

**HOUSE OF REPRESENTATIVES  
FINAL BILL ANALYSIS**

<b>BILL #:</b>	HB 7097	<b>FINAL HOUSE FLOOR ACTION:</b>		
<b>SUBJECT/SHORT TITLE</b>	Direct Support Organization of the Prescription Drug Monitoring Program	117	Y's 0	N's
<b>SPONSOR(S):</b>	Health Quality Subcommittee; Fine	<b>GOVERNOR'S ACTION:</b>		Approved
<b>COMPANION BILLS:</b>	SB 7006			

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**SUMMARY ANALYSIS**

HB 7097 passed the House on April 26, 2017, and subsequently passed the Senate on May 2, 2017.

Direct support organizations (DSOs) are statutorily created entities that are generally required to be non-profit corporations and are authorized to carry out specific tasks in support of public entities or public causes. The functions and purposes of DSOs are prescribed by their enacting statutes and, for most, by a written contract with the state agency the DSO was created to support.

In 2009, the Florida PDMP Foundation, Inc. (Foundation), was established as a DSO for the prescription drug monitoring program (PDMP). The PDMP is an electronic database that tracks the prescribing and dispensing of certain controlled substance prescription drugs to patients. The PDMP is designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with a patient's controlled substance prescription history. State law requires the Department of Health to acquire federal and private funds to operate the PDMP.

The mission of the Foundation is to raise funds for the benefit of the PDMP. Since its inception, the Foundation has acquired almost \$3 million in funds to support the PDMP, including a \$1.9 million donation from the Office of the Attorney General in 2014. Other donations have come from law enforcement agencies and other health care-affiliated entities, such as drug testing laboratories and medical technology providers.

As of January 2017, the Foundation had assets of almost \$1.6 million, of which \$1.35 million is invested. The annual cost to maintain the PDMP is \$600,000. With these funds, the PDMP has sustainable funding through Fiscal Year 2019-2020.

The statutory authority for the Foundation is scheduled to repeal on October 1, 2017, unless reviewed and saved from repeal by the Legislature.

The bill extends the scheduled repeal of the law authorizing the PDMP DSO to October 1, 2027.

The bill was approved by the Governor on June 26, 2017, ch. 2017-192, L.O.F., and will become effective on July 1, 2017.

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF CHANGES:

#### Present Situation

##### Direct Support Organizations

Direct support organizations (DSOs) are statutorily created entities that are generally required to be non-profit corporations and are authorized to carry out specific tasks in support of public entities or public causes. The functions and purposes of DSOs are prescribed by their enacting statutes and, for most, by a written contract with the state agency the DSO was created to support.

Prior to 2014, there was no formal review process in law to determine whether a DSO was established pursuant to such authorization, or whether the rationale for the authorization remained applicable. However, Chapter 2014-96, Laws of Florida,<sup>1</sup> established reporting and transparency requirements for each DSO created or authorized pursuant to law or executive order and created, approved, or administered by a state agency. The DSO must report information related to its organization, mission, and finances to the agency it was created to support by August 1 of each year.<sup>2</sup> Specifically, a DSO must provide:

- The name, mailing address, telephone number, and website address of the organization;
- The statutory authority or executive order that created the DSO;
- A brief description of the mission of, and results obtained by, the organization;
- A brief description of the organization's plans for the next three fiscal years;
- A copy of the organization's code of ethics; and
- A copy of the organization's most recent federal Internal Revenue Service Return of Organization Exempt from Income Tax form (Form 990).<sup>3</sup>

Each agency receiving the above information must make the information available to the public through the agency's website. If the DSO maintains a website, the agency's website must provide a link to the website of the DSO.<sup>4</sup> Additionally, any contract between an agency and a DSO must be contingent upon the DSO submitting and posting the information.<sup>5</sup> If a DSO fails to submit the required information for two consecutive years, the agency must terminate its contract with the DSO.<sup>6</sup>

By August 15 of each year, each agency must report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability the information provided by the DSO. The report must also include a recommendation by the agency, with supporting rationale, to continue, terminate, or modify the agency's association with each organization.<sup>7</sup>

Lastly, a law creating or authorizing the creation of a DSO must state that the creation of or authorization for the DSO is repealed on October 1 of the 5th year after enactment, unless reviewed and saved from repeal through reenactment by the Legislature. DSOs in existence on July 1, 2014, must be reviewed by the Legislature by July 1, 2019.<sup>8</sup>

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<sup>1</sup> Codified at s. 20.058, F.S.

<sup>2</sup> Section 20.058(1), F.S.

