

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 7038

INTRODUCER: For consideration by the Health Policy Committee

SUBJECT: Controlled Substances

DATE: January 6, 2016

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. <u>Looke</u>	<u>Stovall</u>		Pre-meeting

I. Summary:

SPB 7038 amends several sections of law relating to controlled substances in order to:

- Clarify that Schedule II, III, IV, and V controlled substances may be prescribe electronically as allowed by federal law;
- Strike language requiring wholesale distributors of controlled substances to determine whether or not orders of more than 5,000 unit doses of any one controlled substance in any one month are reasonable;¹
- Allow prescribers and dispensers of controlled substances as well as pharmacies to select designees who may access the Prescription Drug Monitoring Program (PDMP) database on behalf of the prescriber, dispenser, or pharmacy; and
- Allow impaired practitioner consultants to access the PDMP information of impaired practitioner program participants who have agreed in writing to allow the consultants such access.

II. Present Situation:

Electronic Prescribing

Electronic prescribing (e-prescribing) makes use of health information technology that enables the electronic transmission of prescriptions and access to medication history by prescribing physicians at the point of care. It improves prescription accuracy, increases patient safety, and reduces costs primarily because of the critical health care information it makes available to the physician or other prescribing practitioner. A major benefit of the electronic transfer of the prescription is the elimination of errors caused by miscommunication of the handwritten paper prescription. E-prescribing can reduce opportunities for fraud and abuse that currently occur due

¹ Wholesale distributors will still be required to take reasonable measures to identify suspicious transactions and to establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions.

to a lack of secure prescription delivery to the pharmacy. E-prescribing also creates a more traceable trail for auditing purposes.²

Section 456.42, F.S., requires that an electronic prescription must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and directions for use of the drug. The prescription must also be dated and signed on the day issued either manually or in electronic format.³ Section 456.43, F.S., specifies that electronic prescribing may not interfere with a patient's freedom to choose a pharmacy and that electronic prescribing software may not influence or attempt to influence a prescribing practitioner's decision at the point of care.

Additionally, s. 408.0611, F.S., establishes the Electronic Prescribing Clearinghouse (clearinghouse) in order to promote the implementation of electronic prescribing with the goal of preventing prescription drug abuse, improving patient safety, and reducing unnecessary prescriptions. The clearinghouse is housed within the Agency for Health Care Administration (AHCA) and the AHCA is required to work in collaboration with relevant stakeholders and publish:

- Information on its website regarding the process of electronic prescribing, the availability of electronic prescribing products, and the advantages of electronic prescribing;
- Links to state, federal and private sector websites that provide guidance on selecting an appropriate electronic prescribing product;
- Links to state, federal, and private sector incentive programs for the implementation of electronic prescribing;⁴ and
- An annual report by January 31 of each year.

Electronic Prescribing of Controlled Substances

Until 2010, the U.S. Drug Enforcement Administration (DEA) regulations required that controlled substances be written on a paper prescription pad. On March 29, 2010, the DEA issued an interim final rule permitting electronic prescribing of controlled substances⁵ and the rule became effective on June 1, 2010.⁶

In Florida, s. 456.42, F.S., states that written prescriptions for controlled substances may be electronically prescribed. Effective December 24, 2015, the Florida Board of Pharmacy rule specifies that all substances listed in schedules II through V may be prescribed electronically pursuant to the provisions of s. 456.42(2), F.S., and federal law.⁷ Although the statutory provision is interpreted in rule and in the AHCA's annual report⁸ to mean that all controlled

² Agency for Health Care Administration, *Florida Electronic Prescribing Annual Report for 2014*, p. 8 (January 2015), available at <http://www.fhin.net/eprescribing/docs/reports/Florida2014ePrescribeReport.pdf> (last visited on Jan. 6, 2016).

³ Electronic signatures are governed by s. 668.003(4), F.S.

⁴ Agency for Health Care Administration, Florida Electronic Prescribing Clearinghouse, available at <http://www.fhin.net/eprescribing/index.shtml> (last visited on Jan. 6, 2016).

⁵ Id. note 2, at 21.

⁶ U.S. Department of Justice, Office of Diversion Control, *Electronic Prescriptions for Controlled Substances (EPCS)*, http://www.deadiversion.usdoj.gov/ecomm/e_rx/ (last visited on Jan. 6, 2016).

⁷ Rule 64B16-27.831, F.A.C.

