blacks, non-Hispanics, and Mexican Americans aged 35-44 years, experience untreated tooth decay nearly twice as much as white, non-Hispanics.[5] One of the greatest racial and ethnic disparities exists among adults aged 35-44 years for untreated tooth decay. The prevalence of untreated tooth decay among non-Hispanic blacks is more than twice that of non-Hispanic whites. Twice as many non-Hispanic blacks, and Mexican American adults aged 20-64 have untreated tooth decay as do non-Hispanic white adults.[6]

Disparities in oral health care also exist between geographic areas. Most research and surveillance information indicate that access to dental care is significantly more limited in rural areas than in metropolitan areas. According to the National Rural Health Association:[7]

- Even after controlling for population density and income, non-metropolitan counties have lower dentist-to-population ratios (62 dentists per 100,000 population in large metropolitan areas versus 29 dentists per 100,000 population in the most rural counties). The pattern is the same in Florida. Dentists are disproportionately concentrated in the more populous areas, particularly the coastal counties of south Florida (ratios ranging from 42 to 97 dentists per 100,000 population) versus ratios in the largely rural interior counties, as well as many central Panhandle counties (a range of ratios as low as 10 to 33 dentists per 100,000 population).[8]

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[2] The Healthy People initiative, which is administered by the U.S. Department of Health and Human Services, provides science-based, 10-year national objectives for improving the health of all Americans. Since its inception, Healthy People has established benchmarks and monitored progress over time in order to: encourage collaborations across communities and sectors; empower individuals toward making informed health decisions; and measure the impact of prevention activities. Since 1979, there have been four Healthy People initiatives. U.S. Dept. of Health and Human Services, *About Healthy People*, http://www.healthypeople.gov/2020/about/default.aspx (last visited Nov. 25, 2013).

[3] Nat'l Center for Health Statistics, *Healthy People 2010 Final Review*, 21-9 (Dec. 2012), *available at* www.cdc.gov/nchs/data/hpdata2010/hp2010_final_review.pdf (last visited Nov.25, 2013).

[4] *Strategic Plan*, *supra* note 1, at 5.

[5] Centers for Disease Control and Prevention, *Disparities in Oral Health*, http://www.cdc.gov/OralHealth/oral_health_disparities (last visited Nov. 25, 2013).

[6] *Strategic Plan*, *supra* note 1, at 7.

[7] Nat'l Rural Health Association, *Meeting Oral Health Care Needs in Rural America*, 1 – 2 (April 2005) (on file with the Senate Health Policy Committee).

[8] Florida Dept. of Health, *Report on the 2009-2010 Workforce Survey of Dentists*, 4 & 59 (March 2011) (on file with the Senate Health Policy Committee). In 2009, the Department of Health developed this workforce survey for dentists. The survey was administered on a voluntary basis in conjunction with biennial renewal of dental licenses and 89 percent of dentists with an active Florida license responded to the survey.

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

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

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

(SCHIP) patients, of which there are many in rural America due to the higher proportion of people living in poverty.[9]

Health Access Dental Licensure

In 2008, the Legislature established the health access dental license in order to attract out-of-state dentists to practice in underserved health access settings.[10] With this license, a dentist actively licensed in good standing in another state, the District of Columbia, or a U.S. territory is authorized to practice dentistry in Florida in a health access setting if the dentist:

- Files a Board-approved application and pays the applicable fees;
- Has not been convicted or pled nolo contendre to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;
- Submits proof of graduation from a dental school accredited by the Commission on Dental Accreditation of the American Dental Association;
- Submits documentation that the dentist has completed, or will obtain prior to licensure, a continuing education equivalent to Florida's requirement for dentists for the last full reporting biennium before applying for a health access license;
- Submits proof of her or his successful completion of parts I and II of the National Boards and a state or regional clinical dental license examination that the Board has determined effectively measures the applicant's ability to practice safely;
- Has never had a license revoked from another state, the District of Columbia, or a U.S. territory;
- Has never failed an exam under s. 466.006, F.S., unless the applicant was reexamined and received a license to practice in Florida;
- Has not been reported to the NPDB, unless the applicant successfully appealed to have his or her name removed from the data bank; and,
- Submits proof that he or she has been engaged in the active, clinical practice of dentistry providing direct patient care for 5 years immediately preceding the date of application, or proof of continuous clinical practice providing direct patient care since graduation if the applicant graduated less than 5 years from his or her application.[11]

A health access dental license is subject to biennial renewal. The Board will renew a health access dental license if the applicant:

- Submits a renewal application and pays the required fees;
- Signs and submits a statement attesting that the applicant has completed all continuing education required of a licensed dentist;

[9] *Id.* (citing the National Advisory Committee on Rural Health and Human Services).
[10] A "health access setting" is defined in s. 466.003(14), F.S., as a program or institution of the Department of Children and Family Services, the Department of Health, or the Department of Juvenile Justice, a nonprofit community health center, a Head Start center, a federally qualified health center (FQHC) or FQHC look-alike as defined by federal law, a school-based prevention program, or a clinic operated by an accredited college of dentistry or an accredited dental hygiene program in this state if such community service programs and institutions immediately report to the Board of Dentistry practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such settings.
[11] Section 466.0067, F. S.

- Submits documentation of continued employment in the health access setting;
- Has not been convicted or pled nolo contendre to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;
- Has never failed an exam under s. 466.006, F.S., since initially receiving a health access dental license or since the last renewal; and,
- Has not been reported to the NPDB, unless the applicant successfully appealed to have his or her name removed from the data bank.[12]

The Board may revoke a health access dental license if the licensee is terminated from employment at the health access setting or practices outside of the health access setting, fails the Florida dental examination, or is found by the Board to have committed a violation of Chapter 466 (the dental practice act), other than a violation that is a citation offense or a minor violation.[13]

Currently, there are a total of 54 health access dental licenses. Of those 31 are in-state active, 5 are in-state delinquent, 13 are out-of-state active, 3 are out-of-state inactive, and 2 are retired.[14] According to data collected by the Department of Health, 14 dentists with health access licenses are currently practicing in county health departments (CHDs). Several CHDs reported they do not think they could have obtained a dentist without the availability of the health access license. CHDs also report that these dentists have been of high quality and have improved access to care on the part of the low income population.[15]

The program is scheduled for repeal effective January 1, 2015, unless reenacted by the Legislature.[16]

National Practitioner Data Bank

The NPDB was originally established by Title IV of the Health Care Quality Improvement Act of 1986, Public Law 99-660. The intent of the act is to improve the quality of health care by encouraging state licensing boards, hospitals and other health care entities, and professional societies to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of physicians, dentists, and other healthcare practitioners to move from state-to-state

[12] Section 466.00671, F.S.
[13] Section 466.00672, F.S.
[14] Florida Dept. of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan FY 2012-2013*, 8, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-12-13.pdf (last visited Nov. 25, 2013). "In-State Active" means the licensed practitioner has a Florida mailing address and is authorized to practice. "In-State Delinquent" means the licensed practitioner has a Florida mailing address and is not authorized to practice in the state because of failure to renew the license by the expiration date. "Out-of-State Active" means the licensed practitioner has an out-of-state mailing address and is authorized to practice. "Out-of-State Inactive" means the licensed practitioner has an out-of-state mailing address and is not authorized to practice. "Retired" means the licensed practitioner is not authorized to practice. The practitioner is not obligated to update licensure data. *Id.* at 10. s. 456.036, F.S.
[15] E-mail from Philip Street, Senior Policy Coordinator, Health Statistics and Performance Management, Florida Dept. of Health, (Nov. 19, 2013) (on file with the Senate Health Policy Committee).
[16] Section 466.00673, F.S.

without disclosure or discovery of previous medical malpractice payments and adverse actions. Adverse actions can involve licensure, clinical privileges, or professional society memberships.[17]

Information in the NPDB is available to:

- Hospitals requesting information concerning a practitioner on their medical staff or to whom they have granted clinical privileges, or with respect to peer review.
- Health care entities (including hospitals) that have entered or may be entering employment or affiliation relationships with a practitioner or to which the practitioner has applied for clinical privileges or appointment to the medical staff, or with respect to peer review.
- Practitioners requesting information about themselves.
- Boards of medical examiners or other state licensing boards.
- Attorneys or individuals representing themselves upon submission of proof that a hospital failed to submit a mandatory query.
- Persons or entities requesting information in a form which does not identify any particular practitioner or entity.[18]

Information in the NPDB is confidential. Violations of the confidentiality provisions are subject to civil money penalties.

According to the NPDB Handbook:

> The NPDB is intended to augment, not replace, traditional forms of credentials review. As a nationwide flagging system, it provides another resource to assist state licensing boards, hospitals, and other health care entities in conducting extensive, independent investigations of the qualifications of the health care practitioners they seek to license or hire, or to whom they wish to grant clinical privileges.

Settlement of a medical malpractice claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the physician, dentist, or other health care practitioner. **Thus, a payment made in settlement of a medical malpractice action or claim shall not be construed as a presumption that medical malpractice has occurred.[19]**

III. Effect of Proposed Changes:

The bill removes reports to the National Practitioner Data Bank as a condition that renders an applicant ineligible for a health access dental license. The bill substitutes instead authority for the Board of Dentistry to deny initial or renewal licensure to any applicant who has committed or is under investigation or prosecution for an act that is grounds for discipline under chapter 466 or

[17] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *NPDB Guidebook*, A-2 (Sept. 2001) *available at* http://www.npdb-hipdb.hrsa.gov/resources/aboutGuidebooks.jsp (last visited Nov. 25, 2013).
[18] *Id.* at A-5.
[19] *Id.* at A-3 (emphasis in the original).

chapter 456. SPB 7010 also reauthorizes the program for an additional five years through January 1, 2020.

The bill has an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

Section 466.0067(2), F.S., authorizes the Board of Dentistry to charge an application license fee for a health access dental license, laws-and-rule exam fee, and an initial licensure fee, which are the same as fees charged to an applicant for an unrestricted dental license. Currently, those fees are:

- Application fee: $100.
- Exam Development fee: $80.
- Licensure fee: $305.

Because the effect of the bill is to reenact and continue an existing program, these fees are not new. Thus, the potential fiscal impact remains the same as when the program was created in 2008.

B. Private Sector Impact:

The health access dental license creates an incentive for out-of-state dentists to practice in settings—defined as "health access settings"—that provide dental care to underserved populations or communities. The definition includes certain nonprofit facilities. Thus, both the facilities and patients they serve may benefit from access to additional dentists.

C. Government Sector Impact:

The health access dental license creates an incentive for out-of-state dentists to practice in settings—defined as "health access settings"—that provide dental care to underserved populations or communities. The majority of these settings are publicly-operated. Thus, the facilities may benefit from access to additional dentists.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 466.0067, 466.00671, and 466.00673.

IX. Additional Information:

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

None.

B. Amendments:

None.

482994

LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
01/14/2014	.	
	.	
	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 117 - 118
and insert:
Section 3. Section 466.00673, Florida Statutes, is amended to read
466.00673 Repeal of a health access dental license.—Effective January 1, 2020 ~~2015~~, ss. 466.0067-466.00673 are repealed unless reenacted by the Legislature. Any health access dental license issued before January 1, 2020 ~~2015~~, shall remain valid according to ss. 466.0067-466.00673, without effect from

repeal.

