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 Rules

BILL:	CS/CS/CS/SB 840
INTRODUCER:	Rules Committee; Governmental Oversight and Accountability Committee; Health Policy Committee and Senator Clemens
SUBJECT:	Controlled Substance Prescribing
DATE:	April 26, 2017 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.	Peacock	Ferrin	GO	**Fav/CS**
3.	Stovall	Phelps	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/CS/SB 840 requires allopathic and osteopathic physicians who have a Drug Enforcement Administration (DEA) registration to complete a 2-hour continuing medical education (CME) course provided by a statewide professional association by December 31, 2017. Failure to complete the course before December 31, 2017, constitutes grounds for disciplinary action. The course must address current standards regarding opiate prescribing and alternatives to these standards, and the risks of opioid addiction following even brief periods of treatment in the management of acute pain. Beginning January 1, 2020, this course will be required as part of the 40-hour CME requirement for biennial licensure renewal.

The bill requires dispensers to report the dispensing of a controlled substance to the Prescription Drug Monitoring Program database (PDMP) by the close of the next business day, rather than 7 days, after the controlled substance is dispensed. This expedited timeframe for reporting is effective January 1, 2018. Reporting must be through the electronic system approved by the DOH.

The bill clarifies an exemption from reporting for rehabilitative hospitals, assisted living facilities, or nursing homes dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician by requiring the dispensing to occur while the patient is present and receiving care.

An employee of the U.S. Department of Veterans Affairs, who is authorized to prescribe controlled substances, may access the PDMP for the purpose of reviewing his or her patient's controlled substance prescription history.

The effective date of the bill is July 1, 2017, except as otherwise expressly provided.

II. Present Situation:

The Prescription Drug Monitoring Program

Starting in the early 2000s, Florida began experiencing a marked increase in deaths resulting from prescription drug abuse. In 2010, the former Florida Office of Drug Control (FODC) identified prescription drug abuse as "the most threatening substance abuse issue in Florida."[1] According to the FODC, 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).[2] The FODC remarked that these numbers translated into seven Floridians dying from prescription drug overdoses per day.[3]

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 PDMP; and stricter regulation on selling, distributing, and dispensing controlled substances.[4]

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.[5] The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[6] Dispensers have reported over 198 million controlled substance prescriptions to the PDMP since its inception.[7] Health care practitioners began accessing the PDMP on October 17, 2011.[8] Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[9]

Dispensers of controlled substances listed in Schedule II, Schedule III, or Schedule IV of s. 893.03, F.S., must report specified information to the PDMP database within seven days after dispensing, each time the controlled substance is dispensed. The information required to be reported includes:[10]

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[1] Executive Office of the Governor, *Florida Office of Drug Control 2010 Annual Report*, p. 8 (on file with the Senate Committee on Health Policy).
[2] *Id.*
[3] *Id.*
[4] *See* chs. 2009-197, 2010-211, and 2011-141, Laws of Fla.
[5] Section 893.055(2)(a), F.S.
[6] Florida Dep't of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report* (December 1, 2013), p. 2, *available at* http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited on Mar. 29, 2017).
[7] Florida Dep't of Health, *2015-2016 Prescription Drug Monitoring Program Annual Report* (December 1, 2016), p. 4, *available at* http://www.floridahealth.gov/statistics-and-data/e-forcse/_documents/2016PDMPAnnualReport.pdf (last visited on Mar. 29, 2017).
[8] *Supra* note 6.
[9] *Supra* note 6.
[10] The specific information reported depends upon the whether the reporter is a pharmacy or practitioner.

- Name of the dispenser [pharmacy], Drug Enforcement Administration registration number, and address of the pharmacy;
- Name of the prescribing practitioner and his or her Drug Enforcement Administration registration number, National Provider Identification, or other applicable identifier, and the date of the prescription;
- Date the prescription is dispensed;
- Name, address, and date of birth of the person to whom the controlled substance is dispensed; and
- Name, national drug code, quantity, and strength of the controlled substance dispensed.[11]

Personal identifying information in the PDMP is confidential and exempt from the public records laws and State Constitution.[12] Specified persons or entities are authorized either direct or indirect[13] access to certain protected information in the PDMP.[14]

Current law exempts certain acts of dispensing or administering from PDMP reporting:
- A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- A practitioner when administering a controlled substance in the emergency room of a licensed hospital.
- A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.
- A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.
- A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician.[15]

A dispenser must submit the required dispensing information 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.[16] Rule 64K-1.004, F.A.C., requires all

[11] *See* s. 893.055(3), F.S.
[12] Section 893.0551, F.S.
[13] Indirect access requires submitting a request to the PDMP program manager for specific information each time information is needed which may be released once the requester and request is verified as authentic and authorized. *See* ss. 893.055(7)(c) and 893.0551(3), F.S.
[14] *See* s. 893.0551, F.S.
[15] *See* s. 893.055(5), F.S.
[16] *See* s. 893.055(4), F.S.

dispensers to electronically report the dispensing information.[17] The DOH allows five electronic data delivery methods.[18]

