

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 313 Prescription Drug Monitoring Program

**SPONSOR(S):** Health Quality Subcommittee; Pilon

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Langston	O'Callaghan
2) Health & Human Services Committee	15 Y, 0 N	Langston	Calamas

### SUMMARY ANALYSIS

Chapter 2009-197, Laws of Fla., established the Prescription Drug Monitoring Program (PDMP) within the Department of Health in s. 893.055, F.S. The PDMP uses a database to monitor the prescribing and dispensing of certain controlled substances.

Dispensers of controlled substances listed in Schedule II, III, or IV must report specified information to the PDMP database, including the name of the prescriber, the date the prescription was filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed. Dispensers must report dispensing to the PDMP database within seven days of dispensing the controlled substance.

However, in certain instances, health care practitioners are exempt from the PDMP reporting requirements. Dispensing and administering controlled substances are exempt in certain health care settings where there is a low risk of controlled substances being overprescribed or diverted. Specifically, the following acts are not required to be reported:

- A health care practitioner administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- A pharmacist or health care practitioner administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- A practitioner administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- A practitioner administering a controlled substance in the emergency room of a licensed hospital.
- A health care practitioner administering or dispensing a controlled substance to a person under the age of 16.
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.

CS/HB 313 adds a PDMP reporting exemption for a rehabilitative hospital, an assisted living facility, or a nursing home when they dispense a controlled substance to a patient as ordered by the patient's treating physician. Consistent with current reporting exemptions, the bill exempts health care settings where there is a low risk of overprescribing or diverting controlled substances from the reporting requirements.

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

The bill provides an effective date of July 1, 2016.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Background

##### 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.<sup>1</sup> PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with critical information regarding a patient's controlled substance prescription history.<sup>2</sup>

Chapter 2009-197, Laws of Fla., established Florida's PDMP within the Department of Health (DOH) in s. 893.055, F.S. The PDMP uses a database to monitor the prescribing and dispensing of certain controlled substances.<sup>3</sup> The PDMP database became operational on September 1, 2011, when it began receiving prescription data, retroactive to December 1, 2010, from pharmacies and dispensing practitioners.<sup>4</sup> By September 2013, 49 states either had an operational PDMP database or had adopted legislation authorizing the creation of one.<sup>5</sup>

##### *PDMP Reporting Requirements*

Dispensers of controlled substances listed in Schedule II, III, or IV of the Florida Comprehensive Drug Abuse Prevention and Control Act must report specified information to the PDMP database.<sup>6</sup> The following information is submitted for inclusion in the PDMP database:

- The name of the prescribing practitioner, the practitioners 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, 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, federal DEA registration number, and address of the pharmacy, other location, or other practitioner from which the controlled substance was dispensed;
- The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's NPI; and
- Other appropriate identifying information as determined by DOH rule.

Dispensers must report dispensing a specified controlled substance to the PDMP database within seven days.<sup>7</sup> By the end of February 2014, more than 90 percent of pharmacies required to report data to the PDMP had uploaded information into the system within the seven-day statutory limit.<sup>8</sup> By that same time, more than 6,100 dispensers had reported over 100 million dispensing records to the PDMP

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<sup>1</sup> Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs*, <http://www.cdc.gov/drugoverdose/pdmp/> (last visited January 14, 2016).

<sup>2</sup> *Id.*

<sup>3</sup> S. 893.055(2)(a), F.S.

<sup>4</sup> Florida Department of Health, *Overview and Status Update of the PDMP*, PowerPoint presentation before Health Quality Subcommittee, Sept. 24, 2013, page 3 (on file with Health Quality Subcommittee staff).

<sup>5</sup> Brandeis University, Institute of Behavioral Health, and the U.S. Department of Justice, Bureau for Justice Assistance, PDMP Center of Excellence, *Addressing the Problem*, <http://pdmpeexcellence.org/content/addressing-problem> (last visited January 14, 2016).

<sup>6</sup> S. 893.055(3)(a)-(c), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.

<sup>7</sup> S. 893.055(4), F.S.

<sup>8</sup> Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2013-2014 Prescription Drug Monitoring Program Annual Report*, Dec. 1, 2014, available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/2014-pdmp-annual-report-final.pdf> (last visited January 18, 2016).

since the program became operational.<sup>9</sup> On average, each month 5,585 pharmacy dispensers report controlled substance prescription information to the PDMP.<sup>10</sup>

### *Exemptions from PDMP Reporting Requirements*

The purpose of the PDMP is to track the dispensing of prescribed controlled substances to provide information to subsequent prescribing physicians and prevent the overprescribing of such substances, and also to prevent the diversion of such substances. However, there are some circumstances in which there is inherently a low risk of controlled substances being overprescribed or diverted, and in those circumstances, the law exempts practitioners from having to report the dispensing of controlled substances. Specifically, the following acts are not required to be reported:

- A health care practitioner administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session;
- A pharmacist or health care practitioner administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state;
- A practitioner administering or dispensing a controlled substance in the health care system of the Department of Corrections;
- A practitioner administering a controlled substance in the emergency room of a licensed hospital;
- A health care practitioner administering or dispensing a controlled substance to a person under the age of 16; and
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.<sup>11</sup>