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

And the title is amended as follows:

Delete line 10

and insert:

amending s. 466.00673, F.S., extending the future

FOR CONSIDERATION By the Committee on Health Policy

588-00677-14 20147010__

A bill to be entitled

An act relating to health access dental licenses; amending ss. 466.0067 and 466.00671, F.S.; deleting the requirement that a license applicant or renewing licensee not have been reported to the National Practitioner Data Bank; authorizing the Board of Dentistry to deny licensure to an applicant or renewing licensee who has committed or is under investigation or prosecution for certain violations; repealing s. 466.00673, F.S., relating to the future repeal of provisions authorizing the health access dental license; providing an effective date.

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

Section 1. Section 466.0067, Florida Statutes, is amended to read:

466.0067 ~~Application for~~ Health access dental license application.—The Legislature finds that there is an important state interest in attracting dentists to ~~practice in~~ underserved health access settings in this state and ~~further,~~ that allowing out-of-state dentists who meet certain criteria to practice in health access settings without the supervision of a dentist licensed in this state is substantially related to achieving this important state interest. ~~Therefore,~~

(1) Notwithstanding the requirements of s. 466.006, the board shall grant a health access dental license to an applicant seeking to practice dentistry in this state in health access settings who meets all of the following requirements ~~as defined~~

~~in s. 466.003 to an applicant that~~:

(a)~~(1)~~ Files an ~~appropriate~~ application approved by the board.~~;~~

(b)~~(2)~~ Pays an application license fee for a health access dental license, a laws-and-rule exam fee, and an initial licensure fee as specified under~~. The fees specified in this subsection may not differ from an applicant seeking licensure pursuant to~~ s. 466.006.~~;~~

(c)~~(3)~~ Has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.~~;~~

(d)~~(4)~~ Submits proof of graduation from a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency.~~;~~

(e)~~(5)~~ Submits documentation that she or he has completed, or will obtain prior to licensure, continuing education equivalent to this state's requirement for dentists licensed under s. 466.006 for the last full reporting biennium before applying for a health access dental license.~~;~~

(f)~~(6)~~ Submits proof of her or his successful completion of parts I and II of the dental examination of ~~by~~ the National Board of Dental Examiners and a state or regional clinical dental licensing examination that the board has determined effectively measures the applicant's ability to practice safely.~~;~~

(g)~~(7)~~ Currently holds a valid, active, dental license in good standing which has not been revoked, suspended, restricted, or otherwise disciplined from another of the United States, the District of Columbia, or a United States territory.~~;~~

(h) ~~(8)~~ Has never had a license revoked from another of the United States, the District of Columbia, or a United States territory. ~~;~~

(i) ~~(9)~~ Has never failed the examination specified in s. 466.006, unless the applicant was reexamined pursuant to s. 466.006 and received a license to practice dentistry in this state. ~~;~~

~~(10) Has not been reported to the National Practitioner Data Bank, unless the applicant successfully appealed to have his or her name removed from the data bank;~~

(j) ~~(11)~~ Submits proof that he or she has been engaged in the active, clinical practice of dentistry providing direct patient care for 5 years immediately preceding the date of application, or if ~~in instances when~~ the applicant ~~has~~ graduated from an accredited dental school within the preceding 5 years, submits proof of continuous clinical practice providing direct patient care since graduation. ~~; and~~

(k) ~~(12)~~ Has passed an examination covering the laws and rules of the practice of dentistry in this state as described in s. 466.006(4)(a).

(2) The board may deny a health access dental license to an applicant who has committed, or is under investigation or prosecution for, an act that would constitute a basis for discipline pursuant to chapter 456 or this chapter.

Section 2. Section 466.00671, Florida Statutes, is amended to read:

466.00671 ~~Renewal of the~~ Health access dental license renewal.—

(1) A health access dental licensee shall apply for renewal

each biennium. At the time of renewal, the licensee shall sign a statement that she or he has complied with all continuing education requirements of an active dentist licensee. The board shall renew a health access dental license for an applicant who meets all of the following requirements ~~that~~:

(a) Submits documentation, as approved by the board, from the employer in the health access setting that the licensee has at all times pertinent remained an employee.~~;~~

(b) Has not been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.~~;~~

(c) Has paid a renewal fee identical to the fee set by the board under~~. The fee specified herein may not differ from the renewal fee adopted by the board pursuant to~~ s. 466.013. The department may provide payment for these fees through the dentist's salary, benefits, or other department funds.~~;~~

(d) Has not failed the examination specified in s. 466.006 since initially receiving a health access dental license or since the last renewal.~~; and~~

~~(e) Has not been reported to the National Practitioner Data Bank, unless the applicant successfully appealed to have his or her name removed from the data bank.~~

(2) The board may ~~undertake measures to~~ independently verify the health access dental licensee's ongoing employment status in the health access setting.

(3) The board may deny health access dental licensure renewal to an applicant who has committed, or is under investigation or prosecution for, an act that would constitute a basis for discipline pursuant to chapter 456 or this chapter.

Section 3. Section 466.00673, Florida Statutes, is repealed.

Section 4. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/14/13
Meeting Date

Topic Health Access Dental License

Bill Number 7010 *(if applicable)*

Name Joe Anne Hart

Amendment Barcode *(if applicable)*

Job Title Director of Governmental Affairs

Address 118 E. Jefferson St
Street

Phone (850) 224.1089

Tallahassee FL 32301
City *State* *Zip*

E-mail jahart@floridadental.org

Speaking: [X] For [ ] Against [ ] Information

Representing Florida Dental Association

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SPB 7014
INTRODUCER:	For consideration by the Health Policy Committee
SUBJECT:	OGSR/Department of Health
DATE:	January 10, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall		**Pre-Meeting**

I. Summary:

SPB 7014 amends section 893.0551 of the Florida Statutes relating to the public records exemption for the prescription drug monitoring program (PDMP).

The proposed bill strengthens the security of personal identifying information in the database by requiring law enforcement agencies to obtain a subpoena from a court prior to receiving confidential information from the PDMP and requiring recipients of PDMP confidential information to take steps to ensure the continued confidentiality of the information received.

The proposed bill also allows health care practitioners to share a patient's PDMP information with that patient and, upon the patient's written consent, put that information in the patient's medical record.

The proposed bill saves the exemption from the public records law for the personal identifying information in the PDMP from repeal on October 2, 2014.

II. Present Situation:

Florida's Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F., established the 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.[1] 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.[2]

[1] S. 893.055(2)(a), F.S.
[2] S. 893.055(3)(a)-(c), F.S.

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[3] Dispensers have reported over 87 million controlled substance prescriptions to the PDMP since its inception.[4] Health care practitioners began accessing the PDMP on October 17, 2011.[5] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[6]

Accessing the PDMP database

Section 893.0551, F.S., makes certain identifying information[7] of patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055, F.S., confidential and exempt from the public records laws in s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution.[8]

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.[9] Currently, prescribers are not required to consult the PDMP database prior to prescribing a controlled substance for a patient however physicians and pharmacists queried the database more than 3.7 million times during fiscal year 2012-2013.[10]

Indirect access to the PDMP database is provided to:

- The DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- Law enforcement agencies during active investigations[11] involving potential criminal activity, fraud, or theft regarding prescribed controlled substances; and
- Patients, or the legal guardians or designated health care surrogates of incapacitated patients.[12]

Law enforcement agencies may receive information from the PDMP database through the procedures outlined in the DOH's "Training Guide for Law Enforcement and Investigative

[3] 2012-2013 PDMP Annual Report, available at http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf, last visited on Jan. 9, 2014.
[4] Id.
[5] Id.
[6] Id.
[7] Such information includes name, address, telephone number, insurance plan number, government-issued identification number, provider number, and Drug Enforcement Administration number, or any other unique identifying information or number.
[8] S. 893.0551(2)(a)-(h), F.S.
[9] S. 893.055(7)(b), F.S.
[10] Supra at n. 3
[11] S. 893.055(1)(h), F.S., defines an "active investigation" as an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.
[12] S. 893.055(7)(c)1.-4., F.S.

Agencies."[13] Agencies that wish to gain access to the PDMP database must first appoint a sworn law enforcement officer as an administrator who verifies and credentials other law enforcement officers' within the same agency.[14] The administrator may then register individual law enforcement officers with the DOH.

Registered law enforcement officers may not directly access the PDMP, instead when they wish to obtain information from the PDMP database, they must submit a query to the DOH.[15] These queries may be for a patient's history, a prescriber's history, or a pharmacy's dispensing history.[16] The registered law enforcement officer must fill out a form indicating what type of search they want to perform, what parameters (name, date, time period, etc.) they want to include, and some details of the active investigation they are pursuing including a case number. This form is submitted to the DOH and, in most instances, the requested information is made available to the requesting officer. In some cases a request is denied. Generally, a request is denied due to lack of sufficient identifying information (incorrect spelling of a name, wrong social security number, etc.) or, alternatively, a request may return no results. The DOH may also deny a request that it finds not to be authentic or authorized.[17]

Prescription Drug Monitoring Programs in Other States

As of December 2013, every state except Missouri has passed PDMP legislation and only New Hampshire and Washington D.C. have yet to bring their PDMP to operation status.[18] The Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) examined the PDMPs of 26 of those states, including Florida.[19] All PDMPs examined are either run by the states in-house or by contract with private vendors. Most states do not require prescribers to register in order to use the PDMP and primarily encourage prescribers to use the database through education and outreach programs.[20] Only three of the 26 states require prescribers to access the database prior to prescribing most or all controlled substances.[21] In 17 of 23 states, including Florida, accessing the database is strictly voluntary and in the remaining six states accessing the database is only required under limited circumstances.[22]

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[13] This training guide may be found at http://www.hidinc.com/assets/files/flpdms/FL%20PDMP_Training%20Guide%20for%20Enforcement%20and%20Investigative%20Agencies.pdf, last viewed on Jan. 9, 2014.
[14] See the DOH's "Law enforcement administrator appointment form," available at http://www.floridahealth.gov/reports-and-data/e-forcse/law-enforcement-information/_documents/admin-appoint-form.pdf, last visited on Jan. 9, 2014.
[15] During FY 2012-2013 a total of 487 authorized law enforcement users queried the PDMP database 32,839 times. Id. at note 3.
[16] Id. at note 11.
[17] S. 893.055(7)(c), F.S., requires the DOH to verify a request as being "authentic and authorized" before releasing information from the PDMP.
[18] National Alliance for Model State Drug Laws. *Compilation of State Prescription Monitoring Programs Maps*, can be found at http://www.namsdl.org/library/6D4C4D9F-65BE-F4BB-A428B392538E0663/, last visited on Jan. 10, 2014.
[19] *OPPAGA Review of State Prescription Drug Monitoring Programs*, Jan. 31, 2013, on file with the Senate Health Policy Committee.
[20] Id., p. 8
[21] Kentucky, New Mexico, and New York. Id., p. 4
[22] These circumstances typically revolve around how often a drug is prescribed, if the drug is in a specific class or schedule, if there is a reasonable suspicion that the patient it abusing drugs, or if the prescription was written in a pain clinic. Id.