<sup>3</sup> Section 20.058(1)(a)-(f), F.S.

<sup>4</sup> Section 20.058(2), F.S.

<sup>5</sup> Section 20.058(4), F.S.

<sup>6</sup> Id.

<sup>7</sup> Section 20.058(3), F.S.

<sup>8</sup> Section 20.058(5), F.S.

## *Direct Support Organization Audit Requirements*

DSOs with annual expenditures in excess of \$100,000 and that are created, approved, or administered by a state agency are statutorily-required to provide for an annual financial audit of accounts and records to be conducted by an independent certified public accountant, with certain exceptions.<sup>9</sup> The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the state agency responsible for its creation, administration, or approval of the DSO.

Additionally, the Auditor General may, pursuant to his or her own authority or at the direction of the Legislative Auditing Committee, conduct audits or other engagements of the accounts and records of the DSO.<sup>10</sup> The Auditor General is authorized to require and receive any records from the DSO, or from its independent auditor.<sup>11</sup>

### 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>12</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>13</sup> As of September 2015, 49 states had an operational PDMP database.<sup>14</sup>

Chapter 2009-197, Laws of Fla., established Florida's PDMP within the Department of Health (DOH), and is codified in s. 893.055, F.S. The PDMP uses an electronic database system to monitor the prescribing and dispensing of certain controlled substances.<sup>15</sup> The PDMP database became operational in September 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.<sup>16</sup>

### PDMP Direct Support Organization

In 2009, the Legislature authorized DOH to establish a DSO to provide assistance, funding, and promotional support for the activities authorized for the PDMP.<sup>17</sup> The Foundation was founded in 2009 as a nonprofit organization under the laws of this state to:

- Conduct programs and activities;
- Raise funds;
- Request and receive grants, gifts, and bequests of money;
- Acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, real or personal; and
- Make expenditures or provide funding to or for the direct or indirect benefit of DOH in furtherance of the PDMP.<sup>18</sup>

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<sup>9</sup> Section 215.981(1), F.S. This subsection does not apply to a DSO of a university, district board of trustees of a community college, district school board, Department of Environmental Protection, or Department of Agriculture and Consumer Services.

<sup>10</sup> Section 11.45(3), F.S.

<sup>11</sup> Id.

<sup>12</sup> Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs*, available at <http://www.cdc.gov/drugoverdose/pdmp/> (last visited May 3, 2017).

<sup>13</sup> Id.

<sup>14</sup> National Alliance for Model State Drug Laws, *2015 Annual Review of Prescription Monitoring Programs*, (September 2015), available at <http://www.namsdl.org/IssuesandEvents/2015%20Annual%20Review%20of%20Prescription%20Monitoring%20Programs.pdf> (last visited May 3, 2017). Missouri is the only state without a PDMP. Legislation was filed in December 2016 to establish a program. See [http://www.senate.mo.gov/17info/BTS\\_Web/Bill.aspx?SessionType=R&BillID=57095432](http://www.senate.mo.gov/17info/BTS_Web/Bill.aspx?SessionType=R&BillID=57095432) (last visited May 3, 2017).

<sup>15</sup> Section 893.055(2)(a), F.S.

<sup>16</sup> Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2015-2016 Prescription Drug Monitoring Program Annual Report*, (December 1, 2016), available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/documents/2016PDMPAnnualReport.pdf> (last visited May 3, 2017).

<sup>17</sup> Chapter 2009-197, Laws of Fla., codified at 893.055(10), F.S.

The PDMP has an executive director and a board of directors who are appointed by the Surgeon General. The Foundation's board currently consists of 10 members and includes health care practitioners, representatives of the pharmaceutical and insurance industries, and a consumer advocate.<sup>19</sup> The Surgeon General provides guidance to the board of directors to ensure that the DSO does not receive funds from inappropriate sources, which include funds from donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by DOH in furtherance of the PDMP.<sup>20</sup>

The Foundation has two major goals. The first goal is to raise funds for the operation of the PDMP and the second goal is to educate law enforcement and licensed health care practitioners about the database and its uses.<sup>21</sup> The Foundation has collaborated with the PDMP, Florida Hospital Association, and Florida Nurse Practitioner Network to develop a three-hour continuing education course regarding controlled substances.<sup>22</sup>

The Foundation operates under a written contract with DOH, which requires the Foundation to:

- Raise funds, request and receive grants, gifts, and bequests of money, acquire and otherwise act in accordance with the goals of the PDMP and in the best interest of the state;
- Obtain written approval from DOH for any activities in support of the PDMP before undertaking those activities;
- Submit an annual budget to DOH by May 15 of each year for review and approval. The budget must detail the Foundation's fundraising plan to support the spending plan for the PDMP; and
- Annually certify that it is complying with the terms of the contract.

