

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Rules

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BILL: CS/SB 862

INTRODUCER: Judiciary Committee and Health Policy Committee

SUBJECT: Prescription Drug Monitoring

DATE: April 8, 2014

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	<u>Looke</u>	<u>Stovall</u>		<b>HP SPB 7016 as introduced</b>
1.	<u>Munroe</u>	<u>Cibula</u>	<u>JU</u>	<b>Fav/CS</b>
2.	<u>Looke</u>	<u>Phelps</u>	<u>RC</u>	<b>Favorable</b>

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**I. Summary:**

CS/SB 862 amends section 893.055, F.S., relating to the prescription drug monitoring program to improve clarity by reorganizing text, rephrasing imprecise language, and deleting outdated or redundant language.

The bill also makes several substantive changes to:

- Require the Department of Health to adopt a user agreement rule that requires users to maintain procedures to protect the confidentiality of information from the prescription drug monitoring program's database;
- Require a law enforcement agency to execute the user agreement before information from the prescription drug monitoring program is released to the agency;
- Allow the Department of Health (DOH or department) to send only relevant information which is not personal identifying information to a law enforcement agency when the DOH determines a pattern consistent with indicators of controlled substance abuse exists;
- Provide requirements for the release of information from the prescription drug monitoring program's database shared with a state attorney in response to a discovery demand;
- Authorize a law enforcement agency to use information from the prescription drug program database to determine whether an active investigation is warranted;
- Allow DOH to provide a patient advisory report to the appropriate health care practitioner if the manager of the prescription drug monitoring program determines that a specified pattern exists;
- Define the term "dispense" or "dispensing" using existing language in the statute and in the definitions section of chapter 893, F.S.;
- Allow an impaired practitioner consultant retained by the DOH access to information in the prescription drug monitoring program's database which relates to a practitioner who has agreed to be evaluated or monitored by the consultant.

- Fund, subject to the General Appropriations Act, the prescription drug monitoring program with up to \$500,000 annually from excess collections related to the practice of pharmacy; and
- Eliminate the direct support organization for the prescription drug monitoring program.

## II. Present Situation:

### Florida's Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F, established the PDMP 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> Dispensers of certain controlled substances 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>2</sup>

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.<sup>3</sup> Dispensers have reported over 87 million controlled substance prescriptions to the PDMP since its inception.<sup>4</sup> Health care practitioners began accessing the PDMP on October 17, 2011.<sup>5</sup> Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.<sup>6</sup>

### Accessing the PDMP database

Section 893.0551, F.S., makes certain identifying information<sup>7</sup> of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055, F.S., confidential and exempt from the public records laws in s. 119.07(1), F.S., and s. 24(a), Article I of the State Constitution.<sup>8</sup>

Direct access to the PDMP database is presently limited to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.<sup>9</sup> Currently, prescribers are not required to consult the PDMP

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<sup>1</sup> Section 893.055(2)(a), F.S.

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

<sup>3</sup> Florida Health, *2012-2013 Prescription Drug Monitoring Program Annual Report*, available at <http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf>, last visited on March 19, 2014.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Such information includes name, address, telephone number, insurance plan number, government-issued identification number, provider number, and Drug Enforcement Administration number, or any other unique identifying information or number.

<sup>8</sup> Section 893.0551(2)(a)-(h), F.S.

<sup>9</sup> Section 893.055(7)(b), F.S.

database before prescribing a controlled substance for a patient however physicians and pharmacists queried the database more than 3.7 million times during fiscal year 2012-2013.<sup>10</sup>

Indirect access to the PDMP database is provided to:

- The DOH or certain health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- Law enforcement agencies during active investigations<sup>11</sup> involving potential criminal activity, fraud, or theft regarding prescribed controlled substances; and
- Patients, or the legal guardians or designated health care surrogates of incapacitated patients.<sup>12</sup>

Law enforcement agencies may receive information from the PDMP database through the procedures outlined in the DOH's "Training Guide for Law Enforcement and Investigative Agencies."<sup>13</sup> Agencies that wish to gain access to the PDMP database must first appoint a sworn law enforcement officer as an administrator who verifies and credentials other law enforcement officers within the same agency.<sup>14</sup> The administrator may then register individual law enforcement officers with the DOH.