⁸ Id. note 2, at 21.

substances Schedules II through V may be electronically prescribed, the statute does not specifically state which schedules are allowed to be prescribed electronically.

Controlled Substances

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

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples: cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.
- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples: alprazolam; diazepam; and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

The Prescription Drug Abuse Crisis and Florida's Response

Starting in the early 2000s, Florida began experiencing a marked increase in deaths resulting from prescription drug abuse. In 2010 the Florida Office of Drug Control identified prescription drug abuse as the most threatening substance abuse issue in Florida.⁹ Between 2003 and 2009 the number of deaths caused by at least one prescription drug increased by 102 percent (from 1,234 to 2,488). These numbers translated into seven Floridians dying from prescription drug overdoses per day.

Between 2009 and 2011, the Legislature enacted a series of reforms to combat prescription drug abuse. These reforms included strict regulation of pain management clinics; creating the Prescription Drug Monitoring Database (PDMP); and stricter regulation on selling, distributing, and dispensing controlled substances.¹⁰ Some of these reforms include the following:

⁹ Executive Office of the Governor, *Florida Office of Drug Control 2010 Annual Report* (on file with the Senate Committee on Health Policy).

¹⁰ See chs. 2009-197, 2010-211, and 2011-141, Laws of Fla.

Due Diligence for Wholesale Distributors of Controlled Substances

In state and out-of-state prescription drug wholesale distributors as well as retail pharmacy drug wholesalers (wholesale distributors) are regulated under the Florida Drug and Cosmetic Act.¹¹ A wholesale distributor is defined in s. 499.003(54), F.S., as “any person engaged in wholesale distribution¹² of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.” Wholesale distributors are required to be permitted by the Department of Business and Profession Regulation (DBPR).

In addition to numerous other requirements, in 2011 as part of the effort to combat prescription drug abuse, the Legislature passed due diligence requirements which wholesale distributors must meet when selling Schedule II or Schedule III controlled substances to physicians and pharmacies.¹³ In order to meet the due diligence requirements, wholesale distributors:

- Must establish and maintain policies and procedures to credential physicians and pharmacies which must at a minimum include:
 - A determination of the clinical nature of the receiving entity;
 - A review of the receiving entity’s history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor; and
 - A determination that the receiving entity’s controlled substance purchasing history is consistent with and reasonable for the entity’s clinical business.
- Must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify transactions that are suspicious in nature.
- Must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable.
- Must report to the DBPR any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that may indicate the listed chemical will be used in violation of the law. The wholesale distributor must also maintain records that document the report to the DBPR.
- May not distribute controlled substances to an entity if a criminal history record check shows that any person associated with that entity has been convicted or pled nolo contendere to a crime related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

The Prescription Drug Monitoring Program

Chapter 2009-197, Laws of Fla., 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

¹¹ Chapter 499, F.S.

¹² Wholesale distribution is also defined in s. 499.003(53), F.S., to mean the distribution of prescription drugs to persons other than a consumer or patient. The definition has numerous exceptions including, among others, exceptions for charitable organizations, hospitals, and certain government entities.

¹³ See s. 499.0121(15), F.S., and ch. 2011-141, s. 18, Laws of Fla.

controlled substances.¹⁴ 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.¹⁵

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.¹⁶ Dispensers have reported over 163 million controlled substance prescriptions to the PDMP since its inception.¹⁷ Health care practitioners began accessing the PDMP on October 17, 2011.¹⁸ Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.¹⁹

Accessing the PDMP database

Section 893.0551, F.S., makes certain identifying information²⁰ 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 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 in article I, section 24(a) of the State Constitution.²¹

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.²² Currently, prescribers are not required to consult the PDMP database before prescribing a controlled substance for a patient however physicians and pharmacists queried the database more than 3.7 million times in 2012, over 9.3 million times in 2014, and over 18.6 million times in 2015.²³

Indirect access to the PDMP database is provided to:

- The Department of Health (DOH) or certain health care regulatory boards;
- The Attorney General for Medicaid fraud cases;

¹⁴ Section 893.055(2)(a), F.S.

¹⁵ Section 893.055(3)(a)-(c), F.S.

¹⁶ Florida Dep't of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report* (December 1, 2013), available at <http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf> (last visited on Jan. 7, 2016).

¹⁷ Florida Dep't of Health, *2014-2015 Prescription Drug Monitoring Program Annual Report* (December 1, 2015), available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/documents/2015-pdmp-annual-report.pdf> (last visited on Jan. 7, 2016).

