

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

BILL #: CS/CS/HB 375 Prescription Drug Monitoring Program
SPONSOR(S): Health & Human Services Committee and Health Quality Subcommittee, Pigman and others
TIED BILLS: IDEN./SIM. **BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee	17 Y, 0 N, As CS	Siples	Calamas
FINAL HOUSE FLOOR ACTION: 114 Y's 0 N's			
GOVERNOR'S ACTION: Approved			

SUMMARY ANALYSIS

CS/CS/HB 375 passed the House on April 24, 2019, and subsequently passed the Senate on May 3, 2019.

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 that all prescribers and dispensers consult the PDMP to review a patient's controlled substance dispensing history prior to prescribing or dispensing a controlled substance for any patient age 16 and older. A prescriber or dispenser may be subject to licensure discipline if he or she fails to consult the PDMP as required.

Hospice is a program of care and support for terminally ill patients. A specially-trained team of professionals and caregivers provide care for the patient's physical, emotional, social, and spiritual needs, and provides support to family caregivers.

CS/HB 375 exempts prescribers and dispensers from the requirement to consult the PDMP prior to prescribing or dispensing a controlled substance to a patient who has been admitted to hospice.

The bill also authorizes the Department of Health to enter into reciprocal agreements to share PDMP data with the U.S. Department of Veterans Affairs, the U.S. Department of Defense, and the federal Indian Health Service. Currently, practitioners employed by these entities may view Florida PDMP data; without a reciprocal agreement, Florida practitioners are not authorized to view PDMP data maintained by the entities.

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

The bill has no fiscal impact on state or local governments.

The bill was approved by the Governor on June 7, 2019, chapter 2019-70, Laws of Florida. The effective date of this bill is July 1, 2019.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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*, (last rev. Oct. 3, 2017), available at <http://www.cdc.gov/drugoverdose/pdmp/> (last visited May 3, 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 May 3, 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 3, 2019).

⁴ 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 3, 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 3, 2019).

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

PDMP Consultation

Each prescriber or dispenser or his or her designee must consult the PDMP to review a patient's controlled substance dispensing history prior to prescribing or dispensing a controlled substance for patients age 16 and older.¹¹ However, a prescriber or dispenser is not required to consult the PDMP if the system is not operational, as determined by DOH, or cannot be accessed by the health care practitioner due to a temporary technological or electrical failure.¹² A health care practitioner is also not required to consult the PDMP when prescribing or dispensing a non-opioid Schedule V drug.¹³

A health care practitioner who fails to consult the system as required is subject to a nondisciplinary citation for the initial offense.¹⁴ Any subsequent offense for failure to consult the PDMP will result in disciplinary action against the health care practitioner's license.¹⁵

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.¹⁶ In addition to Florida-licensed prescribers and dispensers, employees of the United States Department of Veterans Affairs (VA), the United States Department of Defense, and the federal Indian Health Service who are authorized to prescribe or dispense controlled substances and hold an active, unrestricted license in another state have direct access to the PDMP.¹⁷

The Department of Defense provides health care services to its members, retirees, and their dependents at military treatment facilities, 13 of which are located in Florida.¹⁸ Florida also has 20

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(8), F.S.

¹² Section 893.055(8)(a), F.S.

¹³ A "non-opioid controlled substance" as a controlled substance that does not contain any amount of a substance listed as an opioid as defined under the state or federal controlled substance laws (s. 893.055(8), F.S.)

¹⁴ Section 893.055(8)(c), F.S.

¹⁵ *Id.*

¹⁶ Section 893.055(4), F.S. The program manager and the program manager's designated staff, may also directly access the PDMP. The program manager access is for program administration, which may include responding to requests from those with indirect access to the system.

¹⁷ Section 893.055(1)(d), F.S., defines health care practitioner for the purpose of the PDMP program as those practitioners who are subject to licensure or regulation by DOH under ch. 458, F.S., (Medicine), ch. 459, F.S., (Osteopathic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 462, F.S., (Naturopath), ch. 463, F.S., (Optometry), ch. 464, F.S., (Nursing), ch. 465, F.S., (Pharmacy), or ch. 466, F.S., (Dentistry).

¹⁸ See <https://tricare.mil/mtf> (last visited May 3, 2019).

major military installations.¹⁹ Military members, retirees, and their families may access health care services at either military treatment facilities, civilian health care providers, or both.

The Veterans Health Administration within the United States Department of Veterans Affairs (VA) operates one of the nation's largest integrated health care systems, providing care at more than 1,250 health care facilities.²⁰ The system is divided into 23 integrated service networks.²¹ Each service network is comprised of medical centers or hospitals, which oversee the clinics in their regions. Florida is a part of the Sunshine Health Network, which is comprised of eight medical centers and nearly 60 community clinics, and has the fourth largest veteran population in the U.S.²²

The Indian Health Service (IHS) is an agency within the U.S. Department of Health and Human Services that is responsible for providing federal health services to American Indians and Alaska Natives.²³ There are at least five locations in Florida that provide health services to this population.²⁴

Indirect Access

In Florida, the following entities may indirectly access PDMP data:²⁵

- 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.²⁶ Prior to release, the PDMP program manager must verify the legitimacy of the request.²⁷

¹⁹ Enterprise Florida, *Florida's Military Profile*, available at http://www.enterpriseflorida.com/wp-content/uploads/Military_Install_Map.pdf (last visited May 3, 2019).

²⁰ U.S. Department of Veterans Affairs, *Veterans Health Administration*, available at <https://www.va.gov/health/> (last visited May 3, 2019).

