

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1253 Prescription Drug Monitoring Program

SPONSOR(S): Health Quality Subcommittee, Mariano

TIED BILLS: **IDEN./SIM. BILLS:** SB 1700

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Siples	McElroy
2) Judiciary Committee	16 Y, 0 N	Frost	Poche
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Prescription drug monitoring programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of certain controlled prescription drugs. Florida law requires all dispensers to report the dispensing of most controlled substances to the PDMP database by the close of the next business day after dispensing.

Only prescribers and dispensers have direct access to information in the database. Other entities, such as health care regulatory boards and law enforcement, have indirect access and must make a request to the PDMP staff to obtain information from the database. The Attorney General has authority to access PDMP data indirectly for Medicaid fraud cases involving prescribed controlled substances.

CS/HB 1253 requires the Department of Health (DOH) to assign a unique identifier to each patient with a record in the PDMP. The unique identifier must not indicate a patient's identity, or provide a reasonable basis by which an unauthorized person may discover a patient's identity.

The bill permits the Attorney General to indirectly access to PDMP data for any active or pending criminal or civil investigation involving controlled substances. For cases other than those involving Medicaid fraud, DOH may only release limited information regarding a patient, and may not release any personal identification information. The bill authorizes the Attorney General to use PDMP records from any time before or after the bill's effective date to investigate or pursue criminal or civil litigation.

The bill authorizes program staff to testify in a proceeding to authenticate PDMP records, but provides that PDMP information is not discoverable and may not be entered into evidence in a civil or administrative action against a prescriber or patient arising from a matter relating to PDMP information.

The bill may have an indeterminate, negative fiscal impact on the Department of Health.

The bill provides an effective date of upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Prescription Drug Monitoring Program

Prescription drug monitoring programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of certain controlled prescription drugs to patients.¹ PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and dispensers with critical information regarding a patient's controlled substance prescription history.² Forty-nine states and the District of Columbia have an operational PDMP database.³

Chapter 2009-197, Laws of Fla., established Florida's PDMP within the Department of Health (DOH).⁴ The PDMP uses an electronic database system to monitor the prescribing and dispensing of most controlled substances.⁵ The PDMP database became operational in September of 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.⁶ Health care practitioners began accessing the PDMP database on October 17, 2011.⁷

PDMP Reporting Requirements

When dispensing a controlled substance listed in the Florida Comprehensive Drug Abuse Prevention and Control Act or federal law, dispensers must report specified information to the PDMP database:⁸

- The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration (DEA) registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription;
- The date the prescription was filled and the method of payment, such as cash by an individual or third-party payment;
- The full name, address, telephone number, and date of birth of the person for whom the prescription was written;
- The name, national drug code, quantity, and strength of the controlled substance dispensed;
- The full name, DEA registration number, and address of the pharmacy, other location, or practitioner from which the controlled substance was dispensed;
- The name of the dispensing practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's NPI and the practitioner's DOH-issued license number;
- Whether the drug dispensed is an initial prescription or a refill, and the number of refills order;

¹ Centers for Disease Control and Prevention, *What States Need to Know about PDMPs*, (rev. Oct. 3, 2017), available at <http://www.cdc.gov/drugoverdose/pdmp/> (last visited March 24, 2019).

² Id.

³ Prescription Drug Monitoring Program Training and Technical Assistance Center, *Status of PDMPs*, (Aug. 2018), available at http://www.pdmpassist.org/pdf/PDMP_Program_Status_20180801.pdf (last visited March 24, 2019). Missouri is the only state without a statewide PDMP. However, the governor of Missouri issued an executive order in 2017, directing the state health agency to implement a prescription drug monitoring program. See <https://www.sos.mo.gov/library/reference/orders/2017/eo18> (last visited March 24, 2019).

⁴ Codified in s. 893.055, F.S.

⁵ Section 893.055(2)(a), F.S.

⁶ Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2017-2018 Prescription Drug Monitoring Program Annual Report*, (Dec. 1, 2018), available at http://www.floridahealth.gov/statistics-and-data/e-forcse/health_care_practitioners/_documents/2018-pdmp-annual-report.pdf (last visited March 24, 2019).

⁷ Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report*, (Dec. 1, 2013), available at http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited March 24, 2019).

⁸ Section 893.055(3), F.S. For a list of controlled substances, see s. 893.03, F.S., and 21 U.S.C. s. 812.

- The name of the person picking up the prescription and the type and issuer of the identification provided; and
- Other appropriate identifying information as determined by DOH rule.

Current law does not require the following to be reported to the PDMP:⁹

- All acts of administration of controlled substances;¹⁰
- Controlled substances dispensed within the Department of Correction's health care system; and
- Controlled substances dispensed to those under the age of 16.

Access to PDMP Data

Direct Access

Direct access to the PDMP database is presently limited to a pharmacy, prescriber, or dispenser or the designee of a pharmacy, prescriber, or dispenser.¹¹ The program manager¹² and the program manager's designated staff, may also directly access the PDMP.¹³ The program manager access is for program administration, which may include responding to requests from those with indirect access to the system.¹⁴

Indirect Access

In Florida, the following entities may indirectly access PDMP data:¹⁵

- DOH and its relevant health care regulatory boards;
- The Attorney General to investigate Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances;
- A medical examiner when conducting an authorized investigation to determine the cause of death of an individual;
- An impaired practitioner consultant retained by DOH to review the PDMP data of an impaired practitioner program participant and who has agreed to the consultant's access to and review of such information; and
- A patient, or the legal guardian or designated health care surrogate of an incapacitated patient, for verifying the accuracy of database information.