All states reviewed have the authority to take punitive action against dispensers of prescription drugs that do not comply with their state's respective laws and rules on their state's PDMP. These punitive actions can come in the form of fines, licensure disciplinary action, and / or criminal charges, however, states rarely use these punitive measures when dispensers do not comply with PDMP requirements.

As of December 5, 2013, 18 states require law enforcement to obtain a search warrant, subpoena, court order, or other type of judicial process in order to access the information in their state's PDMP.[23]

Unauthorized Release of PDMP Data

In the early summer of 2013, the PDMP information of approximately 3,300 individuals was improperly shared with a person or persons who were not authorized to obtain such information.[24] The original information was released from the PDMP by the DOH during a Drug Enforcement Administration (DEA) investigation of a ring of individuals who used four doctor's information to conduct prescription fraud. Although as a result of the investigation only six individuals were ultimately charged, the information of approximately 3,300 individuals was released to the DEA because the DEA searched the PDMP for the records of all the patients of the four doctors who had been the victims of the prescription drug fraud.[25] During the conduct of the investigation and the resulting prosecution, the DEA shared the full file with the prosecutor who, in turn, shared the full file with the defense attorney during discovery. The improper release of information occurred when a defense attorney associated with the case shared the file with a colleague who was not associated with the case.[26]

Reasonable Suspicion v. Probable Cause

The terms reasonable suspicion and probable cause are legal terms of art that refer to the level of proof which must be proffered before a certain action, generally a police action, may be taken. Reasonable suspicion is the lesser standard which is applied to actions such as Terry stops[27] and to searches in areas where there is a lesser expectation of privacy, such as in a school.[28] Probable cause is the greater of the two standards and is the one the police must meet when arresting a suspect.[29]

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[23] These states are: Alaska, Arkansas, Colorado, Georgia, Iowa, Kansas, Louisiana, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, Oregon, and Wisconsin. See the National Alliance for Model State Drug Laws, *Law Enforcement Access to State PMP Data*, available at http://www.namsdl.org/library/C4AA9EA3-65BE-F4BB-AAFBAB1F5736F070/, last visited on Jan 10, 2014.

[24] See John Woodrow Cox, *Did Florida's prescription pill database really spring a leak?*, Tampa Bay Times, July 5, 2013. Available at http://www.tampabay.com/news/politics/did-floridas-prescription-pill-database-really-spring-a-leak/2130108, Last visited on Jan. 9, 2014, and see the DOH presentation to the Senate Health Policy Committee on the PDMP, Sep. 24, 2013, on file with Health Policy Committee staff.

[25] Id.

[26] Id.

[27] Terry v. Ohio, 392 U.S. 1

[28] See R.M. v. State, 2014 WL 20628

[29] Popple v. State, 626 So. 2d 185, p. 3

In order to meet the standard for reasonable suspicion, a police officer must be able to show a "well-founded, articulable suspicion of criminal activity."[30] In contrast, in order to meet the standard for probable cause, an officer must be able to show that the "facts and circumstances known to the officer warrant a prudent man in believing that the offense has been committed."[31] The key difference between the standards lies in the knowledge of the officer. With reasonable suspicion, the officer must only suspect that a crime has been committed, while with probable cause, the officer must have enough evidence to convince a "prudent man" that a crime has been committed.

Public Records

The State of Florida has a long history of providing public access to governmental records. The Florida Legislature enacted the first public records law in 1892.[32] One hundred years later, Floridians adopted an amendment to the State Constitution that raised the statutory right of access to public records to a constitutional level.[33] Article I, s. 24 of the State Constitution, provides that:

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

In addition to the State Constitution, the Public Records Act,[34] which pre-dates the current State Constitution, specifies conditions under which public access must be provided to records of the executive branch and other agencies. Section 119.07(1)(a), F.S., states:

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

Unless specifically exempted, all agency[35] records are available for public inspection. The term "public record" is broadly defined to mean:

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[30] Id.
[31] Henry v. U.S., 31 U.S. 98, p. 102
[32] Section 1390, 1391 Florida Statutes. (Rev. 1892).
[33] Article I, s. 24 of the State Constitution.
[34] Chapter 119, F.S.
[35] The word "agency" is defined in s. 119.011(2), F.S., to mean ". . . any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency."

> . . .all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.[36]

The Florida Supreme Court has interpreted this definition to encompass all materials made or received by an agency in connection with official business, which are used to perpetuate, communicate, or formalize knowledge.[37] All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.[38]

Only the Legislature is authorized to create exemptions to open government requirements.[39] An exemption must be created in general law, must state the public necessity justifying it, and must not be broader than necessary to meet that public necessity.[40] A bill enacting an exemption[41] may not contain other substantive provisions, although it may contain multiple exemptions that relate to one subject.[42]

There is a difference between records that the Legislature has made exempt from public inspection and those that are *confidential* and exempt. If the Legislature makes a record confidential and exempt, such information may not be released by an agency to anyone other than to the persons or entities designated in the statute.[43] If a record is simply made exempt from disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances.[44]

Open Government Sunset Review Act

The Open Government Sunset Review Act (the Act)[45] provides for the systematic review, through a 5-year cycle ending October 2 of the 5th year following enactment, of an exemption from the Public Records Act or the Sunshine Law.

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

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[36] S. 119.011(12), F.S.
[37] *Shevin v. Byron, Harless, Schaffer, Reid and Associates, Inc.*, 379 So.2d 633, 640 (Fla. 1980).
[38] *Wait v. Florida Power & Light Company*, 372 So.2d 420 (Fla. 1979).
[39] Article I, s. 24(c) of the State Constitution.
[40] *Memorial Hospital-West Volusia v. News-Journal Corporation*, 729 So. 2d 373, 380 (Fla. 1999); *Halifax Hospital Medical Center v. News-Journal Corporation*, 724 So.2d 567 (Fla. 1999).
[41] Under s. 119.15, F.S., an existing exemption may be considered a new exemption if the exemption is expanded to cover additional records.
[42] Article I, s. 24(c) of the State Constitution.
[43] Attorney General Opinion 85-62.
[44] *Williams v. City of Minneola*, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).
[45] S. 119.15, F.S.

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protects information of a sensitive personal nature concerning individuals, the release of which would be defamatory or cause unwarranted damage to the good name or reputation of such individuals, or would jeopardize their safety; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information that is used to protect or further a business advantage over those who do not know or use it, the disclosure of which would injure the affected entity in the marketplace.[46]

The Act also requires the Legislature to consider the following:

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

While the standards in the Act may appear to limit the Legislature in the exemption review process, those aspects of the Act that are only statutory, as opposed to constitutional, do not limit the Legislature because one session of the Legislature cannot bind another.[47] The Legislature is only limited in its review process by constitutional requirements.

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

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

Senate Review of s. 893.0551, F.S.

In the course of conducting the Open Government Sunset Review of s. 893.0551, F.S., Senate Health Policy Committee staff invited input from various stake holders. Staff met with representatives from various agencies and groups including the DOH, the Florida Department of Law Enforcement, the DEA, Florida Sheriffs Association, Florida Police Chiefs Association, the Attorney General's office, and various advocacy groups representing pharmacists and pain

[46] S. 119.15(6)(b), F.S.
[47] *Straughn v. Camp*, 293 So.2d 689, 694 (Fla. 1974).

management physicians. Staff also observed several meetings held by the DOH on proposed rule amendments for the PDMP.

III. Effect of Proposed Changes:

The proposed bill saves the public records exemption for personal identifying information in the PDMP from repeal and enhances the security pertaining to information that is released from the PDMP. Specifically the proposed bill:

- Requires a law enforcement agency to obtain a subpoena from a court of competent jurisdiction showing a finding of reasonable suspicion of potential criminal activity, fraud, or theft regarding prescribed controlled substances before information within the PDMP database may be released to that agency.
- Requires the Attorney General, the DOH's regulatory boards, and law enforcement agencies to maintain the confidentiality of any PDMP information that they disclose to a criminal justice or law enforcement agency. To maintain the confidentiality of the information those entities must, at a minimum, redact or delete any information which is not relevant to their investigation.
- Allows a health care practitioner to share a patient's PDMP information with that patient and, upon the patient's written consent, put that information in the patient's medical record. Information placed in a patient's medical record may be disclosed subject to the requirements of s. 456.057, F.S.
- Allows the DOH to send only relevant information which is not personal identifying information to a law enforcement agency when the DOH determines a pattern consistent with indicators of controlled substance abuse exists.
- Clarifies that any agency or person who obtains confidential and exempt information from the PDMP may not share that information unless specifically authorized to do so by the section.
- Strikes the Open Government Sunset Review language that will automatically repeal the section on October 2, 2014.

The bill provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Law enforcement agencies may incur a cost associated with obtaining a subpoena prior to accessing information in the PDMP. The Attorney General's office, the DOH's regulatory boards, and law enforcement agencies may incur minor costs associated redacting or deleting non-relevant PDMP information before sharing such information with a criminal justice agency.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Some of the provisions in the bill may be considered to substantially amend[48] the public records exemption for the PDMP in s. 893.0551, F.S. If provisions in a bill substantially amend a public records exemption, the bill is required to have a new Open Government Sunset Review and state the public necessity for which the public records exemption was substantially amended.[49]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 893.0551

IX. Additional Information:

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

None.

B. Amendments:

None.

[48] S. 119.15(4)(b), F.S., state that "an exemption is substantially amended if the amendment expands the scope of the exemption to include more records or information or to include meetings as well as records."
[49] S. 119.15, F.S., and Article I s. 24(c) of the State Constitution

954834

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 158 - 165

and insert:

(4) If the department determines that there exists a pattern of controlled substance abuse consistent with department rules for identifying indicators of such abuse, the department may provide: ~~shall disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055(7)(f)~~

(a) A patient advisory report to an appropriate health care

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practitioner; and

(b) Relevant information that does not contain personal identifying information to the applicable law enforcement agency. A law enforcement agency may use such information to support a subpoena pursuant to paragraph (3)(c)~~. The law enforcement agency may~~

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

And the title is amended as follows:

Delete line 24

and insert:

under certain circumstances, a patient advisory report to a health care practitioner and relevant information that

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (954834)

Delete line 16

and insert:

support a court order pursuant to paragraph (3)(c)~~. The law~~

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Delete lines 119 - 165

and insert:

substances and that has obtained a court order issued by a court of competent jurisdiction upon a showing of reasonable suspicion of potential criminal activity, fraud, or theft regarding prescribed controlled substances. The law enforcement agency may disclose to a criminal justice agency as defined in s. 119.011 only ~~the~~ confidential and exempt information received from the

department which is relevant to ~~a criminal justice agency as defined in s. 119.011 as part of~~ an active investigation that prompted the request for the information ~~that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances~~. Before disclosing any information to a criminal justice agency, a law enforcement agency must take steps to ensure the continued confidentiality of all confidential and exempt information. At a minimum, these steps must include redacting or deleting all nonrelevant information. A law enforcement agency may request information from the department but may not have direct access to its database.

