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:	CS/SB 1700
INTRODUCER:	Health Policy Committee and Senator Lee
SUBJECT:	Prescription Drug Monitoring Program
DATE:	April 2, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Fav/CS**
2.	Tulloch	Cibula	JU	**Pre-meeting**
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1700 amends ss. 893.055 and 893.0551, F.S., to expand the Attorney General's (AG's) access to and use of data contained in the prescription drug monitoring program (PDMP) database for use in active investigations or pending civil or criminal litigation against pharmacies and dispensers of prescribed controlled substances (rather than only for Medicaid fraud cases). The bill requires that any patient information released to the AG, other than for Medicaid fraud cases, be de-identified. The Department of Health (DOH) must assign each patient a unique identifying number and may only release that number along with the patient's year of birth and the city, county, and zip code of the patient's residence. Additionally, the bill specifies that the AG may introduce PDMP records released pursuant to the above provision as evidence in a civil, criminal, or administrative action against a dispenser or pharmacy, and provides that the PDMP program manager may be called to testify for purposes of authenticating such records.

The bill takes effect upon becoming law.

II. Present Situation:

Chapter 2009-197, Laws of Florida, established the prescription drug monitoring program (PDMP) in s. 893.055, F.S., "to encourage safer prescribing of controlled substances and to

reduce drug abuse and diversion with the State."[1] The PDMP uses a comprehensive electronic database to monitor the prescribing and dispensing of certain controlled substances.[2] The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[3] Health care practitioners began accessing the PDMP on October 17, 2011.[4]

The PDMP requires that for each controlled substance[5] dispensed to a patient in Florida, the dispensing practitioner must report specified information[6] by the close of the next business day. All acts of administering a controlled substance, dispensing of a controlled substance to a person under the age of 16, and dispensing of a controlled substance in a health care system of the Department of Corrections are exempt from the requirement to report.[7]

During the 2017-2018 reporting period, there were approximately 33 million controlled substances prescribed to Florida patients. This is a decline of 4.64 percent over the previous reporting period.[8]

Protection of Records in the PDMP

Sections 893.055 and 893.0551, F.S., restrict access to records in the PDMP. Specifically, s. 893.0551(2), F.S., makes confidential and exempt from public records laws the name, address, telephone number, insurance plan number, government-issued identification number, provider number, drug enforcement administration number, and any other unique identifying information or number of a patient or the patient's agent a health care practitioner, an employee of the health care practitioner who is acting on behalf and at the direction of the health care practitioner, a pharmacist, or a pharmacy.

The Department of Health (DOH) is required to disclose protected information to specified entities in two ways: (1) by providing direct access to the database; or (2) by disclosing information pursuant to a request.[9]

Persons and entities who (1) may have direct access to the PDMP database are:

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[1] Florida Dept. of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report*, 2 (Dec. 1, 2013), *available at* http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited Apr. 4, 2019).
[2] Section 893.055(2)(a), F.S.
[3] *See* n. 1, *supra*.
[4] *Id.*
[5] Section 893.055(1)(c), F.S., defines "controlled substance" as "a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 or 21 U.S.C. s. 812." Prior to the passage of HB 21 in 2018 controlled substances listed in Schedule V were exempt from reporting. *See* ch. 2018-13, Laws of Fla.
[6] The information required to be reported under s. 893.055(3)(a)1.-8., F.S., includes identifying information of the prescribing practitioner, patient, prescribed drug, pharmacy, and person picking up the prescription; the dates the prescription was written and filled; the method of payment for the prescription; the quantity and strength of the prescription; whether there any refills permitted or filled; and any other appropriate information as determined by DOH rule.
[7] Section 893.055(3)(b)1.-3., F.S.
[8] Florida Dept. of Health, *2017-2018 Prescription Drug Monitoring Program Annual Report*, 15 (December 1, 2018), *available at* http://www.floridahealth.gov/statistics-and-data/e-forcse/health_care_practitioners/_documents/2018-pdmp-annual-report.pdf (last visited Apr. 4, 2019).
[9] Section 893.055(4) & (5), F.S.

- A prescriber, dispenser, or his or her designee;
- An employee of the United States Department of Veterans Affairs, Department of Defense, or Indian Health Services who provides health care services pursuant to such employment and who is authorized to prescribe or dispense controlled substances;
- The PDMP program manager in order to administer the system.[10]

The following entities (2) may request information from the system under specified circumstances:

- The DOH and its health care regulatory boards, as appropriate, for investigations involving licensees authorized to prescribe or dispense controlled substances.
- The AG for Medicaid fraud cases involving prescribed controlled substances.
- A law enforcement agency during active investigations of potential criminal activity, fraud, or theft regarding prescribed controlled substances.
- A medical examiner when conducting an authorized investigation under s. 406.11, F.S., to determine the cause of death of an individual.
- An impaired practitioner consultant who is retained by the DOH under s. 456.076, F.S., to review the system information of an impaired practitioner program participant or a referral who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to the consultant's access to and review of such information.
- A patient or the legal guardian or designated health care surrogate of an incapacitated patient who submits a written and notarized request that includes the patient's full name, address, phone number, date of birth, and a copy of a government-issued photo identification.[11]