Registered law enforcement officers may not directly access the PDMP, instead when they wish to obtain information from the PDMP database, they must submit a query to the DOH.<sup>15</sup> These queries may be for a patient's history, a prescriber's history, or a pharmacy's dispensing history.<sup>16</sup> The registered law enforcement officer must fill out a form indicating what type of search they want to perform, what parameters (name, date, time period, etc.) they want to include, and some details of the active investigation they are pursuing including a case number. This form is submitted to the DOH and, in most instances, the requested information is made available to the requesting officer. In some cases, a request is denied. Generally, a request is denied due to lack of sufficient identifying information (incorrect spelling of a name, wrong social security number, etc.) or, alternatively, a request may return no results. The DOH may also deny a request that it finds not to be authentic or authorized.<sup>17</sup>

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<sup>10</sup> *Supra* at n. 3

<sup>11</sup> Section 893.055(1)(h), F.S., defines an "active investigation" as an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

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

<sup>13</sup> This training guide may be found at

[http://www.hidinc.com/assets/files/flpdms/FL%20PDMP\\_Training%20Guide%20for%20Enforcement%20and%20Investigative%20Agencies.pdf](http://www.hidinc.com/assets/files/flpdms/FL%20PDMP_Training%20Guide%20for%20Enforcement%20and%20Investigative%20Agencies.pdf), last viewed on March 19, 2014.

<sup>14</sup> See the DOH's "Law enforcement administrator appointment form," available at <http://www.floridahealth.gov/reports-and-data/e-forcse/law-enforcement-information/documents/admin-appoint-form.pdf>, last visited on March 19, 2014.

<sup>15</sup> During FY 2012-2013 a total of 487 authorized law enforcement users queried the PDMP database 32,839 times. *Id.* at note 3.

<sup>16</sup> *Id.* at note 11.

<sup>17</sup> Section 893.055(7)(c), F.S., requires the DOH to verify a request as being "authentic and authorized" before releasing information from the PDMP.

## Funding 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>18</sup> Funding for the PDMP comes from three funding sources:<sup>19</sup>

- Donations procured by the Florida PDMP Foundation, Inc.;
- Federal grants; and
- Private grants and donations.

The Legislature appropriated \$500,000 of the DOH's general revenue funds during the 2013 session to fund the PDMP for fiscal year 2013-2014.<sup>20</sup>

## PDMP Direct-Support Organization

The Florida PDMP Foundation, Inc., (Foundation) is the direct-support organization authorized under the prescription drug monitoring program in s. 893.055, F.S. The Foundation is a not-for-profit Florida corporation that operates under contract with the department to acquire funding to support the PDMP. The Foundation transfers money to the department for the development, implementation, and ongoing operation of the PDMP.

Current law provides for the reversion, without penalty, to the state of all money and property held in trust by the Foundation for the benefit of the PDMP if the Foundation ceases to exist or if the contract is terminated.<sup>21</sup>

## Prescription Drug Monitoring Programs in Other States

As of December 2013, every state except Missouri has passed PDMP legislation and only New Hampshire and Washington, D.C., have yet to bring their PDMP to operation status.<sup>22</sup> The Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) examined the PDMPs of 26 of those states, including Florida.<sup>23</sup> All PDMPs examined are either run by the states in-house or by contract with private vendors. Most states do not require prescribers to register in order to use the PDMP and primarily encourage prescribers to use the database through education and outreach programs.<sup>24</sup> Only three of the 26 states require prescribers to access the database before prescribing most or all controlled substances.<sup>25</sup> In 17 of

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<sup>18</sup> Section 893.055(10) and (11)(c), F.S.

<sup>19</sup> Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE) webpage, available at <http://www.floridahealth.gov/reports-and-data/e-forcse/funding/index.html>, last visited on March 19, 2014.

<sup>20</sup> Chapter 2013-153, Laws of Fla.

