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:	SB 840
INTRODUCER:	Senator Clemens
SUBJECT:	Prescription Drug Monitoring Program
DATE:	March 31, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Pre-meeting**
2.			GO	
3.			RI	
4.			RC	

I. Summary:

SB 840 requires dispensers that must report the dispensing of a controlled substance to the Prescription Drug Monitoring Program database (PDMP) to report within 24 hours, rather than 7 days, after the controlled substance is dispensed. This expedited timeframe for reporting is effective January 1, 2018.

The bill requires submission via the Internet, eliminating other approved formats such as submitting on a disc or by regular mail.

The bill also 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.

The effective date of the bill is July 1, 2017.

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

[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).

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]

- 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]

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[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.
[11] *See* s. 893.055(3), F.S.

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

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.[14]

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.[15] Rule 64K-1.004, F.A.C., requires all dispensers to electronically report the dispensing information.[16] The DOH allows five electronic data delivery methods.[17]

On average, each month 6,546 dispensers report controlled substance dispensing information to the PDMP, and 96 percent of dispensers complied with the mandated seven-day timeframe for reporting. Of those dispensers, 66 percent reported the information within 24 hours.[18]

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[12] 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.
[13] *See* s. 893.0551, F.S.
[14] *See* s. 893.055(5), F.S.
[15] *See* s. 893.055(4), F.S.
[16] 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).
[17] *Id.*, p. 21.
[18] *Supra* note 7, p.5.

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 one day, three states require data to be uploaded within three days, 11 states require data to be uploaded within seven days, and one state requires data to be uploaded within 14 days.[19]

III. Effect of Proposed Changes:

Effective January 1, 2018, dispensers of controlled substances that are required to report the dispensing of a controlled substance to the PDMP must report within 24 hours after the controlled substance is dispensed. The DOH may grant an extension to this timeframe for cause as determined by rule.

The bill requires submission via the Internet, eliminating other approved formats that may include being on a disc or submitting by regular mail.

The bill also clarifies an exemption from reporting that was enacted during the 2016 Regular Session[20] 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 the exemption to apply if the controlled substance is dispensed to a patient while the patient is present and receiving care. This ensures that the controlled substance is dispensed and administered[21] at the facility to conform with the other exemptions.

The effective date of the bill is July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[19] Department of Health 2017 Legislative Analysis for SB 840, (February 13, 2017), on file with the Senate Health Policy Committee.
[20] Chapter 2016-177, Laws of Fla.
[21] Dispense means to transfer possession and administer means to inject, inhale, or ingest. *See* s. 893.02, F.S.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Some dispensers may incur additional costs, such as software updates, to develop reporting capabilities via the Internet and within the 24-hour timeframe. The effective date of January 1, 2018, for meeting the 24-hour 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.[22]

VI. Technical Deficiencies:

None.

VII. Related Issues:

Paragraph (7)(a) in s. 893.055, F.S., also addresses submitting the required information and costs. It requires submission in an electronic or other method in an ASAP format[23] approved by the DOH rule unless otherwise provided in s. 893.055, F.S. Costs that are not considered to be material or extraordinary include regular postage, electronic media, regular electronic mail, and facsimile charges. The bill's requirement for submission via the Internet and this paragraph may need to be aligned to avoid ambiguity.

VIII. Statutes Affected:

This bill substantially amends section 893.055 of the Florida Statutes.

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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[22] *Supra* note 19.
[23] ASAP stands for America Society for Automation in Pharmacy, which has set Prescription Monitoring Program Data Reporting Standards to facilitate uniformity in reporting for sharing data among the states that authorize such sharing. *See* http://www.pdmpassist.org/pdf/PPTs/LI2010/ASAP-Format.pdf (last visited Mar. 29, 2017). The EFORCE Dispenser's Implementation Guide uses the ASAP 4.2 format. *Supra* note 16.