Section 893.0551(5), F.S., requires that before disclosing information to a criminal justice agency or a law enforcement agency, the disclosing person or entity must take steps to ensure the continued confidentiality of all information. At a minimum, these steps must include redacting any non-relevant information. Also, s. 893.0551(6), F.S., requires an agency or person who obtains any information pursuant to this section to maintain the confidential and exempt status of that information and not disclose such information unless authorized by law.

Additionally, s. 893.055(10), F.S., specifies that information in the PDMP is for informational purposes only and is not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient. The program manager and other authorized persons are also restricted from testifying to any findings, recommendations, evaluations, opinions, or other actions taken in connection with management of the PDMP in any civil or administrative action.

[10] Section 893.055(4), F.S.
[11] Section 893.055(5), F.S.

Florida's Opioid Lawsuit

In 2018, AG Pam Bondi filed suit against multiple opioid manufacturers and distributors, including major pharmacies, CVS and Walgreens.[12] The complaint alleges that the defendants caused the opioid crisis by, among other things:

- "Engaging in a campaign of misrepresentations and omissions about opioid use designed to increase opioid prescriptions and opioid use, despite the risks."
- "Funding ostensibly neutral and independent (but not) front organizations to publish information touting the benefits of opioids for chronic pain while omitting the information about the risks of opioid treatment."
- "Paying ostensibly neutral medical experts called 'key opinion leaders' who were really manufacturer mouthpieces to publish articles promoting the use of opioids to treat pain while omitting information regarding the risks."[13]

The lawsuit is ongoing.[14]

III. Effect of Proposed Changes:

CS/SB 1700 amends s. 893.055, F.S. to:

- Divide subsection (5)(b) into two parts to allow the AG to request and receive data from the PDMP pursuant to an active investigation or pending civil or criminal litigation involving prescribed controlled substances, rather than only for Medicaid fraud cases;
- Require the DOH, when releasing information to the AG in cases other than for Medicaid fraud cases, to protect patient information by assigning each patient a unique identifying number. The unique identifier may not identify or provide a reasonable basis to identify the patient, and the DOH may only release the patient's assigned number, his or her year of birth, and the county, city, and zip code of his or her residence.
- Allow the AG to introduce information released pursuant to the above provision as evidence in a civil, criminal, or administrative action against a dispenser or pharmacy; and
- Provide that the PDMP program manager, or other authorized persons who participate in preparing, reviewing, issuing, or any other activity related to the management of the system, may testify for the purposes of authenticating the records introduced by the AG.

The bill amends s. 893.0551, F.S., to:

- Conform to the change allowing the AG to request and receive data from the PDMP for pending civil and criminal cases involving prescribed controlled substances; and
- Provide that the AG may release information from the system in response to a discovery demand if the information directly relates to the case for which the information is requested.

The bill's provisions are effective upon becoming law.

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[12] Emily Sullivan, *Florida Sues Walgreens, CVS for Alleged Role in Opioid Crisis*, NATIONAL PUBLIC RADIO (Nov. 19, 2018), *available at* https://www.npr.org/2018/11/19/669146432/florida-sues-walgreens-cvs-for-alleged-role-in-opioid-crisis (last visited Apr. 4, 2019).

[13] Florida Department of Legal Affairs, *Florida's Opioid Lawsuit*, *available at* http://myfloridalegal.com/webfiles.nsf/WF/MNOS-AYSNED/$file/Complaint+summary.pdf, (last visited Apr. 4, 2019).

[14] To review the amended complaint please, see http://myfloridalegal.com/webfiles.nsf/WF/GWRY-B6KV32/$file/Amended+Complaint+(Filed).pdf (last visited on Apr. 4, 2019).

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/SB 1700 may have an indeterminate negative fiscal impact on the DOH as the DOH may experience an increase in workload related to de-identifying records released to the AG, trial preparation, and travel.[15]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[15] Dept. of Health, *House Bill 1253 Analysis*, (Mar. 22, 2019) (on file with the Senate Health Policy Committee).

VIII. Statutes Affected:

This bill substantially amends sections 893.055 and 893.0551 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on April 1, 2019:
The committee substitute:

- Requires that patient information released to the AG for any active investigation or for a civil, criminal, or administrative case, other than for Medicaid fraud cases, be de-identified.
- Narrows the scope of the bill so that only de-identified information released to the AG pursuant to the above provision may be introduced as evidence in a civil, criminal, or administrative suit against a pharmacy or dispenser.
- Revises the effective date.

B. Amendments:

None.