²¹ U.S. Department of Veterans Affairs, *Locations*, available at <https://www.va.gov/directory/guide/division.asp?dnum=1> (last visited May 3, 2019).

²² U.S. Department of Veterans Affairs, Veterans Health Administration, VA Sunshine Healthcare Network (VISN 8), *2018 Annual Report*, available at https://www.visn8.va.gov/VISN8/news/documents/V-508CLEAN_VISN8_2018AnnualReport.pdf (last visited May 3, 2019).

²³ Indian Health Service, *About IHS*, available at <https://www.ihs.gov/aboutihs/> (last visited May 3, 2019).

²⁴ See <https://www.ihs.gov/findhealthcare/#> (last visited May 3, 2019). Enter "Florida" as the search criteria for a list of facilities. Facilities are located in Okeechobee, Clewiston, Immokalee, Miami, and Hollywood.

²⁵ Section 893.055(5), F.S.

²⁶ Id.

²⁷ Section 893.0551(3), F.S.

PDMP Data Sharing

DOH may enter into a single multistate agreement or reciprocal agreements with individual states to share PDMP information with other states or jurisdictions, as long as the other states' PDMP systems are compatible with Florida's.²⁸ To determine compatibility, DOH must consider:²⁹

- The other state's safeguards for the privacy of patient records and the program's success in protecting patient privacy;
- The individuals authorized to view the information in the database and whether such access is comparable to the persons authorized in this state;
- The schedules of controlled substances that are monitored in the other state's program;
- The data reported to or included in the other state's system;
- Any implementing criteria deemed essential for a thorough comparison; and
- The costs and benefits to Florida of sharing prescription information.

DOH must assess such compatibility every four years.³⁰ Any agreement that DOH enters into for sharing PDMP database information must contain the same restrictions on access as Florida law, including privacy protections.³¹ Currently, DOH shares PDMP data with Alabama, Connecticut, Delaware, Georgia, Louisiana, Maine, Minnesota, Michigan, Mississippi, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Virginia, and Wisconsin.³²

DOH may only enter into such reciprocal agreements with other U.S. states and jurisdictions, but does not have authority to enter into a reciprocal agreement to share PDMP data with the U.S. Department of Veterans Affairs, the U.S. Department of Defense, or the federal Indian Health Service. Health care practitioners employed by these entities are currently able to view Florida PDMP data; but without a reciprocal agreement, Florida practitioners may not access the controlled substance dispensing history of patients maintained by these entities.

DOH may also allow the PDMP database to interface with a health care provider's or practitioner's electronic health recordkeeping system through a secure connection.³³ 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.³⁴ 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 the types of software applications that may access the PDMP database.

Hospice

Hospice is a program of care and support for terminally ill patients.³⁵ A specially-trained team of professionals and caregivers provide care for the terminally ill patient's physical, emotional, social, and spiritual needs, and provide support to family caregivers.³⁶ The team that provides hospice services

²⁸ Section 893.055(6), F.S.

²⁹ Section 893.055(6)(a), F.S.

³⁰ Section 893.055(6)(b), F.S.

³¹ Section 893.055(6)(c), F.S.

³² E-mail correspondence with DOH, dated March 22, 2019, (on file with the Health and Human Services Committee).

³³ Section 893.055(7), F.S.

³⁴ Section 408.051(2)(a), F.S.

³⁵ Section 400.6095(2), F.S., requires a physician to make a diagnosis and prognosis of terminal illness to admit a patient to hospice.

³⁶ *Id.*

includes physicians, nurses, medical social workers, spiritual and pastoral counselors, home health aides, therapists, bereavement counselors, and specially trained volunteers.³⁷ Hospice care includes:³⁸

- Nursing services;
- Social work services;
- Pastoral or counseling services;
- Dietary counseling;
- Bereavement counseling services;
- Physician services; and
- Other services needed to meet the palliative and support needs of the patient and family, which may include:
 - Physical or occupational therapy, or speech-language pathology services;
 - Massage therapy;
 - Home health aide services;
 - Homemaker and chore services;
 - Infusion therapy;
 - Medical supplies and durable medical equipment;
 - Day care; and
 - Funeral services.

Hospice care may be provided to a patient in an inpatient hospice facility, in the patient's home, or in another facility, such as a hospital or a nursing home.³⁹ Hospices provide four levels of care:⁴⁰

- **Routine care:** Hospice services are provided at home or in a home-like setting. The patient's family provides primary care, with the assistance of the hospice team.
- **Continuous care:** Skilled nursing services are provided in the patient's home during a medical crisis.
- **Inpatient care:** Hospice services are provided in a healthcare facility for symptoms of a medical crisis that cannot be managed in the patient's home. Inpatient care is provided on a temporary basis as determined by the patient's physician and the hospice team.
- **Respite care:** Hospice services are provided in a healthcare facility and is primarily to provide the patient's family members and caretakers with a period of relief.

Effect of Proposed Legislation

CS/HB 375 exempts prescribers and dispensers from the requirement to consult the PDMP prior to prescribing or dispensing a controlled substance to a patient who has been admitted to hospice.

The bill also authorizes DOH to enter reciprocal agreements to share PDMP data with the U.S. Department of Veteran Affairs, U.S. Department of Defense, and Indian Health Services. Upon execution of an agreement to share such information, Florida practitioners will be able to access the controlled substance dispensing history of patients treated by the health care practitioners employed by these entities.

The bill also 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.

³⁷ Florida Hospice and Palliative Care Association, *About Hospice*, <http://www.floridahospices.org/hospice-palliative-care/about-hospice/> (last visited May 3, 2019).

³⁸ Section 400.609, F.S.

³⁹ *Id.*

⁴⁰ *Supra* note 37.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.