

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 1700

INTRODUCER: Senator Lee

SUBJECT: Prescription Drug Monitoring Program

DATE: March 29, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	Pre-meeting
2.			JU	
3.			RC	

I. Summary:

SB 1700 amends ss. 893.055 and 893.0551, F.S., to expand the Attorney General’s (AG) access to data in the prescription drug monitoring program (PDMP) database. The bill allows the AG access to PDMP records for all cases involving prescribed controlled substances (rather than only for Medicaid fraud cases). Additionally, the bill allows PDMP records to be subject to discovery and to be introduced in civil and administrative actions against dispensers and pharmacies. The bill provides that the PDMP program manager may be called to testify for purposes of authenticating the records contained in the PDMP.

The bill provides an effective date of July 1, 2019.

II. Present Situation:

Chapter 2009-197, Laws of Florida, established the PDMP in s. 893.055, F.S. The PDMP uses a comprehensive electronic database to monitor the prescribing and dispensing of certain controlled substances.¹ The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.² Health care practitioners began accessing the PDMP on October 17, 2011.³

¹ Section 893.055(2)(a), F.S.

² Florida Dept. of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report* (Dec. 1, 2013), available at <http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf> (last visited on March 26, 2019).

³ Id.

Section 893.055, F.S., requires that for each controlled substance⁴ dispensed to a patient in Florida, the dispensing practitioner must report specified information⁵ by the close of the next business day. All acts of administration, the dispensing of a controlled substance to a person under the age of 16, and the dispensing of a controlled substance in a health care system of the Department of Corrections are exempt from the requirement to report. 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.⁶

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, 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: by providing direct access to the database or by disclosing information pursuant to a request.

- Persons and entities who may have direct access to the database are:
 - 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.⁷
- The following entities 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

⁴ Section 893.055, 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.

⁵ For the information required to be reported, see s. 893.055(3)(a)1.-8., F.S.

⁶ Florida Dept. of Health, *2017-2018 Prescription Drug Monitoring Program Annual Report* (Dec. 1, 2018), available at http://www.floridahealth.gov/statistics-and-data/e-force/health_care_practitioners/documents/2018-pdmp-annual-report.pdf (last visited on March 27, 2019).

⁷ Section 893.055(4), F.S.

- 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.⁸

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 may 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.

Florida's Opioid Lawsuit

In 2018, AG Pam Bondi filed suit against multiple opioid manufacturers and distributors. The suit was later expanded to include the pharmacies CVS and Walgreens.⁹ 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 “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.¹⁰

The lawsuit is currently ongoing.¹¹

⁸ Section 893.055(5), F.S.

⁹ See *Florida Sues Walgreens, CVS for Alleged Role in Opioid Crisis*, (November 19, 2018) available at <https://www.npr.org/2018/11/19/669146432/florida-sues-walgreens-cvs-for-alleged-role-in-opioid-crisis> (last visited on March 27, 2019).

¹⁰ See [http://myfloridalegal.com/webfiles.nsf/WF/MNOS-AYSNE/\\$file/Complaint+summary.pdf](http://myfloridalegal.com/webfiles.nsf/WF/MNOS-AYSNE/$file/Complaint+summary.pdf), (last visited on March 27, 2019).

¹¹ To review the amended complaint please see [http://myfloridalegal.com/webfiles.nsf/WF/GWRY-B6KV32/\\$file/Amended+Complaint+\(Filed\).pdf](http://myfloridalegal.com/webfiles.nsf/WF/GWRY-B6KV32/$file/Amended+Complaint+(Filed).pdf) (last visited on March 27, 2019).

III. Effect of Proposed Changes:

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

- Allow the AG to request and receive data from the PDMP relating to all cases involving prescribed controlled substances, rather than only for Medicaid fraud cases;
- To allow PDMP information to be used in a civil or administrative action against a dispenser or pharmacy; and
- To 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 be called to testify for the purposes of authenticating the records contained in the system.

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 all cases;
- Specify that the AG may use all information maintained by the DOH to pursue an investigation and civil and criminal litigation;
- Conform to changes allowing information in the system to be used in civil and administrative actions against a dispenser or pharmacy; and
- Specify that the AG may release information from the system only in response to a discovery demand if such information is directly related to the case for which the information is reported.

The bill provides an effective date of July 1, 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.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

SB 1700 may have an indeterminate negative fiscal impact on the DOH as the DOH may experience an increase in workload related to trial preparation and travel and approving additional requests for information from the PDMP.¹²

VI. Technical Deficiencies:

None.

VII. Related Issues:

SB 1700 amends ss. 893.055 and 893.0551, F.S., to allow records in the PDMP database to be discoverable and to be introduced as evidence in civil and administrative actions against dispensers and pharmacies. However, as written, this portion of the bill is not specific to the AG. It is possible that SB 1700 could make PDMP records subject to discovery and use in any civil and administrative actions against dispensers and pharmacies, including private actions. Additionally, the bill may allow the PDMP director to be subpoenaed to testify in any such actions.

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 Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

¹² See DOH analysis of HB 1253, on file with Senate Health Policy Committee staff.