(d) A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055. A health care practitioner who receives a current patient's confidential and exempt information under this subsection may disclose such information to the patient or the patient's legal representative. Upon the patient's or the legal representative's written consent, the health care practitioner may place such information in the patient's medical record, including electronic medical records, and may disclose such information subject to the requirements of s. 456.057.

(e) A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f) A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.


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(g) The patient's pharmacy, prescriber, or dispenser who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(4) If the department determines that there exists a pattern of controlled substance abuse consistent with department rules for identifying indicators of abuse, the department may ~~shall~~ disclose relevant ~~such confidential and exempt~~ information that does not include personal identifying information to the applicable law enforcement agency ~~in accordance with s. 893.055(7)(f)~~. The law enforcement agency may use such information to support a court order pursuant to paragraph (3)(c)

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

And the title is amended as follows:

Delete lines 18 - 29

and insert:

to obtain a court order before such agency may receive information from the prescription drug monitoring database; authorizing a health care practitioner to share a patient's information with that patient and put such information in the patient's medical record upon consent; authorizing the department to disclose, under certain circumstances, relevant information that does not include personal identifying information to a law enforcement agency, rather than requiring the department to disclose confidential and exempt information; authorizing a law enforcement agency to

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use specified information to support a court order,

FOR CONSIDERATION By the Committee on Health Policy

588-00914-14 20147014__

A bill to be entitled

An act relating to a review under the Open Government Sunshine Review Act; amending s. 893.0551, F.S., which makes confidential and exempt certain information of a patient or patient's agent, health care practitioner, and others held by the Department of Health; specifying that the Attorney General, health care regulatory boards, and law enforcement agencies may disclose certain confidential and exempt information to certain entities only if such information is relevant to an active investigation that prompted the request for the information; requiring the Attorney General, health care regulatory boards, and law enforcement agencies to take certain steps to ensure the continued confidentiality of all nonrelevant confidential and exempt information before disclosing such information; requiring a law enforcement agency to obtain a subpoena before such agency may receive information from the prescription drug monitoring database; authorizing a health care practitioner to share a patient's information with that patient and put such information in the patient's medical record upon consent; authorizing the department to disclose, under certain circumstances, relevant information that does not include personal identifying information to a law enforcement agency, rather than requiring the department to disclose confidential and exempt information; authorizing a law enforcement agency to use specified information to support a subpoena,

rather than to disclose confidential and exempt information to a criminal justice agency; prohibiting an agency or person who obtains specified confidential and exempt information from disclosing such information except under certain circumstances; saving the exemption from repeal under the Open Government Sunset Review Act; providing an effective date.

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

Section 1. Section 893.0551, Florida Statutes, is amended to read:

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

(1) As used in ~~For purposes of~~ this section, the term:

(a) "Active investigation" has the same meaning as provided in s. 893.055.

(b) "Dispenser" has the same meaning as provided in s. 893.055.

(c) "Health care practitioner" or "practitioner" has the same meaning as provided in s. 893.055.

(d) "Health care regulatory board" has the same meaning as provided in s. 893.055.

(e) "Law enforcement agency" has the same meaning as provided in s. 893.055.

(f) "Pharmacist" means a ~~any~~ person licensed under chapter 465 to practice the profession of pharmacy.

(g) "Pharmacy" has the same meaning as provided in s. 893.055.

(h) "Prescriber" has the same meaning as provided in s. 893.055.

(2) The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy which ~~that~~ is contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a) Name.

(b) Address.

(c) Telephone number.

(d) Insurance plan number.

(e) Government-issued identification number.

(f) Provider number.

(g) Drug Enforcement Administration number.

(h) Any other unique identifying information or number.

(3) The department shall disclose such confidential and exempt information to the following persons or entities after using a verification process to ensure the legitimacy of that person's or entity's request for the information:

(a) The Attorney General and his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. The Attorney General or his or her designee may disclose to a criminal justice agency as defined in s. 119.011 only ~~the~~ confidential and exempt information received from the department which is relevant to ~~a criminal justice agency as defined in s.~~

~~119.011 as part of~~ an active investigation that prompted the request for the information ~~that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances~~. Before disclosing any information to a criminal justice agency, the Attorney General or his or her designee must take steps to ensure the continued confidentiality of all confidential and exempt information. At a minimum, these steps must include redacting or deleting all nonrelevant information. The Attorney General's Medicaid fraud investigators may not have direct access to the department's database.

(b) The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide ~~such information~~ to a law enforcement agency pursuant to ss. 456.066 and 456.073 only information that is relevant to the specific controlled substances investigation that prompted the request for the information. Before disclosing any information to a law enforcement agency, a healthcare regulatory board must take steps to ensure the continued confidentiality of all confidential and exempt information. At a minimum, these steps must include redacting or deleting all nonrelevant information.

(c) A law enforcement agency that has initiated an active

investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances and that has obtained a subpoena issued by a court of competent jurisdiction upon a showing of reasonable suspicion of potential criminal activity, fraud, or theft regarding prescribed controlled substances. The law enforcement agency may disclose to a criminal justice agency as defined in s. 119.011 only ~~the~~ confidential and exempt information received from the department which is relevant to ~~a criminal justice agency as defined in s. 119.011 as part of~~ an active investigation that prompted the request for the information ~~that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances~~. Before disclosing any information to a criminal justice agency, a law enforcement agency must take steps to ensure the continued confidentiality of all confidential and exempt information. At a minimum, these steps must include redacting or deleting all nonrelevant information. A law enforcement agency may request information from the department but may not have direct access to its database.

(d) A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055. A health care practitioner who receives a current patient's confidential and exempt information under this subsection may disclose such information to the patient or the patient's legal representative. Upon the patient's or the legal representative's written consent, the health care practitioner may place such information in the patient's medical record, including

electronic medical records, and may disclose such information subject to the requirements of s. 456.057.

(e) A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f) A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.

(g) The patient's pharmacy, prescriber, or dispenser who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(4) If the department determines that there exists a pattern of controlled substance abuse consistent with department rules for identifying indicators of abuse, the department may ~~shall~~ disclose relevant ~~such confidential and exempt~~ information that does not include personal identifying information to the applicable law enforcement agency ~~in accordance with s. 893.055(7)(f)~~. The law enforcement agency may use such information to support a subpoena pursuant to paragraph (3)(c) ~~disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b)~~.

(5) An ~~Any~~ agency or person who obtains any ~~such~~ confidential and exempt information specified in ~~pursuant to~~ this section must maintain the confidential and exempt status of that information and may not disclose such information unless

authorized under this section.

(6) A ~~Any~~ person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

~~(7) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2014, unless reviewed and saved from repeal through reenactment by the Legislature.~~

Section 2. This act shall take effect July 1, 2014.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SPB 7016
INTRODUCER:	For consideration by the Health Policy Committee
SUBJECT:	Prescription Drug Monitoring
DATE:	January 10, 2014 REVISED:

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. Looke	Stovall		**Pre-meeting**

I. Summary:

SPB 7016 amends section 893.055 of the Florida Statutes relating to the prescription drug monitoring program to improve clarity by reorganizing text, rephrasing imprecise language, and deleting outdated or redundant language.

The bill also makes several substantive changes including:

- Requiring a law enforcement agency to obtain a subpoena from a court of competent jurisdiction showing a finding of reasonable suspicion of potential criminal activity, fraud, or theft regarding prescribed controlled substances before information within the prescription drug monitoring program (PDMP) database may be released to that agency;
- Allowing the Department of Health (DOH or department) to send only relevant information which is not personal identifying information to a law enforcement agency when the DOH determines a pattern consistent with indicators of controlled substance abuse exists; and
- Defining the term "dispense" or "dispensing" using existing language in the statute and in the definitions section of ch. 893, F.S.

II. Present Situation:

Florida's Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F, established the 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.[1] 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.[2]

[1] S. 893.055(2)(a), F.S.
[2] S. 893.055(3)(a)-(c), F.S.

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[3] Dispensers have reported over 87 million controlled substance prescriptions to the PDMP since its inception.[4] Health care practitioners began accessing the PDMP on October 17, 2011.[5] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[6]

Accessing the PDMP database

Section 893.0551, F.S., makes certain identifying information[7] of patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055, F.S., confidential and exempt from the public records laws in s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution.[8]

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.[9] Currently, prescribers are not required to consult the PDMP database prior to prescribing a controlled substance for a patient however physicians and pharmacists queried the database more than 3.7 million times during fiscal year 2012-2013.[10]

Indirect access to the PDMP database is provided to:

- The DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- Law enforcement agencies during active investigations[11] involving potential criminal activity, fraud, or theft regarding prescribed controlled substances; and
- Patients, or the legal guardians or designated health care surrogates of incapacitated patients.[12]

Law enforcement agencies may receive information from the PDMP database through the procedures outlined in the DOH's "Training Guide for Law Enforcement and Investigative

[3] 2012-2013 PDMP Annual Report, available at http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf, last visited on Jan. 9, 2014.
[4] Id.
[5] Id.
[6] Id.
[7] Such information includes name, address, telephone number, insurance plan number, government-issued identification number, provider number, and Drug Enforcement Administration number, or any other unique identifying information or number.
[8] S. 893.0551(2)(a)-(h), F.S.
[9] S. 893.055(7)(b), F.S.
[10] Supra at n. 3
[11] S. 893.055(1)(h), F.S., defines an "active investigation" as an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.
[12] S. 893.055(7)(c)1.-4., F.S.

Agencies."[13] Agencies that wish to gain access to the PDMP database must first appoint a sworn law enforcement officer as an administrator who verifies and credentials other law enforcement officers' within the same agency.[14] The administrator may then register individual law enforcement officers with the DOH.

Registered law enforcement officers may not directly access the PDMP, instead when they wish to obtain information from the PDMP database, they must submit a query to the DOH.[15] These queries may be for a patient's history, a prescriber's history, or a pharmacy's dispensing history.[16] The registered law enforcement officer must fill out a form indicating what type of search they want to perform, what parameters (name, date, time period, etc.) they want to include, and some details of the active investigation they are pursuing including a case number. This form is submitted to the DOH and, in most instances, the requested information is made available to the requesting officer. In some cases a request is denied. Generally, a request is denied due to lack of sufficient identifying information (incorrect spelling of a name, wrong social security number, etc.) or, alternatively, a request may return no results. The DOH may also deny a request that it finds not to be authentic or authorized.[17]

Funding the PDMP

Restrictions on how the DOH may fund implementation and operation of the PDMP are also included in statute. The DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.[18] Funding for the PDMP comes from three funding sources:[19]

- 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;
- Federal grants; and
- Private grants and donations.