Entities with indirect access to the PDMP database may request information from the PDMP program manager that is otherwise confidential and exempt from public disclosure under s. 893.0551, F.S.¹⁶ Prior to release, the PDMP program manager must verify the legitimacy of the request.¹⁷

The data in the PDMP database is intended to be informational only.¹⁸ It may not be used in civil or administrative cases against a prescriber, dispenser, pharmacy, or patient. Current law prohibits

⁹ Section 893.055(3)(b), F.S.

¹⁰ "Administration" means obtaining and giving a single dose of a controlled substance by a legally authorized person to a patient for her or his consumption (s. 893.055(1)(b), F.S.)

¹¹ Section 893.055(4), F.S.

¹² The program manager is an employee of DOH who is designated to ensure the integrity of the PDMP in accordance with law (s. 893.055(1)(j), F.S.)

¹³ Section 893.055(4)(c), F.S.

¹⁴ Id.

¹⁵ Section 893.055(5), F.S.

¹⁶ Id.

¹⁷ Section 893.0551(3), F.S.

¹⁸ Section 893.055(10), F.S.

program staff from testifying in any civil or administration action as to any findings, recommendations, evaluations, opinions, or other actions taken while managing the system.

Medicaid Fraud and Abuse

Medicaid is a jointly funded partnership of the federal and state governments that provides access to health care for low-income families and individuals. The Agency for Health Care Administration (AHCA) administers the Florida Medicaid program. AHCA establishes reimbursement for services provided to Medicaid recipients through various methodologies which may include fee schedules, cost-based reimbursement, negotiated fees, competitive procurement and other mechanisms that are efficient and effective for purchasing services or goods on behalf of recipients.¹⁹ Reimbursement is limited to claims for services provided for covered injuries or illnesses²⁰ by a provider with a valid Medicaid provider agreement.²¹

Federal regulation requires each state to detect and investigate Medicaid fraud and abuse.²² AHCA's Office of Medicaid Program Integrity (MPI) and the Medicaid Fraud Control Unit (MFCU) in the Office of the Attorney General are responsible for ensuring that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and for recovering overpayments and imposing sanctions as appropriate.²³

MPI is statutorily required to develop statistical methodologies to identify providers who exhibit aberrant billing patterns.²⁴ Any suspected criminal violation identified by AHCA is referred to the MFCU. MFCU is responsible for investigating and prosecuting provider fraud within the Medicaid program which commonly involves fraud related to providers' billing practices, including billing for services that were not provided, overcharging for services that were provided, and billing for services that were not medically necessary.²⁵

Last year, the PDMP responded to 121 requests for data by MFCU.²⁶

Effect of Proposed Changes

CS/HB 1253 requires the Department of Health (DOH) to assign a unique identifier to each patient with a record in the PDMP. The unique identifier must not indicate a patient's identity, or provide a reasonable basis by which an unauthorized person may discover a patient's identity.

The bill permits the Attorney General to indirectly access PDMP data for an active or pending criminal or civil investigation involving controlled substances. For cases other than those involving Medicaid fraud, DOH may not release a patient's personal identification information and may only release limited information regarding a patient's:

- Unique identifier assigned by DOH;
- Year of birth;
- Gender; and
- City, county, and zip code of residence.

¹⁹ Section 409.908, F.S.

²⁰ "Covered injury or illness" means any sickness, injury, disease, disability, deformity, abnormality disease, necessary medical care, pregnancy, or death for which a third party is, may be, could be, should be, or has been liable, and for which Medicaid is, or may be, obligated to provide, or has provided, medical assistance (s. 409.901(9), F.S.)

²¹ Section 409.907, F.S. Medicaid provider agreements are voluntary agreements between AHCA and a provider for the provision of services to Medicaid recipients and include background screening requirements, notification requirements for change of ownership, authority for AHCA site visits of provider service locations, and surety bond requirements.

²² 42 CFR 455.1.

²³ Section 409.913, F.S.

²⁴ Id.

²⁵ Id.

²⁶ Department of Health, 2019 Agency Legislative Bill Analysis for HB 1253.

The bill authorizes the Attorney General to use PDMP records from any time before or after the bill's effective date to investigate or pursue criminal or civil litigation.

The bill authorizes program staff to testify in a proceeding to authenticate PDMP records, but provides that PDMP information is not discoverable and may not be entered into evidence in a civil or administrative action against a prescriber or patient arising from a matter relating to PDMP information.

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B. SECTION DIRECTORY:

Section 1: Amends s. 893.055, F.S., relating to prescription drug monitoring program.

Section 2: Amends s. 893.0551, F.S., relating to public records exemption for the prescription drug monitoring system.

Section 3: Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may experience an indeterminate, negative fiscal impact associated with a potential increase in requests for PDMP information from the Attorney General, costs associated with trial preparation and travel if staff is required to authenticate records in a civil or administrative action,²⁷ and costs associated with developing and assigning unique identifiers to patients.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

²⁷ Id.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 19, 2019, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Directed the DOH to assign a unique identifier to every patient in the PDMP database;
- Authorized the Attorney General to have indirect access to the PDMP for any active investigation or pending legal action involving prescription drugs;
- Authorized DOH to release only the patient's unique identifier, date of birth, gender and the city, county, and zip code of residence in cases other than Medicaid fraud cases;
- Repealed the prohibition on PDMP data being used in civil or administrative actions against pharmacies and dispensers; and
- Authorized PDMP staff to testify in an administrative or civil action to authenticate PDMP records.

This analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.