¹⁸ *Supra* note 16

¹⁹ *Supra* note 16

²⁰ 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.

²¹ Section 893.0551(2)(a)-(h), F.S.

²² Section 893.055(7)(b), F.S.

²³ *Supra* at notes 16 and 17.

- Law enforcement agencies during active investigations²⁴ involving potential criminal activity, fraud, or theft regarding prescribed controlled substances if the law enforcement agency has entered into a user agreement with the DOH; and
- Patients, or the legal guardians or designated health care surrogates of incapacitated patients.²⁵

Indirect access means the person must request the information from the PDMP manager. After an extensive process to validate and authenticate the request and the requestor, the PDMP manager or support staff provides the specific information requested.²⁶

Effectiveness of Florida’s Response to the Prescription Drug Abuse Crisis

The increased regulation of pain management clinics and other controlled substance prescribing changes correspond with significant reductions in the number of drug overdose deaths in Florida. A Centers for Disease Control and Prevention report published on July 4, 2014, documents a 61 percent increase in drug overdose deaths in Florida from 2003 to 2010.²⁷ Additionally, Florida had become the primary destination for distributors and abusers of diverted prescription drugs through the proliferation of illegitimate pain management clinics known as pill mills.²⁸

After the reforms adopted between 2009 and 2011 were in place, instead of continuing the upward trend of the seven years between 2010 – when many of the current controlled substance prescribing regulations became effective – and 2012, drug overdose deaths in Florida fell by 16.7 percent. Also, during that period, deaths from prescription drugs declined by 23.2 percent and deaths from oxycodone declined by 52.1 percent.²⁹ Prescription drug deaths also continued to fall in 2013, when compared to 2012, with 8.3 percent fewer people dying with at least one prescription drug in their system that was identified as the cause of death.³⁰ Between 2010 and 2014, the number of deaths from oxycodone fell from eight deaths per 100,000 to 2.4 deaths per

²⁴ Section 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.

²⁵ Section 893.055(7)(c)1.-4., F.S.

²⁶ See s. 893.055(7)(c), F.S., and Rule 64k-1.003, F.A.C.

²⁷ The Centers for Disease Control and Prevention, *Decline in Drug Overdose Deaths after State Policy Changes — Florida, 2010–2012* (July 4, 2014), available at

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm?s_cid=mm6326a3_w#Fig1 (Last visited Jan. 7, 2016).

²⁸ Pill mills are pain management clinics that serve as a front for drug traffickers and can be identified through characteristics which include: taking only cash, not taking appointments, employing armed guards, keep little to no medical records, performing only grossly inadequate physical examinations, and prescribing large doses of narcotics that exceed the boundaries of acceptable medical care. See Florida Office of the Attorney General, *Pill Mill Initiative* (2012-2015), available at <http://myfloridalegal.com/pages.nsf/Main/AA7AAF5CAA22638D8525791B006A30C8>, (Last visited Jan. 7, 2016),

²⁹ *Supra* note 27.

³⁰ Florida Dep’t of Law Enforcement, *Medical Examiners Commission 2013 Annual Report*, p. i, (October 2014), available at <http://www.fdle.state.fl.us/Content/getdoc/05c6ff97-00cc-49b2-9ca5-5dacd4539b1a/2013-Annual-Drug-Report.aspx> (Last visited Jan. 7, 2016).

100,000, a decrease of nearly 75 percent.³¹ Additionally, the number of doctors in Florida who prescribed high volumes of narcotics fell from 98 in 2010 to 13 in 2012 and to zero in 2013.³²

One negative unintended consequence of both Florida's reforms and the national crack-down on prescription drug abuse has been a shortage of controlled substances for patients who have legitimate needs. Due to the difficulty in receiving drugs or the fear of government action and criminal penalties, many pharmacies have not been able to or have refused to fill prescriptions for controlled substances for people with legitimate medical issues such as chronic pain. This shortage has been documented both in Florida and nationwide.^{33, 34}

Treatment Programs for Impaired Practitioners

The DOH administers the impaired practitioner treatment program to ensure that licensed health care practitioners, applicants for licensure, and students enrolled in prelicensure education programs who are impaired and may pose a threat to the public if allowed to obtain or retain a license are evaluated and referred for treatment. Impaired practitioner consultants (IPC) are retained by the DOH to monitor the treatment of an impaired practitioner and coordinate services.³⁵ An IPC must be a licensed physician, a licensed nurse, or an entity with a licensed physician or nurse as its medical director.³⁶ The IPC assist the DOH in determining if the practitioner is actually impaired, connecting the practitioner to appropriate resources for treatment of the impairment, and monitoring the practitioner's progress.³⁷