The Legislature appropriated $500,000 of the DOH's general revenue funds during the 2013 session to fund the PDMP for fiscal year 2013-2014.[20]

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[13] This training guide may be found at http://www.hidinc.com/assets/files/flpdms/FL%20PDMP_Training%20Guide%20for%20Enforcement%20and%20Investigative%20Agencies.pdf, last viewed on Jan. 9, 2014.
[14] See the DOH's "Law enforcement administrator appointment form," available at http://www.floridahealth.gov/reports-and-data/e-forcse/law-enforcement-information/_documents/admin-appoint-form.pdf, last visited on Jan. 9, 2014.
[15] During FY 2012-2013 a total of 487 authorized law enforcement users queried the PDMP database 32,839 times. Id. at note 3.
[16] Id. at note 11.
[17] S. 893.055(7)(c), F.S., requires the DOH to verify a request as being "authentic and authorized" before releasing information from the PDMP.
[18] S. 893.055(10) and (11)(c), F.S.
[19] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE) webpage, available at http://www.floridahealth.gov/reports-and-data/e-forcse/funding/index.html, last visited on Jan. 9, 2014.
[20] Ch. 2013-153, L.O.F.

Prescription Drug Monitoring Programs in Other States

As of December 2013, every state except Missouri has passed PDMP legislation and only New Hampshire and Washington D.C. have yet to bring their PDMP to operation status.[21] The Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) examined the PDMPs of 26 of those states, including Florida.[22] All PDMPs examined are either run by the states in-house or by contract with private vendors. Most states do not require prescribers to register in order to use the PDMP and primarily encourage prescribers to use the database through education and outreach programs.[23] Only three of the 26 states require prescribers to access the database prior to prescribing most or all controlled substances.[24] In 17 of 23 states, including Florida, accessing the database is strictly voluntary and in the remaining six states accessing the database is only required under limited circumstances.[25]

All states reviewed have the authority to take punitive action against dispensers of prescription drugs that do not comply with their state's respective laws and rules on their state's PDMP. These punitive actions can come in the form of fines, licensure disciplinary action, and / or criminal charges, however, states rarely use these punitive measures when dispensers do not comply with PDMP requirements.

As of December 5, 2013, 18 states require law enforcement to obtain a search warrant, subpoena, court order, or other type of judicial process in order to access the information in their state's PDMP.[26]

Unauthorized Release of PDMP Data

In the early summer of 2013, the PDMP information of approximately 3,300 individuals was improperly shared with a person or persons who were not authorized to obtain such information.[27] The original information was released from the PDMP by the DOH during a Drug Enforcement Administration (DEA) investigation of a ring of individuals who used four doctor's information to conduct prescription fraud. Although as a result of the investigation only six individuals were ultimately charged, the information of approximately 3,300 individuals was released to the DEA because the DEA searched the PDMP for the records of all the patients of

[21] National Alliance for Model State Drug Laws. *Compilation of State Prescription Monitoring Programs Maps*, can be found at http://www.namsdl.org/library/6D4C4D9F-65BE-F4BB-A428B392538E0663/, last visited on Jan. 10, 2014.
[22] *OPPAGA Review of State Prescription Drug Monitoring Programs*, Jan. 31, 2013, on file with the Senate Health Policy Committee.
[23] Id., p. 8
[24] Kentucky, New Mexico, and New York. Id., p. 4
[25] These circumstances typically revolve around how often a drug is prescribed, if the drug is in a specific class or schedule, if there is a reasonable suspicion that the patient it abusing drugs, or if the prescription was written in a pain clinic. Id.
[26] These states are: Alaska, Arkansas, Colorado, Georgia, Iowa, Kansas, Louisiana, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, Oregon, and Wisconsin. See the National Alliance for Model State Drug Laws, *Law Enforcement Access to State PMP Data*, available at http://www.namsdl.org/library/C4AA9EA3-65BE-F4BB-AAFBAB1F5736F070/, last visited on Jan 10, 2014.
[27] See John Woodrow Cox, *Did Florida's prescription pill database really spring a leak?*, Tampa Bay Times, July 5, 2013. Available at http://www.tampabay.com/news/politics/did-floridas-prescription-pill-database-really-spring-a-leak/2130108, Last visited on Jan. 9, 2014, and see the DOH presentation to the Senate Health Policy Committee on the PDMP, Sep. 24, 2013, on file with Health Policy Committee staff.

the four doctors who had been the victims of the prescription drug fraud.[28] During the conduct of the investigation and the resulting prosecution, the DEA shared the full file with the prosecutor who, in turn, shared the full file with the defense attorney during discovery. The improper release of information occurred when a defense attorney associated with the case shared the file with a colleague who was not associated with the case.[29]

Reasonable Suspicion v. Probable Cause

The terms reasonable suspicion and probable cause are legal terms of art that refer to the level of proof which must be proffered before a certain action, generally a police action, may be taken. Reasonable suspicion is the lesser standard which is applied to actions such as Terry stops[30] and to searches in areas where there is a lesser expectation of privacy, such as in a school.[31] Probable cause is the greater of the two standards and is the one the police must meet when arresting a suspect.[32]

In order to meet the standard for reasonable suspicion, a police officer must be able to show a "well-founded, articulable suspicion of criminal activity."[33] In contrast, in order to meet the standard for probable cause, an officer must be able to show that the "facts and circumstances known to the officer warrant a prudent man in believing that the offense has been committed."[34] The key difference between the standards lies in the knowledge of the officer. With reasonable suspicion, the officer must only suspect that a crime has been committed, while with probable cause, the officer must have enough evidence to convince a "prudent man" that a crime has been committed.

III. Effect of Proposed Changes:

Section 1 amends s. 893.055, F.S., to significantly, but technically, revise the section by grouping related items, clarifying imprecise language, and deleting outdated or redundant language.

The bill also makes several substantive changes to the section. The bill:

- Requires a law enforcement agency to obtain a subpoena from a court of competent jurisdiction showing a finding of reasonable suspicion of potential criminal activity, fraud, or theft regarding prescribed controlled substances before information within the PDMP database may be released to that agency.
- Allows the DOH to send only relevant information which is not personal identifying information to a law enforcement agency when the DOH determines a pattern consistent with indicators of controlled substance abuse exists. A law enforcement agency is authorized to use such information to support the subpoena necessary to obtain identified records.

[28] Id.
[29] Id.
[30] Terry v. Ohio, 392 U.S. 1
[31] See R.M. v. State, 2014 WL 20628
[32] Popple v. State, 626 So. 2d 185, p. 3
[33] Id.
[34] Henry v. U.S., 31 U.S. 98, p. 102

- Defines the term "dispense" or "dispensing" using existing language in the statute and in the definitions section of ch. 893, F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Law enforcement agencies may incur a cost associated with obtaining a subpoena prior to accessing information in the PDMP.

VI. Technical Deficiencies:

In current law and this bill, the definition of "patient advisory report" includes a requirement that the report be provided in compliance (or in accordance) with s. 893.13(7)(a)8.[35] It is improper to place such a substantive requirement within a definition and, as such, the requirement should be moved to paragraph (6)(e) of the bill.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 893.055

[35] S. 893.055(1)(a), F.S., and lines 36-37 in SPB 7016.

IX. Additional Information:

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

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 458 - 640

and insert:

(8) ~~(10)~~ Notwithstanding s. 456.025 and subject to the General Appropriations Act, up to $500,000 of ~~all~~ costs incurred by the department in administering the prescription drug monitoring program may ~~shall~~ be funded through funds available in the Medical Quality Assurance Trust Fund that are related to the regulation of the practice of pharmacy under ch. 465. The department may also apply for and receive federal grants or

963500

private funding to fund the prescription drug monitoring program except that the department may not receive funds provided, directly or indirectly, by prescription drug manufacturers ~~applied for or received by the state~~. The department may not commit state funds for the monitoring program if such funds are necessary for the department's regulation of the practice of pharmacy under ch. 465 ~~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 if 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)(e), 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.~~

~~(a) As used in this subsection, the term "direct-support organization" means an organization that is:~~

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~~1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.~~

~~2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.~~

~~(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.~~

~~(c) The 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 that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.~~

~~(d) The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:~~

~~1. Approval of the articles of incorporation and bylaws of the direct-support organization by the department.~~

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~~2. Submission of an annual budget for the approval of the department.~~

~~3. Certification by the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.~~

~~4. The reversion, without penalty, to the state of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.~~

~~5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.~~

~~6. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the department and the direct-support organization.~~

~~7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is authorized. The direct-support organization may collect and~~

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~~expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the department. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:~~

~~a. Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.~~

~~b. Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).~~

~~c. Providing funds for future enhancements of the program within the intent of this section.~~

~~d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.~~

~~e. Providing funds for travel expenses.~~

~~f. Providing funds for administrative costs, including personnel, audits, facilities, and equipment.~~

~~g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.~~

~~(c) The activities of the direct-support organization must be consistent with the goals and mission of the department, as determined by the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the department for any activities in support of the prescription drug monitoring program before undertaking~~

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~~those activities.~~

~~(f) The department may permit, without charge, appropriate use of administrative services, property, and facilities of the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the department may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the department. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the department if the direct-support organization is no longer approved by the department to operate in the best interests of the state.~~

~~(g) The department may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.~~

~~(h) The department may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.~~

~~(i) The direct-support organization shall provide for an~~

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~~independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the department and the Office of Policy and Budget in the Executive Office of the Governor.~~

~~(j) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).~~

~~(12) A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.~~

(9) ~~(13)~~ To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the

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overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. ~~In addition, the direct-support organization shall provide funding for the department to conduct training for health care practitioners and other appropriate persons in using the monitoring program to support the program enhancements.~~

(10)~~(14) A Pharmacist, pharmacy, or dispensing health care~~

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

And the title is amended as follows:

Delete line 20

and insert:

Support a subpoena; authorizing the department to fund the program with up to $500,000 of funds generated under ch. 465, F.S.; authorizing the department to see federal or private funds to support the program; repealing language creating a direct-support organization to fund the program; deleting obsolete provisions;

336376

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 36 - 37

and insert:

or patient. ~~The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8.~~ An

Delete lines 412 - 417

and insert:

(e) If the program manager determines a pattern consistent

336376

with the rules established under subparagraph (2)(c)4., the department may provide:

(a) A patient advisory report to an appropriate health care practitioner; and

(b) Relevant information that does not contain personal identifying information to the applicable law enforcement agency. A law enforcement agency may use such information to support a subpoena pursuant to subparagraph (b)3.

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

And the title is amended as follows:

Delete line 18

and insert:

determines a specified pattern exists; authorizing the department to provide a patient advisory report to any appropriate health care practitioner if the program manager determines a specified pattern exists; authorizing the

106398

LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (336376)

Delete line 19
and insert:
support a court order pursuant to subparagraph (b)3.

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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Delete lines 354 - 417

and insert:

and pursuant to the submission of a court order issued by a court of competent jurisdiction upon a showing of reasonable suspicion of ~~regarding~~ potential criminal activity, fraud, or theft regarding prescribed controlled substances. The court order may be issued without notice to the affected patients, prescribers, or dispensers.


861816

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth~~, and includes the same information if the legal guardian or health care surrogate submits the request~~. If the patient's legal guardian or health care surrogate is the requestor, the request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate~~, if the patient's legal guardian or health care surrogate is the requestor~~. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

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

(c)~~(d)~~ Other than the program manager and his or her program or support staff as authorized in paragraph (d), department staff are~~, for the purpose of calculating performance measures pursuant to subsection (8), shall~~ not ~~be~~ allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's

861816

program and support staff, information that does not contain ~~contains no~~ identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt for the purpose of calculating performance measures pursuant to subsection (7).

