#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

# BILL #: HB 1381 Prescription Drug Monitoring Program SPONSOR(S): Davis TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 2 N	Poche	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

## SUMMARY ANALYSIS

Chapter 2009-197, Laws of Fla., established the Prescription Drug Monitoring Program (PDMP) within the Department of Health (DOH) in s. 893.055, F.S. The PDMP uses a comprehensive electronic system/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 the dispensing of a specified controlled substance to the PDMP database within seven days of dispensing the controlled substance.

House Bill 1381 makes two substantive changes to current law by requiring:

- A physician to access the PDMP database and review a new patient's prescription drug history prior to issuing a prescription for a Schedule II, III, or IV controlled substance at the initial visit with the patient. The bill also makes any failure to comply with this requirement grounds for discipline against the license of the physician. Physicians are not required to access the PDMP database under current law.
- A law enforcement agency to submit a court order to the PDMP program manager in order to indirectly access information contained in the PDMP database.

The bill also makes comprehensive, but non-substantive, changes to the current law by reorganizing and rewording s. 893.055, F.S. The changes improve the clarity and functionality of the statute.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2014.

### **FULL ANALYSIS**

## I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

#### Background

#### Prescription Drug Monitoring Program

Chapter 2009-197, Laws of Fla., established the Prescription Drug Monitoring Program (PDMP) within the Department of Health (DOH) in s. 893.055. F.S. The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.<sup>1</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>2</sup>

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.<sup>3</sup> Dispensers must report the dispensing of a specified controlled substance to the PDMP database within seven days of dispensing the controlled substance.<sup>4</sup> As of February 2014, over 100 million dispensing records have been reported to the PDMP by more than 6.100 dispensers since the program became operational.<sup>5</sup>

Direct access to the PDMP database is presently limited by law<sup>6</sup> to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.<sup>7</sup> More than 24,000 prescribers and pharmacists have registered with the PDMP, and over 19,200 of those practitioners, or 79% of all registered practitioners, have gueried the database.<sup>8</sup>

Although Florida law does not require physicians to access the PDMP database to review a patient's controlled substance prescription history prior to prescribing the patient a controlled substance, many other states' laws contain such a requirement. The following map<sup>9</sup> shows the states (in yellow) that require prescribers or dispensers to access a "prescription management program" database, in certain circumstances.<sup>10</sup>

<sup>&</sup>lt;sup>1</sup> S. 893.055(2)(a), F.S.

<sup>&</sup>lt;sup>2</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>&</sup>lt;sup>3</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>4</sup> S. 893.055(4), F.S.

<sup>&</sup>lt;sup>5</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, February 6, 2014, page 1 (responding to request for updated information from Health Quality Subcommittee staff, on file with subcommittee).

<sup>&</sup>lt;sup>6</sup> S. 893.055(7)(b), F.S.

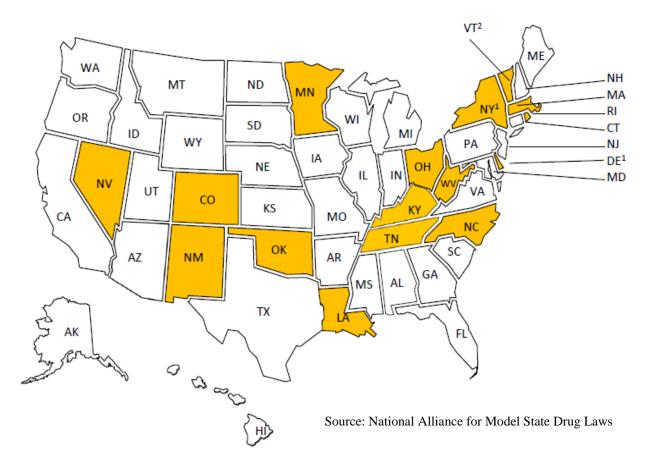
<sup>&</sup>lt;sup>7</sup> Health care practitioners began accessing the PDMP database on October 17, 2011. Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report, December 1, 2013, page 2, available at www.floridahealth.gov/reports-and-data/eforcse/news-reports/ documents/2012-2013pdmp-annual-report.pdf (last viewed on March 14, 2014).

See supra, FN 5 at page 1.

