HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1253 Prescription Drug Monitoring Program
SPONSOR(S): Health & Human Services Committee, 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	18 Y, 0 N, As CS	Siples	Calamas

SUMMARY ANALYSIS

The Florida prescription drug monitoring programs (PDMP) is a state-run electronic database used to track 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 authorizes the Attorney General to indirectly access PDMP data for active criminal or civil investigations or pending criminal or civil litigation 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 personally identifying information. The bill requires the Attorney General to maintain the confidential and exempt status of PDMP information, and provides that it may only be release in response to a relevant discovery demand.

The bill authorizes program staff to testify in legal proceedings to authenticate PDMP records and authorizes PDMP information to be entered into evidence in a civil or administrative action against a dispenser or pharmacy.

The bill 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.

Under current law, DOH may authorize the PDMP database to interface with electronic health recordkeeping systems that are maintained by health care providers and practitioners. The bill defines "electronic health recordkeeping system," to clarify the types of software applications that may access the system.

The bill may have an indeterminate, negative fiscal impact on the Department of Health. The bill has no fiscal impact on local governments.

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;

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[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 Corrections health care system; and
- Controlled substances dispensed to those under the age of 16.

PDMP Data Sharing

In 2018, the Legislature authorized DOH to allow the PDMP database to interface with a health care provider's or practitioner's electronic health recordkeeping system through a secure connection.[11] An electronic health record is a record of a person's medical treatment that is created by a licensed health care provider or practitioner and stored in an interoperable and accessible digital format.[12] There may be multiple technologies that contribute or interchange with that electronic health record, and are a part of health care provider's or practitioner's electronic health recordkeeping system. However, there is no statutory definition of electronic health recordkeeping system which has caused some confusion on what types of software applications may access the PDMP database.

Access to PDMP Data

Direct Access

Direct access to the PDMP database is limited to a pharmacy, prescriber, or dispenser or the designee of a pharmacy, prescriber, or dispenser.[13] The program manager[14] and the program manager's designated staff, may also directly access the PDMP.[15] The program manager access is for program administration, which includes responding to requests from those with indirect access to the system.[16]

Indirect Access

In Florida, the following entities may indirectly access PDMP data:[17]

- 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 such information; and

[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(7), F.S.
[12] Section 408.051(2)(a), F.S.
[13] Section 893.055(4), F.S.
[14] 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.
[15] Section 893.055(4)(c), F.S.
[16] Id.
[17] Section 893.055(5), F.S.

- 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.[18] Prior to release, the PDMP program manager must verify the legitimacy of the request.[19]

The data in the PDMP database is intended to be informational only.[20] It may not be in used in civil or administrative cases against a prescriber, dispenser, pharmacy, or patient. Current law prohibits 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.[21] There are 16 other states that, like Florida, statutorily prohibit PDMP information from being used in civil litigation.[22] Two states, California and Connecticut, permit the use of PDMP data for civil purposes, and other states are silent on the matter.[23]

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.[24] Reimbursement is limited to claims for services provided for covered injuries or illnesses[25] by a provider with a valid Medicaid provider agreement.[26]

Federal regulation requires each state to detect and investigate Medicaid fraud and abuse.[27] 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.[28]

MPI is statutorily required to develop statistical methodologies to identify providers who exhibit aberrant billing patterns.[29] 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.[30]

[18] Id.
[19] Section 893.0551(3), F.S.
[20] Section 893.055(10), F.S.
[21] Id.
[22] Those states are: Alabama, Arkansas, Colorado, Kansas, Kentucky, Louisiana, Maryland, Montana, New Hampshire, New Mexico, North Carolina, Ohio, Tennessee, Utah, Virginia, and West Virginia.
[23] *See* Conn. Agencies Regs. s. 21a-254-6 and CAL. HEALTH & SAFETY CODE s. 11165, respectively.
[24] Section 409.908, F.S.
[25] "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.)
[26] 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.
[27] 42 CFR s. 455.1.
[28] Section 409.913, F.S.
[29] Id.
[30] Id.

Last year, the PDMP responded to 121 requests for data by MFCU.[31]

Attorney General Opioid Litigation

In May 2018, the Florida Attorney General (AG) filed an action in state court against opioid manufacturers, distributors, and sellers for their role in the national opioid crisis.[32] The complaint alleges that the defendants caused the opioid crisis by, among other things:[33]

- 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; and
- Paying ostensibly neutral medical experts who were really manufacturer mouthpieces to publish articles promoting the use of opioids to treat pain while omitting information regarding the risks;
- Marketing the manufacturers' opioid products to pharmacies;
- Failing to properly assess customers to determine the validity of orders;
- Failing to report suspicious orders of opioids despite knowing their customers' opioid orders were inordinately high;
- Continuing to fill suspicious orders for opioids from their Florida customers; and
- Despite massive fines, continuing to allow diversion to occur on an enormous scale.

The litigation is ongoing. Currently, the AG does not have statutory authority to access PDMP data for cases unrelated to Medicaid fraud, and current law prohibits the use of PDMP data for civil or administrative cases against patients, prescribers, pharmacies, and dispensers.

Effect of Proposed Changes

CS/CS/HB 1253 requires 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 investigation or pending civil or criminal litigation 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; and
- City, county, and zip code of residence.

The bill authorizes the Attorney General to introduce PDMP information into evidence in a civil, criminal, or administrative action against a dispenser or pharmacy, but maintains the current law prohibition on such use against prescribers and patients. The bill authorizes DOH program staff to testify in a proceeding to authenticate PDMP records.

The bill requires the Attorney General to maintain the confidential and exempt status of PDMP information, and provides that it may only be release in response to a relevant discovery demand.

[31] Department of Health, *2019 Agency Legislative Bill Analysis for HB 1253*, on file with the Health Quality Subcommittee.
[32] Florida Office of the Attorney General, *Combating the National Opioid Crisis*, available at http://myfloridalegal.com/pages.nsf/Main/D0263EB06FDFD00F8525828E0064EE0F (last visited April 3, 2019). An amended complaint was filed in November 2018.
[33] Florida Office of the Attorney General, *Florida's Opioid Lawsuit*, available at http://myfloridalegal.com/webfiles.nsf/WF/MNOS-AYSNED/$file/Complaint+summary.pdf (last visited April 3, 2019).

The bill defines “electronic health recordkeeping system” as an electronic or computer-based information system used by a health care practitioner or provider to create, collect, store, manipulate, exchange, or make available personal health information for the delivery of patient care.

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

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 insignificant, 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,[34] and costs associated with developing and assigning unique identifiers to patients. These impacts can be absorbed within existing resources.

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.

[34] 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.

On April 9, 2019, the Health and Human Services Committee adopted a strike-all amendment and two amendments to the amendment and reported the bill favorably as a committee substitute. The amendments:

- Clarified that the Attorney General may only obtain de-identified patient information from the PDMP for active investigations or pending civil or criminal litigation involving controlled substances, for cases other than Medicaid fraud cases;
- Clarified that the Attorney General may introduce into evidence de-identified patient information from the PDMP in civil, criminal, or administrative actions against a dispenser;
- Defined "electronic health recordkeeping system;"
- Made technical corrections; and
- Changed the effective date to upon becoming a law.

This analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.