(d) The program manager and designated support staff, upon the direction of the program manager or as otherwise authorized during the program manager's absence, may access the prescription drug monitoring program database only to manage the program or to manage the program database and systems in support of the requirements of this section or as established by the department in rule pursuant to subparagraph (2)(c)4. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

(e) If the program manager determines a pattern consistent with the rules established under subparagraph (2)(c)4., the department may provide relevant information that does not contain personal identifying information to the applicable law enforcement agency. A law enforcement agency may use such information to support a court order pursuant to subparagraph (b)3.

861816

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70 ================ T I T L E A M E N D M E N T ================
71 And the title is amended as follows:
72 Delete lines 8 - 20
73 and insert:
74 agency to submit a court order as a condition of
75 direct access to information in the program; requiring
76 that the court order be predicated upon a showing of
77 reasonable suspicion of criminal activity, fraud, or
78 theft regarding prescribed controlled substances;
79 providing that the court order may be issued without
80 notice to the affected patients, subscribers, or
81 dispensers; authorizing the department to provide
82 relevant information that does not contain personal
83 identifying information if the program manager
84 determines a specified pattern exists; authorizing the
85 law enforcement agency to use such information to
86 support a court order; deleting obsolete provisions;

FOR CONSIDERATION By the Committee on Health Policy

588-00915-14 20147016__

A bill to be entitled

An act relating to prescription drug monitoring; amending s. 893.055, F.S.; defining and redefining terms; revising provisions relating to the comprehensive electronic database system and prescription drug monitoring program maintained by the Department of Health; requiring a law enforcement agency to submit a subpoena as a condition of direct access to information in the program; requiring that the subpoena be predicated upon a showing of reasonable suspicion of criminal activity, fraud, or theft regarding prescribed controlled substances; providing that the subpoena may be issued without notice to the affected patients, subscribers, or dispensers; authorizing the department to provide relevant information that does not contain personal identifying information if the program manager determines a specified pattern exists; authorizing the law enforcement agency to use such information to support a subpoena; deleting obsolete provisions; providing an effective date.

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

Section 1. Section 893.055, Florida Statutes, is amended to read:

893.055 Prescription drug monitoring program.—

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

(a) "Patient advisory report" or "advisory report" means

information provided by the department ~~in writing, or as determined by the department,~~ to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. ~~All~~ Advisory reports are for informational purposes only and do not impose any obligation ~~no obligations of any nature~~ or ~~any~~ legal duty on a prescriber, dispenser, pharmacy, or patient except that the~~. The~~ patient advisory report shall be provided in compliance ~~accordance~~ with s. 893.13(7)(a)8. An advisory report ~~The advisory reports~~ issued by the department is ~~are~~ not subject to discovery or introduction into evidence in a ~~any~~ civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report. A department employee~~; and a person~~ who participates in preparing, reviewing, issuing, or any other activity related to an advisory report is ~~may~~ not allowed ~~be permitted~~ or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

(b) "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c) "Dispenser" means a pharmacy, dispensing pharmacist, or dispensing health care practitioner, and includes a pharmacy, dispensing pharmacist, or health care practitioner that is not located in this state but is otherwise subject to the jurisdiction of this state as to a particular dispensing transaction.

(d) "Health care practitioner" or "practitioner" means a

~~any~~ practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, or chapter 466.

(e) "Health care regulatory board" means a ~~any~~ board for a practitioner or health care practitioner who is licensed or regulated by the department.

(f) "Pharmacy" means a ~~any~~ pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g) "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(h) "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it will ~~could~~ lead to the filing of administrative, civil, or criminal proceedings~~,~~ or an investigation that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

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

(j) "Program manager" means an employee of or a person contracted by the Department of Health who is designated to

ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2)(a) and (b).

(k) "Dispense" or "dispensing" means the transfer of possession of one or more doses of a medicinal drug by a health care practitioner to the ultimate consumer or to the ultimate consumer's agent, including, but not limited to, a transaction with a dispenser pursuant to chapter 465 and a dispensing transaction to an individual or address in this state with a dispenser that is located outside this state but is otherwise subject to the jurisdiction of this state as to that dispensing transaction.

(2)(a) The department shall maintain ~~design and establish~~ a comprehensive electronic database system in order to collect and store specified information from dispensed ~~that has~~ controlled substance prescriptions and shall release information to authorized recipients in accordance with subsection (6) and s. 893.0551 ~~provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them~~. ~~Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist.~~ The system must ~~shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall~~ not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice and must~~. The system shall~~ be consistent with standards of the American Society for Automation

in Pharmacy (ASAP). The ~~electronic~~ system must ~~shall~~ also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and ~~all~~ other relevant state and federal privacy and security laws and regulations. ~~The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.~~

(b) The department shall maintain the electronic system so that a patient's health care practitioner or pharmacist is able to receive a patient advisory report upon request~~, 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.~~

(c) The department shall:

1. Establish policies and procedures and adopt rules necessary to provide for access to and evaluation, management, and operation of the electronic system.

2. Establish policies and procedures and adopt rules necessary to provide for the reporting, storage, and security of information within the electronic system, including:

a. Any additional information, other than the information listed in subsection (3), which must be reported to the system.

b. The process by which dispensers must provide the required information concerning each controlled substance that it has dispensed in a 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.

c. The process by which the department may approve an extended period of time for a dispenser to report a dispensed

prescription to the system.

d. Procedures providing for reporting during a state-declared or nationally declared disaster.

e. Procedures for determining when a patient advisory report is required to be provided to a pharmacy or prescriber.

f. Procedures for determining whether a request for information under paragraph (6)(b) is authentic and authorized by the requesting agency.

3. Cooperate with 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, the Florida Osteopathic Medical Association, and 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 ~~All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements~~.

4.~~(d)~~ Cooperate ~~The program manager shall work~~ with professional health care licensure boards and the stakeholders listed in subparagraph 3. ~~paragraph (b)~~ to develop rules appropriate for identifying indicators of controlled substance abuse.

(3) The dispenser of ~~The pharmacy dispensing the controlled substance and each prescriber who directly dispenses~~ a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and

consistent with an ASAP-approved format, the following information for each prescription dispensed ~~inclusion in the database~~:

(a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.

(c) The full name, address, and date of birth of the person for whom the prescription was written.

(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g) Other appropriate identifying information as determined by department rule.

(4) Each time a controlled substance is dispensed to an

individual, the information specified in subsection (3) ~~controlled substance~~ shall be reported by the dispenser to the department through the system using a department-approved process as soon thereafter as possible, but not more than 7 days after the date the controlled substance is dispensed unless an extension is approved by the department. Costs to the dispenser for submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges. A 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 ~~for cause as determined by rule~~. ~~A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.~~

(5) ~~When the following acts of dispensing or administering occur,~~ The following acts are exempt from the reporting ~~under~~ requirements of this section ~~for that specific act of dispensing or administration~~:

(a) The administration of ~~A health care practitioner when administering~~ a controlled substance directly to a patient by a health care practitioner if the amount of the controlled substance is adequate to treat the patient during that

particular treatment session.

(b) The administration of ~~A pharmacist or health care practitioner when administering~~ a controlled substance by a health care practitioner to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(c) The administration or dispensing of ~~A practitioner when administering or dispensing~~ a controlled substance by a health care practitioner within ~~in~~ the health care system of the Department of Corrections.

(d) The administration of ~~A practitioner when administering~~ a controlled substance by a health care practitioner in the emergency room of a licensed hospital.

(e) The administration or dispensing of ~~A health care practitioner when administering or dispensing~~ a controlled substance by a health care practitioner to a person under the age of 16.

(f) The ~~A pharmacist or a dispensing practitioner when~~ dispensing of a one-time, 72-hour emergency resupply of a controlled substance by a dispenser to a patient.

(6) Confidential and exempt information in the prescription drug monitoring program's database may be released only as provided in this subsection and s. 893.0551 ~~The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster~~.

~~(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by~~

~~this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.~~

(a)~~(b)~~ A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information ~~Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the~~

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

(b) ~~(c)~~ The following entities are ~~shall~~ not ~~be~~ allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Before ~~Prior to~~ release, the request by the following entities shall be verified as authentic and authorized with the requesting organization by the program manager or~~,~~ the program manager's program and support staff~~, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity~~:

1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled

substance investigation involving a designated person for one or more prescribed controlled substances.

2. The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

3. A law enforcement agency during active investigations and pursuant to the submission of a subpoena issued by a court of competent jurisdiction upon a showing of reasonable suspicion of ~~regarding~~ potential criminal activity, fraud, or theft regarding prescribed controlled substances. The subpoena may be issued without notice to the affected patients, prescribers, or dispensers.

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth~~, and includes the same information if the legal guardian or health care surrogate submits the request~~. If the patient's legal guardian or health care surrogate is the requestor, the request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate~~, if the patient's legal guardian or health care surrogate is the requestor~~. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

Information in or released from the prescription drug monitoring program database ~~for the electronic prescription drug monitoring~~

~~system~~ is not discoverable or admissible in any civil or administrative action~~,~~ except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(c)~~(d)~~ Other than the program manager and his or her program or support staff as authorized in paragraph (d), department staff are~~, for the purpose of calculating performance measures pursuant to subsection (8), shall~~ not ~~be~~ allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that does not contain ~~contains no~~ identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt for the purpose of calculating performance measures pursuant to subsection (7).

(d) The program manager and designated support staff, upon the direction of the program manager or as otherwise authorized during the program manager's absence, may access the prescription drug monitoring program's database only to manage the program or to manage the program's database and systems in support of the requirements of this section or as established by the department in rule pursuant to subparagraph (2)(c)4. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established

by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

(e) If the program manager determines a pattern consistent with the rules established under subparagraph (2)(c)4., the department may provide relevant information that does not contain personal identifying information to the applicable law enforcement agency. A law enforcement agency may use such information to support a subpoena pursuant to subparagraph (b)3.

(f) ~~(e)~~ All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, an ~~any~~ authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

~~(f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.~~

(7) ~~(8)~~ To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1~~, beginning in~~

~~2011~~. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

(a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

(c) Increased coordination among partners participating in the prescription drug monitoring program.

(d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

~~(9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.~~

(8)~~(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 (9) ~~(11)~~ in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department if 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)(e), 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.~~

(9) ~~(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.

(a) As used in this subsection, the term "direct-support organization" means an organization that is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or

provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c) The 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 that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program and any funds provided, directly or indirectly, by prescription drug manufacturers.

(d) The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:

1. Approval of the articles of incorporation and bylaws of the direct-support organization by the department.

2. Submission of an annual budget for the approval of the department.

3. Certification by the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made

annually and reported in the official minutes of a meeting of the direct-support organization.

4. The reversion, without penalty, to the state of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.

5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

6. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the department and the direct-support organization.