<sup>&</sup>lt;sup>9</sup> National Alliance for Model State Drug Laws, Prescription Drug Monitoring Programs, States that Require Prescribers and/or Dispensers to Access PMP In Certain Circumstances, Map. July 2013, available at

www.namsdl.org/library/15016036-1C23-D4F9-74B7207D8ED67C96 (last viewed on March 14, 2014). <sup>10</sup> The New York law went into effect in August 2013. Delaware began requiring dispensers to check the database in March 2014.

Vermont began requiring mandatory use for replacement prescriptions in October 2013 and in other circumstances in November 2013.



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

- The DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- A law enforcement agency;<sup>11</sup> and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient.<sup>12</sup>

Entities with indirect access to the PDMP database may request information from the PDMP program manager that is confidential and exempt under s. 893.0551, F.S., which is discussed below. A law enforcement agency, for example, may request such information during an active investigation regarding potential criminal activity, fraud, or theft relating to prescribed controlled substances.<sup>13</sup> As of February 2014, law enforcement agencies queried the PDMP database more than 36,000 times in conjunction with active criminal investigations.<sup>14</sup>

Florida law only requires the PDMP program manager to verify that a request from a law enforcement agency to query the database is authentic and that it is related to an active investigation, but no supporting documentation is required to be submitted to the PDMP program manager to query the database. The following map, by state, shows what documentation, if any, law enforcement agencies across the U.S. are required to submit before information from the PDMP database is released to those agencies.<sup>15</sup>

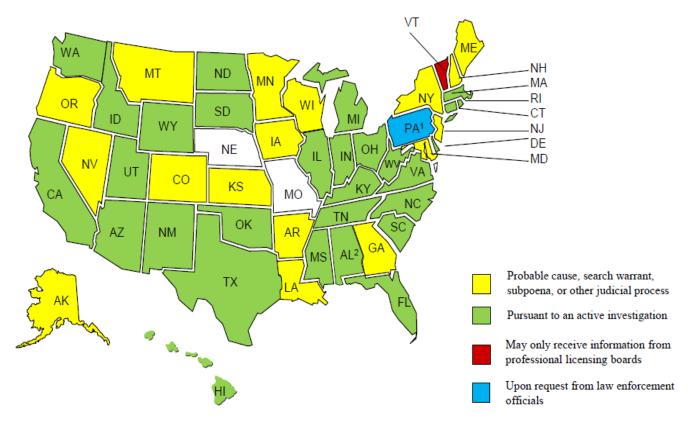
<sup>&</sup>lt;sup>11</sup> Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011. See *supra*, FN 7.

<sup>&</sup>lt;sup>12</sup> S. 893.055(7)(c)1.-4., F.S.

<sup>&</sup>lt;sup>13</sup> S. 893.055(7)(c)3., F.S.; see also 64K-1.003(2)(c), F.A.C.

<sup>&</sup>lt;sup>14</sup> See *supra*, FN 5 at page 2.

<sup>&</sup>lt;sup>15</sup> National Alliance for Model State Drug Laws, Prescription Drug Monitoring Programs, *Law Enforcement Access*, Map, July 2013, available at <u>www.namsdl.org/library/17AEB855-1C23-D4F9-7464F56193EA3DEC</u> (last viewed on March 14, 2014).



Source: National Alliance for Model State Drug

# Funding for the PDMP

Restrictions on how the DOH may fund implementation and operation of the PDMP are also included in statute. The DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.<sup>16</sup> Since 2010, the PDMP has spent \$1,519,297 for system and database infrastructure, personnel, and facility expenses.<sup>17</sup> Funding for the PDMP comes from three funding sources<sup>18</sup>:

1. Donations procured by the Florida PDMP Foundation, Inc. (Foundation), the direct-support organization authorized by s. 893.055(11), F.S., to fund the continuing operation of the PDMP. The following amounts have been donated to the Foundation since its inception<sup>19</sup>:

FY 2009-2010	\$125,000
FY 2010-2011	\$339,443
FY 2011-2012	\$120,010
FY 2012-2013	\$73,910

<sup>&</sup>lt;sup>16</sup> S. 893.055(10) and (11)(c), F.S.

<sup>&</sup>lt;sup>17</sup> Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report, December 1, 2013, page 8, available at <u>www.floridahealth.gov/reports-and-data/e-forcse/news-reports/ documents/2012-2013pdmp-annual-report.pdf</u> (on file with Health Quality Subcommittee staff); information also came from Florida Department of Health documents detailing the funding history of the PDMP, also on file with Health Quality Subcommittee staff.