On average, each month 6,546 dispensers report controlled substance dispensing information to the PDMP, and 96 percent of dispensers complied with the mandated 7-day timeframe for reporting. Of those dispensers, 66 percent reported the information within 24 hours.[19]

PDMP Reporting in Other States

Data reporting frequency varies from state to state. Oklahoma is the only state that requires its dispensers to report controlled substance dispensing data at the point of sale, real time. Thirty-five states require data to be uploaded within 1 day, three states require data to be uploaded within 3 days, 11 states require data to be uploaded within 7 days, and one state requires data to be uploaded within 14 days.[20]

Guidelines for Prescribing Opioids

Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled. From 2000 to 2015 more than half a million people died from drug overdoses. Ninety-one Americans die every day from an opioid overdose.[21]

In March 2016, the Centers for Disease Control and Prevention (CDC) issued Guidelines for Prescribing Opioids for Chronic Pain.[22] The guidelines is a series of recommendations that focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.[23] However, among the 12 recommendations is one relating to prescribing short durations for acute pain. This recommendation is summarized as follows:

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[17] The DOH may grant a dispenser a waiver of the electronic submission requirement for good cause. "Good cause" includes financial hardship and lack of an automated recordkeeping system. The dispenser must notify the DOH in writing by completing an electronic reporting waiver form provided by the DOH. The DOH will work with the dispenser to determine the format, method, and frequency of the alternative non-electronic submissions. *See* E-FORCSE Dispenser's Implementation Guide ASAP 4.2 (July 2015) DH8013-PDMP, p. 7, *available at* https://www.flrules.org/gateway/reference.asp?No=Ref-06459 and click on the DH8013-PDMP (01.15) 64K-1.004 (v2).pdf link, (last visited on Mar. 29, 2017).

[18] *Id.*, p. 21.

[19] *Supra* note 7, p.5.

[20] Department of Health, *Senate Bill 840 Analysis* (February 13, 2017) (on file with the Senate Committee on Health Policy).

[21] Centers for Disease Control and Prevention, *Opioid Overdose, Understanding the Epidemic* (updated December 16, 2016) *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited April 4, 2017).

[22] Dowell D. Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1): 1-49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501el *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr650el.htm (last visited April 4, 2017).

[23] Centers for Disease Control and Prevention, *Opioid Overdose, CDC Guidelines for Prescribing Opioids for Chronic Pain* (updated March 15, 2017) *available at* https://www.cdc.gov/drugoverdose/prescribing/guideline.html (last visited April 4, 2017).

> Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.[24]

A number of states have enacted legislation or otherwise limited the initial duration of prescriptions for opioids for acute pain. On February 15, 2017, Governor Chris Christie of New Jersey signed legislation, reported as the strictest in the nation, limiting initial opioid prescriptions to a 5-day supply.[25] Over the past year, Connecticut, Delaware, Maine, Massachusetts, New York, Pennsylvania, Rhode Island, and Vermont, have enacted laws or adopted rules for imposing 7-day limits for initial opioid prescriptions, mostly for acute pain.[26] Bills to restrict opioid prescriptions are pending in Georgia, Hawaii, Indiana, Kentucky, Montana, Oregon, and Washington.[27]

Florida Practitioners Authorized to Prescribe Controlled Substances

Certain licensed health care providers and veterinarians are authorized to prescribe controlled substances. Section 893.02(23), F.S., defines "practitioner" as a physician licensed under chapter 458, a dentist licensed under chapter 466, a veterinarian licensed under chapter 474, an osteopathic physician licensed under chapter 459, an advanced registered nurse practitioner (ARNPs) certified under chapter 464, a naturopath licensed under chapter 462, a certified optometrist licensed under chapter 463, a psychiatric nurse as defined in s. 394.455, a podiatric physician licensed under chapter 461, or a physician assistant licensed under chapter 458 or chapter 459, provided such practitioner holds a valid federal controlled substance registry number.

Effective January 1, 2017, certain ARNPs and physician assistants were authorized to prescribe controlled substances.[28] As a part of this authorization, the ARNPs and physician assistants are required to complete a 3-hour continuing education course on the safe and effective prescribing of controlled substances as a part of biennial licensure renewal.[29]

III. Effect of Proposed Changes:

The bill requires allopathic and osteopathic physicians who have a Drug Enforcement Administration (DEA) registration to complete a 2-hour continuing medical education (CME)

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[24] Centers for Disease Control and Prevention, Opioid Overdose, Guidelines at a Glance, (updated February 9, 2017), *available at* https://www.cdc.gov/drugoverdose/ (last visited April 4, 2017).
[25] Christine Vestal, *New Jersey Enacts Nation's Strictest Opioid Prescribing Limit* (February 16, 2017), *available at* http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/02/16/new-jersey-enacts-nations-strictest-opioid-prescribing-limit (last visited April 4, 2017).
[26] Association of State and Territorial Health Officials, *A Look at State Legislation Limiting Opioid Prescriptions* (February 23, 2017), *available at* http://astho.org/StaatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/?terms=acute+pain (last visited April 4, 2017).
[27] *Id.*
[28] Chapter 2016-224, Laws of Fla.
[29] *See* ss. 458.347(4)(e)3. and 464.013(3)(b), F.S.w

course provided by a statewide professional association by December 31, 2017. The failure to complete the course by December 31, 2017, constitutes grounds for disciplinary action. The course must address current standards regarding opiate prescribing and alternatives to these standards, and the risks of opioid addiction following even brief periods of treatment in the management of acute pain. The course may be offered in a distance-learning format. Beginning January 1, 2020, this course will be required as part of the 40-hour CME requirement for biennial licensure renewal.