7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the department. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

a. Establishing and administering the prescription drug monitoring program's electronic database, including hardware and

552 software.
553 b. Conducting studies on the efficiency and effectiveness
554 of the program to include feasibility studies as described in
555 subsection (13).
556 c. Providing funds for future enhancements of the program
557 within the intent of this section.
558 d. Providing user training of the prescription drug
559 monitoring program, including distribution of materials to
560 promote public awareness and education and conducting workshops
561 or other meetings, for health care practitioners, pharmacists,
562 and others as appropriate.
563 e. Providing funds for travel expenses.
564 f. Providing funds for administrative costs, including
565 personnel, audits, facilities, and equipment.
566 g. Fulfilling all other requirements necessary to implement
567 and operate the program as outlined in this section.
568 (e) The activities of the direct-support organization must
569 be consistent with the goals and mission of the department, as
570 determined by the department, and in the best interests of the
571 state. The direct-support organization must obtain a written
572 approval from the department for any activities in support of
573 the prescription drug monitoring program before undertaking
574 those activities.
575 (f) The department may permit, without charge, appropriate
576 use of administrative services, property, and facilities of the
577 department by the direct-support organization, subject to this
578 section. The use must be directly in keeping with the approved
579 purposes of the direct-support organization and may not be made
580 at times or places that would unreasonably interfere with

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

(g) The department may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(h) The department may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(i) The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the department and the Office of Policy and Budget in the Executive Office of the Governor.

(j) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

~~(12) A prescriber or dispenser may have access to the~~

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

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

the program enhancements.

(11)~~(14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent,~~ Before releasing a controlled substance to any person not known to him or her ~~such dispenser~~, the dispenser shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity ~~to the dispenser~~. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is ~~will be~~ considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

~~(15) The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.~~

~~(16) The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the reporting, accessing, evaluation, management, development, implementation,~~

~~operation, and storage of information within the monitoring program's system.~~

Section 2. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/14/14
Meeting Date

Topic Prescription Drug Monitoring

Bill Number SPB 7016 *(if applicable)*

Name PAMELA BURCH FORT

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 104 S. Monroe Street
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-425-1344

E-mail TcgLobby@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Representing ACLU of Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/14/2014
Meeting Date

Topic PRESCRIPTION DRUG MONITORING PROGRAM

Bill Number 7016

Name MICHAEL JACKSON

Amendment Barcode 963500 *(if applicable)*

(if applicable)

Job Title EVP + CEO

Address 610 N. ADAMS STREET
Street

TALLAHASSEE, FL 32301
City *State* *Zip*

Phone 850 222-2400

E-mail MJACKSON@PHARMVIEW.COM

Speaking: [X] For [ ] Against [ ] Information

Representing FLORIDA PHARMACY ASSOCIATION

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

(1)

1/14/14
Meeting Date

Topic POMP

Bill Number 7016 *(if applicable)*

Name DAVID KING

Amendment Barcode 861816 *(if applicable)*

Job Title AGENT

Address 300 INTERNATIONAL PKWY
Street

LAKE MARY FL 32746
City *State* *Zip*

Phone 407-832-1875

E-mail DAVID.M.KING@USDOT.GOV
DJKING@VCSO.US

Speaking: ☐ For ☐ Against ☒ Information

Representing FLORIDA SHERIFFS ASSOCIATION

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

(2)

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

1-14-14
Meeting Date

Topic BDMP

Bill Number 7016 *(if applicable)*

Name Raul Rogue

Amendment Barcode 861816 *(if applicable)*

Job Title Agent

Address 100 S. Hughey Ave
Street

Orlando FL 32801
City *State* *Zip*

Phone 407-333-7000

E-mail Raul.Rogue@CityofOrlando.Net

Speaking: ☐ For ☐ Against ☒ Information

Representing Florida Police Chiefs Assoc.

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/20/11)

(3)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1.14.2014
Meeting Date

Topic PDMP

Bill Number SPB 7014 *(if applicable)*

Name Sarah Carroll

Amendment Barcode 806180 *(if applicable)*

Job Title Asst Executive Dir

Address 2617 Mahan Dr
Street
Tallahassee
City *State* *Zip*

Phone 877.2165

E-mail

Speaking: ☐ For ☐ Against ☐ Information

Representing Florida Sheriffs Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

A bill to be entitled

An act relating to telemedicine; creating the Florida Telemedicine Act; providing definitions for telemedicine; creating licensure requirements and standards for telemedicine; providing standards for the provision of telemedicine; providing requirements for coverage of telemedicine, in the Medicaid program; requiring a report on usage and costs of telemedicine in Medicaid; providing a sunset date for coverage of telemedicine in Medicaid; providing an effective date.

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

Section 1. Section XX is created as the Florida Telemedicine Act:

XXX.XX Definitions relating to the Florida Telemedicine Act. — As used in ss. XXX.XX-XXX.XX, Florida Statutes, the term:

(1) "Department" means the Florida Department of Health.

(2)° "Distant site" means the location at which the health care professional or other licensed professional delivering the service is located at the time the service is provided via the telecommunications service.

(3)° "Originating site" means the location of the patient at the time the service being furnished via a telecommunications system occurs. The originating site may also mean the location at which the telecommunications equipment that facilitates the telemedicine, telehealth or telemonitoring is located, with or without the patient present.

(4)° "Patient presenter" means an individual with a clinical

background trained in the use of telemedicine equipment who is available at the originating site to present the patient, manage the cameras or equipment, and perform any “hands on” activities to complete the tele-exam successfully.

(5)° ""Practice of a health care profession across state lines" means any medical act that occurs when the patient and the health care professional are physically separated with one person located within the state and the other located outside of the state.

(6)° ”Store and forward” means the type of telehealth encounter or consult that uses still digital images of patient data for rendering a medical opinion or diagnosis. Store and forward includes the asynchronous transmission of clinical data from one site to another.

(7)° ""Telemedicine" or "Telemedicine medical service” means a health care service that is initiated by a physician or other authorized health care provider acting under any appropriate delegation or supervision, as may be required by the designated licensing board that is provided through the use of advanced telecommunications technology. Services under telemedicine may include patient assessment, diagnosis, consultation, treatment, or transfer of medical data. Telemedicine medical services does not include audio-only telephone calls, e-mail messages or facsimile transmissions. Medical services may be provided via:

(a)° compressed, digital interactive video, audio, or data transmission;

(b)° clinical data transmission using computer imaging by way of still-image capture and store and forward; and,

(c)° other technology that facilitates access to health care

services or medical specialty expertise.

Section 2. Section XXX.XX, Florida Statutes, is created to read:

XXX.XX Application of law; licensure requirements; training and knowledge requirements.—

(1)°Health care professionals providing services through telemedicine either in Florida or to a patient located in Florida must have a Florida license to practice the health care profession with a Florida primary practice location.

(2)°Exceptions to licensure requirements.

(a)°An out of state health care provider not otherwise licensed in this state may engage in the practice of his or her profession across state lines via telemedicine if the respective health care licensing board implements a special licensure process for that specific purpose and the health care provider obtains such licensure. Any such process must include the following conditions:

1.°The special licensure process must prohibit the out of state practitioner from entering the state to practice the profession unless a full, unrestricted license issued by the applicable regulatory board has been obtained;

2.°The originating site must be located in a rural health professional shortage area or in a county defined as rural; and,

3.°Access to a health care professional in the designated field or specialty of the out of state practitioner is not within a reasonable driving distance or appointment standard for the patient.

(b)°Store and forward activities and consultations by an out of state provider that do not include a patient examination

are not considered the practice of a health care profession across state lines.

(c)˚Licensure of out of state health care practitioners in this state is only required for those providers who engage in the practice of a health care profession across state lines more than ten times per calendar year. Physician consultations that occur on an emergency basis are also exempt from licensure requirements.

(3)˚Regardless of the location of the health care practitioner, a health care practitioner engaging in the practice of his or her profession under subsection (2) must agree to make himself or herself available to this state's medical board, the medical board of the out of state practitioner's location and other legal and regulatory authorities, along with any pertinent records, upon request of the boards, department or regulatory authority. Failure to comply with any such requests may result in revocation of the practitioner's special license at the discretion of the applicable licensing board or the department, or a fine as established by the department, whichever is applicable.

(4)˚This section does not preclude a health care practitioner, as defined in s.˚456.001, Florida Statutes, who acts within the scope of his or her practice from using the technology of telemedicine within his or her practice, or using telemedicine technology under the direction and supervision of another health care practitioner who is using telemedicine technology within the supervising practitioner's scope of practice. A health care practitioner acting under the direction and supervision of a physician through the use of telemedicine

may not be interpreted as practicing medicine without a license. However, a health care practitioner must be trained in, educated on, and knowledgeable about the procedure and technology and may not perform duties for which the practitioner does not have sufficient training, education and knowledge. Failure to have adequate training, education, and knowledge is grounds for disciplinary action by the appropriate health care licensing board, or the department if there is no board.

(5)˚The department, in consultation with those boards within the department which exercise regulatory authority or rulemaking authority relating to healthcare practitioners as defined in s.˚456.001, Florida Statutes, may adopt rules, as necessary, to administer the requirements of this Act and must repeal any such rules that prohibit the use of telemedicine in this state.

(6)˚The department, in consultation with the appropriate regulatory boards, may develop standards and adopt rules relating to requirements for patient presenters. Such rules may not require the utilization of patient presenters in telemedicine services when no special skills or training is needed for the patient to participate in the encounter.

Section 3. Section XXX.XX, Florida Statutes, is created to read:

XXX.XX Telemedicine standards.—

(1)˚The standard of care for telemedicine providers must be the same as the standard of care for an in person encounter with a patient unless the applicable board adopts rules specifically related to the standard of care for a telemedicine service.

(2)˚For the purposes of this Act, the non-emergency

prescribing of legend drugs based solely on an electronic questionnaire without a visual examination is considered the failure to practice medicine with the level of care, skill and treatment which is recognized by a reasonably prudent physician and is not authorized under the Act.

(3)˚To engage in telemedicine, the health care professional is not required to conduct a history or physical examination of the patient before engaging in an encounter, provided that the healthcare professional conducts a patient evaluation sufficient to meet the community standard of care for the services provided.

(4)˚Medical records must be kept by each health care practitioner under this section that participates in the patient telemedicine encounter to the same extent as required for an in person encounter, as required by state and federal law. Practitioners are encouraged to create electronic health records to record the encounter and to transmit information in the most efficient manner possible.

(5)˚Any medical records generated, including records maintained via video, audio, electronic, or other means, due to a telemedicine encounter must conform to the confidentiality and record-keeping requirements of federal law, state law and nationally recognized health care accreditation organizations.

(6)˚Each health care practitioner is subject to the laws, rules and regulations of this state governing the maintenance of patient medical records, including patient confidentiality requirements, regardless of the state where the medical records of any patient within the state may be maintained.

(7)˚If telemedicine services are an included benefit in a

health insurance policy or health plan coverage, such health care services must be treated as an equivalent service to an in-person consultation or service for the purposes of health insurance coverage and payment. Reimbursement amounts for the distant site and the originating site are to be determined between the individual health care providers and the health insurance plan or provider.