Impairment can result from the use or misuse of drugs or alcohol, or both, or due to a mental or physical condition that could affect the person's ability to practice with skill and safety.³⁸ A practitioner's participation in a treatment program is voluntary, but requires him or her have voluntarily withdrawn from practice or limited the scope of his or her practice until the practitioner has successfully completed the treatment program. By entering and successfully completing the impaired practitioner treatment program, a practitioner may avoid formal disciplinary action if the impairment is the only violation of the licensing statute under which the practitioner is regulated.³⁹

An IPC does not provide medical treatment or render decisions relating to licensure of a particular practitioner. However, an IPC is required to make recommendations to the probable

³¹ *Supra* note 17

³² Sabrina Tavernise, *Prescription Overdose Deaths in Florida Plunge After Tougher Measures, Report Says*, THE NEW YORK TIMES, July 1, 2014, available at http://www.nytimes.com/2014/07/02/health/prescription-drug-deaths-in-florida-plunge-after-tougher-laws.html?_r=0, (last visited Jan. 7, 2016). Also see *supra* note 26.

³³ Marni Jameson, *Drug shortages ups suffering for legitimate pain patients*, THE ORLANDO SENTINEL, July 10, 2012, available at http://articles.orlandosentinel.com/2012-07-10/health/os-drug-shortage-20120710_1_pain-patients-prescription-drug-abuse-oxycodone-pills (last visited on Jan. 7, 2016); and Samuel Adams, *Florida Pain Victims Trapped by Prescription Crackdown: Health*, Bloomberg Business August 16, 2013, available at <http://www.bloomberg.com/news/articles/2013-08-16/florida-pain-victims-trapped-by-prescription-crackdown-health> (last visited on Jan. 7, 2016).

³⁴ U.S. Government Accountability Office, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (February 2015)

³⁵ Section 456.076(2)(a), F.S.

³⁶ *Id.*

³⁷ Section 456.076(2)(c)1., F.S.

³⁸ Section 456.076(4)(a), F.S.

³⁹ *Id.*

cause panel, or the DOH when there is no board, regarding a practitioner's ability to practice safely.⁴⁰

There are two IPC entities currently retained by the DOH: the Intervention Project for Nurses (IPN) and the Professionals Resource Network (PRN) for other health care professions. As of December 23, 2014, there were approximately 2,449 participants enrolled in the programs: 1,461 in the IPN and 988 in the PRN.⁴¹

III. Effect of Proposed Changes:

Section 1 amends s. 456.42, F.S., to clarify that controlled substances in schedules II through V may be prescribed electronically pursuant to applicable federal law.

Section 2 amends s. 499.0121, F.S., to strike the requirement that wholesale distributors assess orders of more than 5,000 unit doses of any one controlled substance in any one month to determine whether or not such orders are reasonable. Removing this specific provision may eliminate a perceived cap on the distribution of controlled substances. This change may facilitate the availability of sufficient stock for pharmacies to fill valid prescriptions. Other due diligence requirements remain in effect.

Sections 3 and 4 amend ss. 893.055⁴² and 893.0551,⁴³ F.S., to:

- Allow prescribers and dispensers of controlled substances, as well as pharmacies, to select designees who may access the PDMP on behalf of the prescriber, dispenser, or pharmacy; and
- To allow impaired practitioner consultants to have indirect access to PDMP information regarding an impaired practitioner program participant who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to allow the consultant to access his or her information in the PDMP.

Section 5 states that the act shall take effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

This bill does not create or expand a public records exemption and therefore does not require two-thirds vote for passage.

⁴⁰ Section 456.076(2)(c)1., F.S.

⁴¹ E-mail from Paul Runk, Deputy Legislative Planning Director, Dep't of Health (Dec. 23, 2014) (on file with the Senate Committee on Health Policy).

⁴² Section 893.055, F.S., is the substantive law enacting the PDMP.

⁴³ Section 893.0551, F.S., is the public records exemption for information held within the PDMP.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

SPB 7038 may have a negative fiscal impact on the DOH as the DOH may be required to modify the PDMP in order to allow access to prescriber, dispenser, and pharmacy designees as well as impaired practitioner consultants.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.42, 499.0121, 893.055, and 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.