### *Access to PDMP Database*

Direct access to the PDMP database is presently limited by law to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.<sup>12</sup> A pharmacy, prescriber, or dispenser has access to information in the PDMP database that relates to a patient of that pharmacy, prescriber, or dispenser, as needed, for reviewing the patient's controlled substance prescription history.<sup>13</sup>

Health care practitioners<sup>14</sup> began accessing the PDMP database on October 17, 2011.<sup>15</sup> From October 1, 2014 to September 30, 2015, 32,054 health care practitioners, or 20.7 percent of all licensed health care practitioners, were registered to use the PDMP Database.<sup>16</sup> Pharmacists have had the highest utilization rate of the PDMP; from October 1, 2014 to September 30, 2015, 89.6 percent of licensed pharmacists were trained to use the PDMP, 51.4 percent of pharmacists were registered to

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<sup>9</sup> Memorandum from Rebecca Poston, Program Manager for PDMP, and Bob MacDonald, Executive Director, The Florida PDMP Foundation, Inc., to Marco Paredes, Director of Legislative Planning, Florida Department of Health, Feb. 6, 2014, p. 1 (on file with Health Quality Subcommittee staff).

<sup>10</sup> Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2014-2015 Prescription Drug Monitoring Program Annual Report, Dec. 1, 2015, p. 5, available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/documents/2015-pdmp-annual-report.pdf> (last visited January 18, 2016).

<sup>11</sup> S. 893.055(5), F.S.

<sup>12</sup> S. 893.055(7)(b), F.S.

<sup>13</sup> Id.

<sup>14</sup> S. 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).

<sup>15</sup> 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 [www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf](http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf) (last visited November 13, 2015).

<sup>16</sup> *Supra*, note 10, p. 12

use the PDMP, and 89.1 percent of pharmacists registered to use the PDMP had queried it.<sup>17</sup> From October 1, 2014 to September 30, 2015, in-state prescribers issued 36,491,586 controlled substance prescriptions to 7,359,995 Florida residents.<sup>18</sup> During that same timeframe, 25,833 registered health care practitioners queried the PDMP database 21,167,947 times.<sup>19</sup>

In Florida, indirect access to the PDMP database is provided to:

- DOH and its relevant health care regulatory boards;
- The Attorney General for 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; and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient, for verifying the accuracy of database information.<sup>20</sup>

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.<sup>21</sup> Prior to release, the PDMP program manager must verify that the request is authentic and authorized with the requesting organization.<sup>22</sup>

#### *Public Records Exemption for Information in the PDMP Database*

Section 893.0551, F.S.,<sup>23</sup> provides that personal information of a patient and certain information concerning health care practitioners contained in the PDMP database are confidential and exempt from s. 119.07(1), F.S., and article I, section 24 of the Florida Constitution.<sup>24</sup> The statute makes confidential and exempt identifying information, including, but not limited to, the name, address, telephone number, insurance plan number, government-issued identification number, provider number, Drug Enforcement Administration number, or any other unique identifying number of a patient, patient's agent, health care practitioner or practitioner as defined in s. 893.055, F.S., or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy, which is contained in the PDMP database.

Any agency or person that obtains information pursuant to s. 893.0551, F.S., must maintain the confidential and exempt status of that information.<sup>25</sup>

#### **Effect of Proposed Changes**

CS/HB 313 adds a PDMP reporting exemption for a rehabilitative hospital, an assisted living facility (ALF), or a nursing home when they dispense a controlled substance to a patient as ordered by the patient's treating physician. Consistent with current law, which exempts dispensing and administering controlled substances from the PDMP reporting requirements in certain health care settings where there may be a lower risk of controlled substances being overprescribed or diverted, the bill exempts additional health care settings with similar risk levels from the PDMP reporting requirements. The bill provides an effective date of July 1, 2016.

#### **B. SECTION DIRECTORY:**

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<sup>17</sup> Id. at p. 12, 19.

<sup>18</sup> Id. at p. 15-16.

<sup>19</sup> Id. at p. 19.

<sup>20</sup> S. 893.055(7)(c)1.-4., F.S.

<sup>21</sup> S. 893.055(7)(c), F.S.

<sup>22</sup> Id.

<sup>23</sup> The public records exemption was established in 2009 in conjunction with the PDMP. See s. 1, ch. 2009-197, Laws of Fla. Additionally, the public records exemption was reauthorized in 2014. See s. 1 ch. 2014-156, Laws of Fla.

<sup>24</sup> S. 893.0551(2)(a)-(h), F.S.

<sup>25</sup> S. 893.0551(5), F.S. However, a law enforcement agency with lawful access to such information is permitted to disclose confidential and exempt information received from the DOH to a criminal justice agency as part of an active investigation of a specific violation of law. S. 893.0551(4).

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

**Section 2:** Provides an effective date.

## **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.

## **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.

2. Other:

None.

### **B. RULE-MAKING AUTHORITY:**

None.

### **C. DRAFTING ISSUES OR OTHER COMMENTS:**

None.

## **IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On November 17, 2015, the Health Quality Subcommittee adopted an amendment to delete the bill's requirement that a patient be transferred to the a rehabilitative hospital, an ALF, or a nursing home after surgery and the patient's physician directly order an advanced registered nurse practitioner at the facility to provide the controlled substance, if needed, to expand the exemption to the PDMP reporting requirements to include when a rehabilitative hospital, an ALF, or a nursing home dispenses a controlled substance, as needed, to a patient as ordered by the patient's treating physician.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.