<sup>21</sup> See s. 893.055(11)(d)4., F.S.

<sup>22</sup> National Alliance for Model State Drug Laws. *Compilation of State Prescription Monitoring Programs Maps*, can be found at <http://www.namsdl.org/library/> last visited on March 19, 2014.

<sup>23</sup> *OPPAGA Review of State Prescription Drug Monitoring Programs*, January 31, 2013, on file with the Senate Health Policy Committee.

<sup>24</sup> *Id.* at 8.

<sup>25</sup> Kentucky, New Mexico, and New York. *Id.* at 4.

23 states, including Florida, accessing the database is strictly voluntary, and in the remaining six states accessing the database is only required under limited circumstances.<sup>26</sup>

All states reviewed have the authority to take punitive action against dispensers of prescription drugs which do not comply with their state's respective laws and rules on their state's PDMP. These punitive actions can come in the form of fines, licensure disciplinary action, or criminal charges. However, states rarely use these punitive measures when dispensers do not comply with PDMP requirements.

As of December 5, 2013, 18 states require law enforcement agencies to obtain a search warrant, subpoena, court order, or other type of judicial process in order to access the information in their state's PDMP.<sup>27</sup>

### **Unauthorized Release of PDMP Data**

In the early summer of 2013, the PDMP information of approximately 3,300 individuals was improperly shared with a person or persons who were not authorized to obtain such information.<sup>28</sup> The original information was released from the PDMP by the DOH during a Drug Enforcement Administration (DEA) investigation of a ring of individuals who used four doctor's information to conduct prescription fraud. Although as a result of the investigation only six individuals were ultimately charged, the information of approximately 3,300 individuals was released to the DEA because the DEA searched the PDMP for the records of all the patients of the four doctors who had been the victims of the prescription drug fraud.<sup>29</sup> During the conduct of the investigation and the resulting prosecution, the DEA shared the full file with the prosecutor who, in turn, shared the full file with the defense attorney during discovery. The improper release of information occurred when a defense attorney associated with the case shared the file with a colleague who was not associated with the case.<sup>30</sup>

### **Reasonable Suspicion v. Probable Cause**

The terms reasonable suspicion and probable cause are legal terms of art that refer to the level of proof that be proffered before a certain action, generally a police action, may be taken. Reasonable suspicion is the lesser standard which is applied to actions such as Terry stops<sup>31</sup> and to searches in areas where there is a lesser expectation of privacy, such as in a school.<sup>32</sup> Probable

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<sup>26</sup> These circumstances typically revolve around how often a drug is prescribed, if the drug is in a specific class or schedule, if there is a reasonable suspicion that the patient is abusing drugs, or if the prescription was written in a pain clinic. *Id.*

<sup>27</sup> These states are: Alaska, Arkansas, Colorado, Georgia, Iowa, Kansas, Louisiana, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, Oregon, and Wisconsin. See the National Alliance for Model State Drug Laws, *Law Enforcement Access to State PMP Data*, available at <http://www.namsdl.org/library/>, last visited on March 19, 2014.

<sup>28</sup> See John Woodrow Cox, *Did Florida's prescription pill database really spring a leak?*, Tampa Bay Times, July 5, 2013. Available at <http://www.tampabay.com/news/politics/did-floridas-prescription-pill-database-really-spring-a-leak/2130108>, last visited on March 19, 2014, and see the DOH presentation to the Senate Health Policy Committee on the PDMP, September 24, 2013, on file with Health Policy Committee staff.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Terry v. Ohio*, 392 U.S. 1 (1968).

<sup>32</sup> See *R.M. v. State*, 129 So. 3d 1157 (Fla. 3d DCA 2014).

cause is the greater of the two standards and is the one the police must meet when arresting a suspect.<sup>33</sup>

In order to meet the standard for reasonable suspicion, a police officer must be able to show a “well-founded, articulable suspicion of criminal activity.”<sup>34</sup> In contrast, in order to meet the standard for probable cause, an officer must be able to show that the “facts and circumstances known to the officer warrant a prudent man in believing that the offense has been committed.”<sup>35</sup> The key difference between the standards lies in the knowledge of the officer. With reasonable suspicion, the officer must only suspect that a crime has been committed, while with probable cause, the officer must have enough evidence to convince a “prudent man” that a crime has been committed.

