

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS
FINAL BILL ANALYSIS**

BILL #: CS/CS/HB 1253 Prescription Drug Monitoring Program
SPONSOR(S): Health & Human Services Committee and Health Quality Subcommittee, Mariano and others
TIED BILLS: IDEN./SIM. **BILLS:** CS/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
FINAL HOUSE FLOOR ACTION: 111 Y's 0 N's			
GOVERNOR'S ACTION: Approved			

SUMMARY ANALYSIS

CS/CS/HB 1253 passed the House on April 29, 2019, as amended, and subsequently passed the Senate on May 3, 2019.

The Florida prescription drug monitoring program (PDMP) is a state-run electronic database used to track prescribing and dispensing of certain controlled prescription drugs. 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.

The bill authorizes the Attorney General to indirectly access de-identified patient information in the PDMP database for an active investigation or pending criminal or civil litigation involving prescribed controlled substances. For cases other than those involving Medicaid fraud, the Department of Health (DOH) may release de-identified patient information that is compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) under the following conditions:

- A trial court must grant a petition or motion for the release of information;
- The information obtained is only used for the matter requested in the petition or motion;
- The Attorney General maintains a log of each person with whom the information is shared; and
- The Attorney General executes a confidentiality agreement or an agreement bound by a protective order with each person with whom the information is shared and ensures the security and disposal of the information at the conclusion of the matter for which it is shared.

The bill authorizes the Attorney General to enter PDMP information into evidence in a civil, criminal, or administrative action against a dispenser, manufacturer, or pharmacy and authorizes program staff to testify in legal proceedings to authenticate this information.

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 DOH. The bill has no fiscal impact on local governments.

The bill was approved by the Governor on June 24, 2019, chapter 2019-127, Laws of Florida. The effective date of this bill is July 1, 2019.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h1253z1.HQS.DOCX

DATE: 6/25/2019

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

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;

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 May 7, 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 May 7, 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 May 7, 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 May 7, 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.

- Whether the drug dispensed is an initial prescription or a refill, and the number of refills order;
- 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 manager¹⁴ 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;

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.

- 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
- 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 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 illnesses²⁵ 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

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.

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

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.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The federal Health Insurance Portability and Accountability Act (HIPAA), enacted in 1996, protects personal health information (PHI).³⁴ In 2000, the U.S. Department of Health and Human Services promulgated privacy rules which established national standards to protect medical records and other PHI held by a covered entity or its business associate.³⁵ These rules address, among other things, the use and disclosure of an individual's PHI. PHI is information that identifies an individual and identifies:³⁶

³⁰ Id.

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 May 7, 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](http://myfloridalegal.com/webfiles.nsf/WF/MNOS-AYSNED/$file/Complaint+summary.pdf) (last visited May 7, 2019).

³⁴ Pub. L. No. 104-191 (1996). Protected health information includes all individually identifiable health information held or transmitted by a covered entity or its business associate.

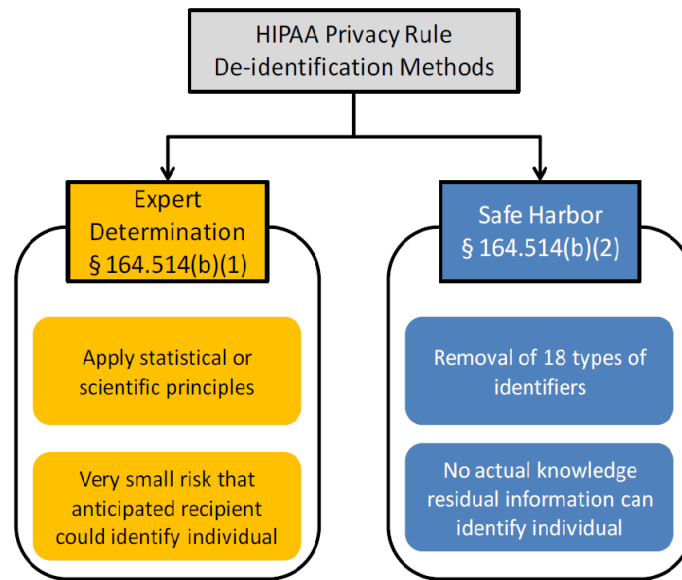
³⁵ U.S. Department of Health and Human Services, *Health Information Privacy*, available at <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html> (last visited May 7, 2019). The rules were modified in 2002. Covered entities include health plans, health care providers, and health care clearinghouses.

³⁶ U.S. Department of Health and Human Services, Office for Civil Rights, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, (Nov. 2012), available at https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf (last visited May 7, 2019).

- An individual's past, present, or future physical or mental health condition;
- The provision of health care to an individual; or
- The past, present, or future payment for the provision of health care to an individual.

Identification information alone, such as a name or address, is not necessarily PHI, but if such information is listed with a health condition or health payment data, then the information is PHI.³⁷

Under the privacy rule, a covered entity or its business associate may create information that is not individually identifiable by following the authorized de-identification standard. The privacy rule requires that de-identified health information does not identify an individual and does not provide a reasonable basis to believe that the information can be used to identify an individual.³⁸ There are two methods by which health information may be designated as de-identified.³⁹



The expert determination method requires a person with the appropriate knowledge of and experience with generally accepted statistical and scientific principals and to apply such principals and methods and determine that the risk is very small that the anticipated recipient may use the information, alone or in combination with other available information, to identify the subject of the information.⁴⁰

The safe harbor method requires the following to be removed:⁴¹

- Name;
- Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, except for the initial three digits of the zip code if the zip code with the three initial digits contain more than 20,000 people;⁴²
- All elements of dates (except year), if directly related to the individual's birth date, admission date, discharge date, death, and death date;⁴³
- Telephone numbers;

³⁷ Id.

³⁸ Id.

³⁹ Id.

⁴⁰ Id.

⁴¹ Id.

⁴² If there are fewer than 20,000 people, the initial three digits of the zip code must be 000.

⁴³ For all ages over 89, the elements may be aggregated into a single category of age 90 or older.

- Fax numbers;
- E-mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate or license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web universal resource locators (URLs);
- Internet protocol (IP) addresses;
- Biometric identifiers, including finger and voice prints;
- Full-face photographs and any comparable images; and
- Any other unique identifying number, characteristic, or code, except as permitted under the privacy rule.

The privacy rule authorizes a covered entity to assign a code or other means to allow information that has been de-identified to be re-identified by the covered entity.⁴⁴ The re-identification code or means must not be derived from or related to information about the individual. The re-identification code or means must also not be used or disclosed for any other purpose and may not disclose the mechanism for re-identification.

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 authorizes the Attorney General to indirectly access de-identified patient information in the PDMP database for an active investigation or pending criminal or civil litigation involving prescribed 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.

Such information must be HIPAA-compliant and may only be released under the following conditions:

- A trial court must grant a petition or motion for the release of information upon a determination that the release of such information appears reasonably calculated to lead to the discovery of admissible evidence;⁴⁵
- The information obtained is only used for the matter requested in the petition or motion;
- The Attorney General maintains a log of each person with whom the information is shared; and
- The Attorney General executes a confidentiality agreement or an agreement bound by a protective order with each person with whom the information is shared and ensures the security and disposal of the information at the conclusion of the matter for which it is shared.

⁴⁴ *Supra* note 36.

⁴⁵ The bill only requires notice of a petition or motion to parties in pending civil litigation.

The bill authorizes the Attorney General to introduce PDMP information into evidence in a civil, criminal, or administrative action against a dispenser, manufacturer, 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.

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.

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,⁴⁶ 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.

⁴⁶ Id.