<sup>&</sup>lt;sup>18</sup> See *supra*, FN 5 at pages 2-4.

<sup>&</sup>lt;sup>19</sup> Information contained in a document received from Florida Department of Health, on file with subcommittee staff. **STORAGE NAME:** h1381a.HQS **PAGE: 4 DATE:** 3/19/2014

FY 2013-2014	\$134,625
TOTAL	\$792,988

2. Federal Grants. The PDMP has been awarded four Harold Rogers Prescription Drug Monitoring Program ("Rogers") grants from the U.S. Department of Justice and one additional federal grant. The amount and purpose of each grant follows:

- A Rogers "Implementation" grant of \$400,000 to implement the prescription drug monitoring system. The grant project period ended August 31, 2012.
- A Rogers "Enhancement" grant of \$400,000 for system enhancements. The grant period ended March 31, 2013.
- A second Rogers "Enhancement" grant of \$399,300 to enhance collaborations with law enforcement agencies, enhance the PDMP's ability to analyze collected data to identify drug abuse trends and identify and address sources of prescription drug diversion, and increase the number of PDMP users. The grant period ends September 30, 2014.
- A third Rogers "Enhancement" grant of \$399,950 to form multi-disciplinary and multijurisdictional groups to identify areas of greatest risk for prescription drug abuse and diversion and create data-driven responses to these areas at the local level. The grant period ends March 31, 2015.
- A grant of \$240,105 from the Substance Abuse and Mental Health Services Administration to integrate PDMP data into existing clinical workflow and technology and to expand interoperability. The grant period ends September 30, 2014.

The total amount of federal grants received is \$1,839,355.

3. Private grants and donations. The DOH has been awarded three private grants from the National Association of State Controlled Substance Authorities. These grants, totaling \$49,952, were used to create a website, to purchase office equipment, and to purchase promotional items. The grant period ended on June 30, 2011, and \$44,886 was drawn down by the PDMP.

The following chart illustrates the breakdown of costs for the PDMP from FY 2012-13 through FY 2014-  $15.^{20}$ 

COST	FY 2012-13	FY 2013-14*	FY 2014-15*
Infrastructure	\$240,086	\$240,087	\$240,087
Personnel (2 FTEs)	\$211,016	\$209,454	\$209,454
Facilities	\$26,186	\$12,858	\$12,858
PDMP Enhancements	\$0	\$0	\$37,601
TOTAL	\$477,288	\$494,699	\$500,000

\*Projected

The PDMP is currently funded through fiscal year 2013-2014.<sup>21</sup>

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

Section 893.0551, F.S.,<sup>22</sup> provides an exemption from public records for personal information of a patient and certain information concerning health care professionals outlined in the statute.<sup>23</sup> The statute details exceptions for disclosure of information after the DOH ensures the legitimacy of the person's request for the information.<sup>24</sup> The statute makes confidential and exempt from the Public

<sup>&</sup>lt;sup>20</sup> See *supra*, FN 5 at page 4.

<sup>&</sup>lt;sup>21</sup> See s. 10, Ch. 2013-153, Laws of Fla. (appropriating \$500,000 for FY 2013-2014 for the general administration of the PDMP).

<sup>&</sup>lt;sup>22</sup> The public records exemption was established in 2009 in conjunction with the PDMP. See s. 1, ch. 2009-197, Laws of Fla.

<sup>&</sup>lt;sup>23</sup> S. 893.0551(2)(a)-(h), F.S.

<sup>&</sup>lt;sup>24</sup> S. 893.0551(3)(a)-(g), F.S.

Records Law<sup>25</sup> and s. 24(a), Art. 1 of the State Constitution 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, 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.

The DOH is required to disclose the confidential and exempt information to the following entities after verifying that entity's request for the information is legitimate:

- The Attorney General or his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs.
- Any relevant health care regulatory board within the DOH which is responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and is involved in a specific controlled substances investigation for prescription drugs involving a designated person.
- A law enforcement agency as defined in s. 119.011(4)(a), F.S., which enforces the laws of this state or the United States relating to controlled substances and which has initiated an ongoing and active investigation, as defined in ss. 119.011 and 893.07, F.S., involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances.
- A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055, F.S.
- A pharmacist, as defined in s. 465.003, F.S., who certifies that the requested information is to be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055, F.S.
- A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable making a request as provided in s. 893.055(7)(c), F.S.
- The patient's pharmacy, prescriber, or dispenser, as defined in s. 893.055, who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055, F.S.
- The program manager of the PDMP, the program and support staff, and individuals designated by the program manager as necessary to process validated requests for information or to perform database administrative tasks necessary to support the monitoring program.