(8)˚This Act does not preclude a health insurer or health plan from imposing deductibles or copayments or coinsurance requirements for a health care service provided through telemedicine if the deductible, copayment or coinsurance does not exceed the amount applicable to an in-person consultation for the same health care service.

Section 4. 409.XX, Florida Statutes, is created to read:

409.XX Requirements for providing telemedicine services in Medicaid.—

(1)˚The agency must pay for telemedicine services under Part III and Part IV of Chapter 409, Florida Statutes in the same manner and equivalent to services provided in-person, except as provided in subsection (6).

(2)˚Telemedicine services delivered under this section must meet the standards and requirements of the Florida Telemedicine Act as set forward under s. XXX.XX - XXX.XX, Florida Statutes.

(3)˚Except as provided in subsection (6), the agency may not require in person contact between a health care provider and patient as a prerequisite for payment for services appropriately provided through telemedicine in accordance with generally accepted health care practices and standards prevailing in the applicable health care community at the time the services are

provided.

(4)˚Any Medicaid service that is provided through a fee-for-service or managed care program may not be denied as a creditable Medicaid service solely on the basis that the service is provided through telemedicine.

(5)˚Reimbursement of telemedicine services under Medicaid will be the amount negotiated between the parties involved. Regardless of the reimbursement methodology or amount, health care professionals located at the originating site and the distant site should both receive reimbursement based on the services rendered, if any, during the telemedicine encounter.

(6)˚All Medicaid benefits are eligible for reimbursement as a telemedicine service to the extent permitted under federal law. If, after implementation, the agency determines that the delivery of a particular service through telemedicine is no longer cost effective or does not adequately meet the clinical needs of recipients and the determination has been documented, the agency may discontinue reimbursement for that service.

(7)˚The agency must submit a report on the usage and costs, including any savings, associated with telemedicine in the Medicaid program by January 1, 2017 to the Senate President, Speaker of the House of Representatives, and the Minority Leaders of the Senate and House of Representatives.

(8)˚This section is repealed June 30, 2017, unless reenacted by the Legislature before that date.

Section 5. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

11/4/14
Meeting Date

Topic Telemedicine

Bill Number Workshop *(if applicable)*

Name Stan Whittaker

Amendment Barcode *(if applicable)*

Job Title Chair Florida Association of Nurse Practitioners

Address 6294 NW Torreya Pk Rd
Street

Phone 850-545-8301

Bristol FL 32321
City *State* *Zip*

E-mail stanwhitt@aol.com

Speaking: ☐ For ☐ Against ☑ Information

Representing Florida Association of Nurse Practitioners

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/14/2014
Meeting Date

Topic Telemedicine

Bill Number Workshop *(if applicable)*

Name Tamara Demko, JD, MPH

Amendment Barcode *(if applicable)*

Job Title Director, TaxWatch Center for Health + Aging

Address 106 N. Bronough St.
Street

Phone 850-222-5052

Tallahassee FL 32301
City *State* *Zip*

E-mail tdemko@floridataxwatch.org

Speaking: ☐ For ☐ Against ☐ Information

Representing Florida TaxWatch

Appearing at request of Chair: ☒ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

10/14/14
Meeting Date

Topic Telemedicine

Bill Number workshop. *(if applicable)*

Name David Christian

Amendment Barcode _____ *(if applicable)*

Job Title VP - GA

Address 136 S. Bronough St.
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850/521-1211

E-mail dchristian@flchamber.com

Speaking: ☐ For ☐ Against ☑ Information

Representing Florida Chamber of Commerce

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-14-14
Meeting Date

Topic Telemedicine - PCB

Bill Number workshop *(if applicable)*

Name Paul Sanford

Amendment Barcode *(if applicable)*

Job Title

Address 106 S. Monroe St.
Street
Tallahassee, FL 32301
City *State* *Zip*

Phone 222-7200

E-mail

Speaking: ☐ For ☐ Against ☒ Information

Representing FIC

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/14/14
Meeting Date

Topic Telemedicine

Bill Number Workshop *(if applicable)*

Name Travis Cummings

Amendment Barcode _____ *(if applicable)*

Job Title State Rep Dist 18

Address _____ *Street*

Phone _____

_____ *City* *State* *Zip*

E-mail _____

Speaking: ☐ For ☐ Against ☒ Information

Representing _____

Appearing at request of Chair: ☒ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/20/11)

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Policy **Judge:**

Started: 1/14/2014 2:04:38 PM
Ends: 1/14/2014 3:39:39 PM Length: 01:35:02

2:04:41 PM Meeting Called to Order
2:04:55 PM Chair Bean delivers opening remarks
2:06:22 PM Roll Call
2:06:46 PM Chair Bean opening remarks
2:09:15 PM Sen. Brandes respondes regarding bills in work
2:09:37 PM Chair Bean postpones 7014 and 7016
2:10:05 PM Tab 1- Senate Confirmation Hearing
2:10:23 PM State Surgeon General, John Armstrong Oath
2:10:38 PM Chair Bean talks about Mr. Armstrong's background
2:11:29 PM Mr. Armstrong delivers opening statements
2:15:30 PM Chair Bean asks for questions
2:15:42 PM Sen. Joyner asks question
2:15:59 PM Mr. Armstrong responds with explanation of responsibilities
2:17:06 PM Sen. Joyner asks follow-up question
2:18:22 PM Mr. Armstrong responds
2:21:07 PM Sen. Joyner asks question
2:21:24 PM Mr. Armstrong responds with regard to the mediator
2:22:13 PM Sen. Joyner asks question
2:22:27 PM Mr. Armstrong responds
2:22:59 PM Sen. Joyner asks question
2:23:04 PM Mr. Armstrong responds about timeline goals
2:23:55 PM Sen. Joyner has question
2:24:01 PM Mr. Armstrong responds
2:24:50 PM Sen. Joyner asks question
2:25:15 PM Mr. Armstrong responds
2:26:29 PM Sen. Joyner asks question about the caseload division
2:26:44 PM Mr. Armstrong responds
2:27:04 PM Sen. Joyner asks question about community support
2:27:21 PM Mr. Armstrong responds with regard to community need
2:29:44 PM Sen. Joyner asks question about caseload
2:30:56 PM Sen. Joyner asks question
2:31:01 PM Mr. Armstrong responds
2:34:27 PM Sen. Joyner asks question
2:35:04 PM Mr. Armstrong responds
2:36:05 PM Chair Bean thanks Sen. Joyner
2:36:25 PM Sen. Braynon asks question wth regard to purpose for change
2:36:42 PM Mr. Armstrong responds
2:37:44 PM Chair Bean asks for additional questions
2:37:51 PM Sen. Sobel asks question
2:38:26 PM Mr. Armstrong responds
2:40:10 PM Sen. Sobel asks follow-up question about increase in funds
2:40:44 PM Mr. Armstrong responds
2:41:20 PM Sen. Sobel asks question
2:41:35 PM Mr. Armstrong responds
2:41:48 PM Sen. Sobel responds
2:42:33 PM Mr. Armstrong responds with regard to patient privacy
2:43:41 PM Chair Bean asks for additional questions
2:43:50 PM Sen. Garcia asks question
2:44:23 PM Mr. Armstrong responds with regard to weight problems
2:46:34 PM Sen. Garcia gives concluding remarks
2:46:52 PM Mr. Armstrong responds with agreement
2:47:33 PM Chair Bean asks for additional questions

2:48:10 PM Confirmation of John H. Armstrong to State Surgeon General
2:48:28 PM Roll Call on confirmation of John H Armstrong to State Surgeon General
2:49:05 PM Tab 2 SPB 7010
2:50:12 PM Karen Peterson, Committee of Health Policy
2:51:06 PM Chair Beam follow up remarks and asks for questions
2:51:26 PM Amendment to SPB 7010 Barcode 482994 passed
2:52:18 PM Joe Anne Hart, Florida Dental Association waives in support
2:52:29 PM Roll call SPB 7010 as committee bill
2:52:59 PM Chair Bean declares approval of bill 7010
2:53:31 PM Chair Bean explains bill
2:55:01 PM Chair Bean explains SPB 7008/Nonresident Pharmacies
2:56:00 PM Barcode 634504
2:56:27 PM Barcode 724630
2:56:40 PM Sen. Sobel asks for questions, testimony, debate
2:56:47 PM Sen. Sobel shows amendment adopted
2:57:12 PM Michael Jackson, Florida pharmacy Association waives in support
2:57:24 PM Roll call on SPB 7014
2:57:43 PM Sen. Sobel declares bill passed
2:58:19 PM Chair Bean makes statments
2:59:33 PM Tab 6 workshop on Telemedicine
3:05:07 PM Sen. Garcia responds
3:06:35 PM Chair Bean responds
3:06:41 PM Sen. Sobel asks question about quality of care
3:07:50 PM Chair Bean asks follow-up question
3:08:01 PM Sen. Sobel responds
3:08:39 PM Chair Bean asks for other thoughts
3:08:47 PM Sen. Brandes asks question about cash transactions
3:09:21 PM Chair Bean asks for other thoughts
3:09:29 PM Sen. Sobel responds
3:10:34 PM Sen. Braynon comments
3:11:16 PM Sen. Galvano comments
3:11:51 PM Chair Bean responds
3:12:41 PM Sen. Garcia offers comments
3:13:23 PM Chair Bean asks for other points
3:13:37 PM Testimony by Stan Whittaker, Florida Association of Nurse Practitioners
3:17:39 PM Chair Bean asks for further questions
3:17:46 PM Sen. Garcia asks question about definition of telemedicine
3:17:58 PM Mr. Whittaker responds
3:18:30 PM Sen. Garcia asks follow-up question
3:19:30 PM Mr. Whittaker responds
3:20:29 PM Chair Bean thanks Mr. Whittaker
3:20:44 PM Testimony by Tamara Demko, Director of Florida TaxWatch Center for Health and Aging
3:26:37 PM Chair Bean asks for further questions
3:26:44 PM Sen. Sobel asks question
3:26:55 PM Ms. Demko responds
3:27:01 PM Sen. Sobel asks follow-up question
3:27:08 PM Ms. Demko responds
3:27:24 PM Sen. Sobel asks questions about evaluation of programs in progress
3:27:36 PM Ms. Demko responds
3:27:40 PM Sen. Sobel asks question about goals
3:27:46 PM Ms. Demko responds
3:28:05 PM Chair Bean thanks Ms. Demko
3:28:23 PM Testimony by David Christian, Florida Chamber of Commerce
3:31:05 PM Sen. Sobel asks question
3:31:13 PM Mr. Christian responds with regard to unlicensed doctors
3:32:11 PM Sen. Sobel responds
3:32:37 PM Mr. Christian responds with plans for cancer
3:33:21 PM Chair Bean thanks Mr. Christian
3:33:29 PM Testimony by Paul Sanford, Florida Insurance Counsil
3:37:32 PM Chair Bean thanks Mr. Stanford
3:38:41 PM Rep. Travis Cummings offers remarks
3:38:52 PM Chair Bean delivers closing remarks

3:39:24 PM Motion to Rise
3:39:30 PM Meeting Adjourned