The Foundation may also collect, expend, and provide funds to DOH to develop, implement, and operate the PDMP.

### Funding for the PDMP

Current law restricts how DOH may fund the implementation and operation of the PDMP. Section 893.055(10), F.S., prohibits DOH from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.<sup>23</sup> Since 2010, the PDMP has spent \$3,615,939 for system and database infrastructure, personnel, and facility expenses.<sup>24</sup> Funding for the PDMP comes from three funding sources: federal and private grants, state appropriations, and donations procured by its DSO, the Florida PDMP Foundation, Inc. (Foundation).

#### *PDMP Funding from DOH - Federal and Private Grants*

Since its inception, DOH applied for and was awarded several grants for the implementation and enhancement of the PDMP. DOH has been awarded a total of \$2,443,471 in federal grants.<sup>25</sup> The federal grants and the purpose of each are as follows:

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<sup>18</sup> Articles of Incorporation of the Florida PDMP Foundation, Inc., dated Dec. 30, 2009, *available at* <http://search.sunbiz.org/Inquiry/CorporationSearch/ConvertTiffToPDF?storagePath=COR%5C2010%5C0126%5C63623995.Tif&documentNumber=N10000000221> (last visited May 3, 2017). *See also* s. 893.055(10), F.S.

<sup>19</sup> E-mail correspondence with DOH, dated March 24, 2017 (on file with the Health Quality Subcommittee). The appointment of a member of law enforcement is also pending. *See also* Florida PDMP Foundation, *About Us*, *available at* <http://www.flpdmpfoundation.com/about/> (last visited March 25, 2017).

<sup>20</sup> Section 893.055(11), F.S.

<sup>21</sup> Florida PDMP Foundation, *Goals*, *available at* <http://www.flpdmpfoundation.com/goals/> (last visited May 3, 2017).

<sup>22</sup> DOH, *E-FORCSE: 2015-2016 PDMP Annual Report*, (Dec. 1, 2016), *available at* <http://www.floridahealth.gov/statistics-and-data/e-forcse/documents/2016PDMPAnnualReport.pdf> (last visited May 3, 2017).

<sup>23</sup> Section 893.055(10) and (11)(c), F.S.

<sup>24</sup> *Supra* note 16.

<sup>25</sup> *Id.*

Grant	Grant Amount	Grant Purpose	Project End Date
U.S. DOJ Harold Rogers PDMP Implementation Grant	\$400,000	Implementation of the PDMP system.	August 31, 2012
U.S. DOJ Harold Rogers PDMP Enhancement Grant	\$400,000	Performance of system enhancements.	March 31, 2013
U.S. DOJ Harold Rogers PDMP Enhancement Grant	\$399,300	To enhance of collaborations with law enforcement; enhance the PDMP's ability to analyze data to identify drug abuse trends; and increase the number of PDMP users.	September 30, 2014
U.S. Substance Abuse and Mental Health Services Administration Grant	\$240,105	To integrate PDMP data into existing clinical workflow and technology and to expand operability.	March 31, 2015
U.S. DOJ Harold Rogers PDMP Enhancement Grant	\$399,950	To form multidisciplinary and multijurisdictional groups to identify areas of greatest risk of drug abuse and diversion and create data-driven responses at the local level.	March 31, 2017
U.S. DOJ Harold Rogers PDMP Enhancement Grant	\$499,991	To enhance proactive reporting efforts to health care practitioners and law enforcement and analysis of impact on prescriber behavior and law enforcement efforts.	September 30, 2017
DCF Partnership for Success	\$86,625	To ensure the PDMP includes additional alert features and computer based training, to encourage safer prescribing and reduce drug abuse and diversion.	September 30, 2017
Harold Rogers PDMP: Data Driven Responses to Prescription Drug Abuse awarded to University of Florida	\$17,500	To link de-identified PDMP data with other key data sources to improve care coordination.	September 30, 2019

In addition, the National Association of State Controlled Substance Authorities awarded three private grants to DOH, totaling \$49,952. These funds were used to create a website and to purchase office equipment and promotional items.<sup>26</sup>

#### *PDMP Funding from State Appropriations*

Although s. 893.055(1), F.S., makes the PDMP contingent on nonstate funding, and restricts funding to only federal grants and private donations, the Legislature has, on three separate occasions, appropriated state funds for the operation of the PDMP:

- In 2013, the Legislature appropriated \$500,000 to DOH for Fiscal Year 2013-2014, for the general administration of the PDMP;<sup>27</sup>
- In 2015, the Legislature appropriated \$500,000 to DOH to administer the PDMP for Fiscal Year 2015-2016, and prohibited DOH or the Office of the Attorney General (OAG) from using funds received as a part of a settlement agreement to administer the PDMP;<sup>28</sup> and
- In 2016, the Legislature appropriated \$500,000 to DOH to administer the PDMP for Fiscal Year 2016-2017, and prohibited DOH and the OAG from using funds received as a part of a settlement agreement to administer the PDMP.<sup>29</sup>

<sup>26</sup> DOH, *E-Forcse Funding*, available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/index.html> (last visited May 3, 2017).

<sup>27</sup> Chapter 2013-153, Laws of Fla.

<sup>28</sup> Chapter 2015-522, Laws of Fla.

<sup>29</sup> Chapter 2016-62, Laws of Fla.

PDMP funding is now a recurring appropriation of \$500,000 from the General Revenue Fund, in the base budget.<sup>30</sup>

*PDMP Funding from the Foundation*

The Foundation has provided \$1,010,513 to fund the PDMP.<sup>31</sup> Since its inception, the Foundation has acquired almost \$3 million in funds to support the PDMP. The majority of its revenues is from an \$1.973 million unsolicited donation from the OAG in 2014. These funds were from a settlement of a fraud case against CVS/Caremark. At the time of the contribution, the Foundation entered into Memorandum of Understanding (MOU) with the OAG that restricts use of the funds for the sole operation of the PDMP and may not exceed \$500,000 in any one state fiscal year. The MOU authorizes the Foundation to invest the funds in FDIC-protected products, such as certificates of deposit. In Fiscal Year 2014-2015, the Foundation disbursed \$500,000 of the OAG donation to DOH for the PDMP.

However, in Fiscal Years 2015-2016 and 2016-2017, the Implementing Bills for the General Appropriations Act prohibited use of the settlement funds for the PDMP.<sup>32</sup> The current prohibition expires July 1, 2017, unless reenacted. The Legislature passed Senate Bill 2502, the Implementing Bill for the General Appropriations Act for Fiscal Year 2017-2018, which reenacts the prohibition.<sup>33</sup> The Foundation invested the remainder of the donation, pending a change in law.

The Foundation’s fundraising efforts, as well as expenditures, are detailed below.<sup>34</sup> In the Fiscal Year 2014-2015 and Fiscal Year 2015-2016, the Foundation’s expenses exceeded its revenues.

Fiscal Year	Donations	Expenses	Provided to DOH for PDMP
2009-2010	\$125,000	N/A	\$39,108
2010-2011	*\$339,443	\$39,134	\$201,552
2011-2012	\$120,010	\$4,570	\$96,758
2012-2013	\$73,910	\$4,147	\$205,308
2013-2014	†\$2,161,881	\$46,080	\$0
2014-2015	\$35,650	\$75,130	\$500,000
2015-2016	\$26,050	\$76,325	\$7,811
<b>Totals</b>	<b>\$2,881,944</b>	<b>\$245,386</b>	<b>\$1,050,537</b>

\*A portion of the funds donated were specified for expenses related to legal services and government fees.

† Includes a donation of \$1,973,156 from the OAG, and \$179,675 in other donations.

As of January 2017, the Foundation had assets of almost \$1.6 million, of which \$1.35 million is invested.<sup>35</sup> The annual cost to maintain the PDMP is \$600,000,<sup>36</sup> so these funds are sufficient to fund the PDMP through Fiscal Year 2019-2020, if the Legislature eliminates the prohibition on using the OAG settlement funds.

**Effect of Proposed Changes**

The bill extends the scheduled repeal of the PDMP DSO to October 1, 2027.

The bill provides an effective date of July 1, 2017.

<sup>30</sup> In the 2017 Legislative Session, the Legislature passed House Bill 5203, which eliminates the prohibition against the use of state funds for the PDMP. Subject to the Governor’s veto powers, the effective date of this bill is July 1, 2017.

<sup>31</sup> *Supra* note 16.

<sup>32</sup> Sections 893.055(17), F.S. (2015, 2016).

<sup>33</sup> Subject to the Governor’s veto powers, the effective date of the bill is July 1, 2017.

<sup>34</sup> Based on information received from DOH and the Foundation (on file with the Health Quality Subcommittee).

<sup>35</sup> E-mail correspondence with DOH, dated January 30, 2017, (on file with the Health Quality Subcommittee).

<sup>36</sup> *Supra* note 21.

## 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.