Any agency that obtains information pursuant to s. 893.0551, F.S., must maintain the confidential and exempt status of that information.<sup>26</sup> 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.<sup>27</sup>

A person who willfully and knowingly violates the restrictions on the use of the confidential and exempt information commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.803, or s. 775.084, F.S.<sup>28</sup>

The exemption is subject to future review and repeal on October 2, 2014, in accordance with the Open Government Sunset Review Act.<sup>29</sup>

Recent Disclosure of PDMP Database Information

<sup>&</sup>lt;sup>25</sup> Ch. 119, F.S.

<sup>&</sup>lt;sup>26</sup> S. 893.0551(5), F.S.

<sup>&</sup>lt;sup>27</sup> S. 893.0551(4), F.S.

<sup>&</sup>lt;sup>28</sup> S. 893.0551(6), F.S.

<sup>&</sup>lt;sup>29</sup> The Open Government Sunset Review Act provides for the systematic review, through a 5-year cycle ending October 2 of the 5th year following enactment, of an exemption from the Public Records Act or the Sunshine Law. See s. 119.15, F.S.

In May 2013, members of a drug task force investigating prescription drug fraud and trafficking in central Florida queried the PDMP database for the prescription medication history of doctors and their pharmacies, and six individuals accused of forging prescriptions. The response to the query contained 3,300 patient names and prescription drug histories. The investigators uncovered, through verification by the doctors whose names were queried, 63 fictitious names and the stolen identities of seven other people. The six individuals were alleged to be using fictitious names and stolen identities to fraudulently obtain prescription drugs to be illegally distributed.

The State Attorney's Office in the Seventh Judicial Circuit of Florida, which was responsible for prosecuting the six individuals, provided defense counsel for five of the six accused persons with computer disks containing the 3,300 names and prescription drug histories. One defense counsel reviewed the information, recognized the name of a colleague, and disclosed the 3,300 names and prescription drug histories to the colleague, who was not involved in any of the six criminal cases resulting from the investigation.

The colleague, who was also a defense attorney, filed a lawsuit against the State Attorney seeking an injunction preventing the reviewing, revealing, copying, distributing, or discussing his private prescription medication history and seeking an order to require the State Attorney to notify the remaining 3,299 individuals that their names and prescription drug histories were published or disclosed by the State Attorney's Office. The lawsuit was dismissed by the circuit court in February 2014. However, the colleague refiled the lawsuit in March 2014, asking the court to declare unconstitutional s. 893.055(7)(c), F.S., and any other related provision which allows law enforcement agencies to access information in the PDMP database without a court order or search warrant. Litigation remains ongoing.

# **Effect of Proposed Changes**

The bill makes comprehensive, but non-substantive, changes to the current law by reorganizing and rewording s. 893.055, F.S. All of the substantive provisions governing the establishment, maintenance, and operation of the PDMP that are currently in the statute are included in the bill.

However, the bill makes two substantive changes to current law. First, the bill requires a physician to access the PDMP database and review a new patient's prescription drug history prior to issuing a prescription for a Schedule II, III, or IV controlled substance at the initial visit with the patient. The bill also makes any failure to comply with this requirement grounds for discipline against the license of the physician. Physicians are not required to access the PDMP database under current law.

Second, the bill allows a law enforcement agency to receive information from the PDMP database by submitting an order from a court of competent jurisdiction with the request for release of information to the PDMP program manager. Currently, a law enforcement agency may obtain information from the PDMP database by attesting to the reason for the request for information and must include a case number. Alternatively, a law enforcement agency may currently access records of dispensing histories at individual pharmacies.<sup>30</sup>

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2014.

# B. SECTION DIRECTORY:

Section 1: Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
Section 2: Amends s. 893.055, F.S., relating to prescription drug monitoring program.
Section 3: Provides an effective date of July 1, 2014.

### **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:

The bill requires a law enforcement agency to obtain an order from a court of competent jurisdiction and provide the order to the PDMP program manager to receive information from the PDMP database. The agency may realize administrative costs in preparing a motion or request for the order, arguing in favor of the order before a judge or through filings with the court, and transmitting the order to the court.

# **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:

The DOH has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

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