The bill imposes the disciplinary action against applicable physicians as grounds for disciplinary action under s. 456.072(1)(e), F.S., and the respective practice acts. Section 456.072(1)(e), F.S., provides grounds for discipline for failing to comply with the educational course requirement for human immunodeficiency virus and acquired immune deficiency syndrome, without specific reference to the opioid prescribing course. Sections 458.331 and 459.015, F.S., provide grounds for disciplinary action within the specific practice acts.

Effective January 1, 2018, dispensers of controlled substances that are required to report the dispensing of a controlled substance to the PDMP must report no later than the close of the next business day after the controlled substance is dispensed. The DOH may grant an extension to this timeframe for cause as determined by rule. The bill requires the submission via the Department-approved electronic system and eliminates other approved formats that may include being on a disc or submitting by regular mail.

The bill clarifies an exemption from reporting to the PDMP that was enacted during the 2016 Regular Session[30] for rehabilitative hospitals, assisted living facilities, or nursing homes dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician. The bill limits application of the exemption such that the controlled substance must be dispensed to a patient while the patient is present and receiving care in the facility. This ensures that the controlled substance is dispensed and administered[31] at the facility to conform with the other exemptions.

The bill also authorizes an employee of the U.S. Department of Veterans Affairs, who provides health care services pursuant to that employment and is authorized to prescribe controlled substances, to access the PDMP only for the purpose of reviewing his or her patient's controlled substance prescription history.

The effective date of the bill is July 1, 2017, except as otherwise expressly provided.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The mandate restrictions do not apply because the bill does not require counties or municipalities to spend funds, reduce the counties' or municipalities' ability to raise revenue or reduce the percentage of state tax shared with counties or municipalities.

[30] Chapter 2016-177, Laws of Fla.
[31] Dispense means to transfer possession and administer means to inject, inhale, or ingest. *See* s. 893.02, F.S.

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:

Physicians licensed under ch. 458 or ch. 459, F.S., are subject to disciplinary action if they fail to complete the 2-hour CME course regarding opioid prescribing by December 31, 2017. Logistically, completing the course within this short timeframe may result in action against a practitioner's license.

Some dispensers may incur additional costs, such as software updates, to develop electronic reporting capabilities and being able to submit within the next business day reporting timeframe. The effective date of January 1, 2018, for meeting the submission timeframe may ease the transition.

C. Government Sector Impact:

The DOH indicates it will incur non-recurring costs for rulemaking, which can be absorbed within existing resources.[32]

VI. Technical Deficiencies:

None.

VII. Related Issues:

Physicians licensed under ch. 458 or ch. 459, F.S., are subject to disciplinary action if they fail to complete the 2-hour CME course regarding opioid prescribing by December 31, 2017. Logistically, learning of this requirement, having access to this new course which may not yet exist, and completing the course within this short timeframe may be difficult. It is unclear what form of disciplinary action may be imposed for a violation.

VIII. Statutes Affected:

This bill substantially amends section 893.055 of the Florida Statutes.

[32] *Supra* note 19.

The bill creates an undesignated section of Florida law.

IX. Additional Information:

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

CS/CS/CS by Rules on April 25, 2017:
The committee substitute removes the more general requirement for the boards within the DOH with jurisdiction over practitioners who are authorized to prescribe controlled substances to require certain continuing education requirements relating to risks when prescribing opioids for brief periods for acute pain. It substitutes a more specific CME requirement for physicians only.

CS/CS by Governmental Oversight and Accountability on April 17, 2017:
The committee substitute:

- Removes section pertaining to definition of "acute pain" and limitation for initial prescription of opioids for acute pain not to exceed 5 days;
- Removes section pertaining to a conforming cross reference within ch. 463, F.S., relating to optometrists; and
- Directs the DOH to include as part of a practitioner's continuing medical education requirements information on the risks of opioid addiction following even brief periods of treatment in the management of acute pain.

CS by Health Policy on April 3, 2017:
The committee substitute:

- Limits an initial prescription for controlled substances for "acute pain" (associated with surgery, trauma, or acute illness) to a 5-day supply.
- Revises reporting to the PDMP to: the close of the next business day and via the department-approved electronic system. The bill as filed provided for reporting within 24 hours and via the Internet.
- Authorizes a prescriber of controlled substances with the U.S. Department of Veterans Affairs access to the PDMP.
- Includes a conforming cross-reference within ch. 463, F.S., relating to optometrists.
- Changes the title of the bill from the Prescription Drug Monitoring Program.

B. Amendments:

None.