### III. Effect of Proposed Changes:

The bill amends s. 893.055, F.S., to significantly, but technically, revise the section by reorganizing and grouping related items, clarifying imprecise language, and deleting outdated or redundant language.

The bill also makes several substantive changes to:

- Require the Department of Health to adopt a user agreement rule that requires users to protect the confidentiality of information from the prescription drug monitoring program’s database;
- Require a law enforcement agency to execute the user agreement before information from the prescription drug monitoring program is released to the agency;
- Allow the Department of Health (DOH or department) to send only relevant information which is not personal identifying information to a law enforcement agency when the DOH determines a pattern consistent with indicators of controlled substance abuse exists;
- Provide requirements for the release of information from the prescription drug monitoring program’s database shared with a state attorney in response to a discovery demand;
- Authorize a law enforcement agency to use information from DOH to determine whether an active investigation is warranted;
- Allow DOH to provide a patient advisory report to the appropriate health care practitioner if the manager of the prescription drug monitoring program determines that a specified pattern exists;
- Define the term “dispense” or “dispensing” using existing language in the statute and in the definitions section of ch. 893, F.S.;
- Allow an impaired practitioner consultant retained by the DOH access to information in the prescription drug monitoring program’s database which relates to a practitioner who has agreed to be evaluated or monitored by the consultant;
- Fund, subject to the General Appropriations Act, the prescription drug monitoring program with up to \$500,000 annually from excess collections related to the practice of pharmacy; and
- Eliminate the direct support organization for the prescription drug monitoring program.

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<sup>33</sup> *Popple v. State*, 626 So. 2d 185, 186-187 (Fla. 1993).

<sup>34</sup> *Id.*

<sup>35</sup> *Henry v. U.S.*, 361 U.S. 98, 102 (1959) (internal citations omitted).

Additionally, the bill imposes minimum requirements for the user agreement. The agreement must:

- Provide for access control and information security in order to ensure the confidentiality of information
- Require training;
- Require each agency head to submit an annual attestation to the program manager of the prescription drug monitoring program that the user agreement is being complied with and to disclose any findings and actions taken to maintain compliance;
- Require each agency that receives information from the database to electronically update the database semiannually with the status of the case for which the information was requested, in accordance with procedures established by department rule;
- Require each agency head to appoint one agency administrator to be responsible for appointing authorized users to request and receive investigative reports on behalf of the agency to ensure the agency maintains compliance with the user agreement and laws governing access, use, and dissemination of information received;
- Require each authorized user to attest that each request for confidential information from the database is predicated on and related to an active investigation;
- Require the agency to conduct annual audits of the administrator and of each user to ensure the user agreement is followed; and
- Allow the program manager of the prescription drug monitoring program to restrict, suspend, or terminate an administrator's or authorized user's access to information in the database if the department finds the administrator or user has failed to comply with the user agreement.

The bill takes effect July 1, 2014.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

Law enforcement agencies may incur a cost associated with obtaining a court order prior to accessing information in the PDMP.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 893.055 of the Florida Statutes.

**IX. Additional Information:****A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Judiciary Committee on April 1, 2014:**

The committee substitute deletes the obligation for law enforcement agencies seeking information from the prescription drug monitoring program's database to obtain a court order based upon a showing of reasonable suspicion of potential criminal activity. In lieu of that requirement, law enforcement agencies must execute user agreements with the Department of Health to ensure access, security, and confidentiality of information released from the prescription drug monitoring program's database. The Department of Health must establish a user agreement by rule that follows the guidelines established in the committee substitute. The committee substitute allows an impaired practitioner consultant retained by the Department of Health access to information in the prescription drug monitoring program's database which relates to a practitioner who has agreed to be evaluated or monitored by the consultant.

**B. Amendments:**

None.