

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HQS 17-04 Direct Support Organization of the Prescription Drug Monitoring Program
SPONSOR(S): Health Quality Subcommittee; Fine
TIED BILLS: **IDEN./SIM. BILLS:**

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|--|-----------|---------|--|
| Orig. Comm.: Health Quality Subcommittee | 13 Y, 0 N | Siples | McElroy |

SUMMARY ANALYSIS

Citizen support and direct-support organizations (CSOs and 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 CSOs and DSOs are prescribed by their enacting statutes and, for most, by a written contract with the agency the CSO or 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 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 (DOH) to acquire federal and private funds to operate the PDMP, which requires approximately \$600,000 annually to maintain.

The mission of the Foundation is to raise funds for the benefit of the PDMP, in order to reduce prescription drug abuse and diversion. 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.

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

PCB HQS 17-04 extends the scheduled repeal of the law authorizing the PDMP DSO to October 1, 2027.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Citizen Support Organizations and Direct-support Organizations

Citizen support and direct-support organizations (CSOs and 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 CSOs and DSOs are prescribed by their enacting statutes and, for most, by a written contract with the agency the CSO or DSO was created to support.

Prior to 2014, there was no formal review process in law to determine whether a CSO or DSO was established pursuant to such authorization, or whether the rationale for the authorization remained applicable. However, Chapter 2014-96, Laws of Florida,¹ established reporting and transparency requirements for each CSO and DSO created or authorized pursuant to law or executive order and created, approved, or administered by a state agency. The CSO or 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.² Specifically, a CSO or 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).³

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

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 CSO or 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.⁷

Lastly, a law creating or authorizing the creation of a CSO or DSO must state that the creation of or authorization for the CSO or DSO is repealed on October 1 of the 5th year after enactment, unless

¹ Codified at s. 20.058, F.S.

² Section 20.058(1), F.S.

³ Section 20.058(1)(a)-(f), F.S.

⁴ Section 20.058(2), F.S.

⁵ Section 20.058(4), F.S.

⁶ Id.

⁷ Section 20.058(3), F.S.

reviewed and saved from repeal through reenactment by the Legislature. CSOs or DSOs in existence on July 1, 2014, must be reviewed by the Legislature by July 1, 2019.⁸

CSO and DSO Audit Requirements

CSOs or 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.⁹ 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 CSO or 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 CSO or DSO.¹⁰ The Auditor General is authorized to require and receive any records from the CSO or DSO, or from its independent auditor.¹¹

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.¹² 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.¹³ As of September 2015, 49 states either had an operational PDMP database.¹⁴

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.¹⁵ The PDMP database became operational in September 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.¹⁶

Funding for the PDMP

Current law restricts how DOH may fund 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.¹⁷ Since 2010, the PDMP has spent \$3,615,939 for system and database infrastructure, personnel, and facility expenses.¹⁸ 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).

⁸ Section 20.058(5), F.S.

⁹ Section 215.981(1), F.S. This subsection does not apply to a CSO or 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.

¹⁰ Section 11.45(3), F.S.

¹¹ *Id.*

¹² Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs*, available at <http://www.cdc.gov/drugoverdose/pdmp/> (last visited March 17, 2017).

¹³ *Id.*

¹⁴ 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 March 20, 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 (last visited March 17, 2017).

¹⁵ Section 893.055(2)(a), F.S.

¹⁶ 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 March 17, 2017).

¹⁷ Section 893.055(10) and (11)(c), F.S.

¹⁸ *Supra* note 16.

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.¹⁹ The federal grants and the purpose of each are as follows:

| Grant | Grant Amount | Grant Purpose | Project End Date |
|---|--------------|--|--------------------|
| U.S. Department of Justice 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 |
| UF Harold Rogers PDMP: Data Driven Responses to Prescription Drug Abuse | \$17,500 | To link de-identified PDMP data with other key data sources to improve care coordination. | September 30, 2019 |

The National Association of State Controlled Substance Authorities has 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.²⁰

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;²¹

¹⁹ Id.
²⁰ DOH, *E-Forcse Funding*, available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/index.html> (last visited March 24, 2017).
²¹ Chapter 2013-153, Laws of Fla.
STORAGE NAME: pcb04a.HQS
DATE: 3/31/2017

- 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;²² 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.²³

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

Funding from the Foundation

The Foundation has provided \$1,010,513 to fund the PDMP.²⁴ With the funds held by the Foundation, the PDMP has sustainable funding through fiscal year 2019-2020.²⁵ Please see below for more information about the fundraising activities of the Foundation.

The Florida PMDP Foundation

In 2009, the Legislature authorized DOH to establish a DSO to provide assistance, funding, and promotional support for the activities authorized for the PDMP.²⁶ 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.²⁷

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.²⁸ The Surgeon General provides guidance to 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.²⁹

The Foundation has two major goals. The first goal is to raise funds for the operation of the PDMP and the second is to educate law enforcement and licensed health care practitioners about the database and its uses.³⁰ The Foundation has collaborated with the PDMP, Florida Hospital Association, and

²² Chapter 2015-522, Laws of Fla.

²³ Chapter 2016-62, Laws of Fla.

²⁴ *Supra* note 16.

²⁵ *Id.*

²⁶ Chapter 2009-197, Laws of Fla., codified at 893.055(10), F.S.

²⁷ 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=N1000000221> (last visited March 24, 2017). See also s. 893.055(10), F.S.

²⁸ 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.flpdpmpfoundation.com/about/> (last visited March 25, 2017).

²⁹ Section 893.055(11), F.S.

³⁰ Florida PDMP Foundation, *Goals*, available at <http://www.flpdpmpfoundation.com/goals/> (last visited March 25, 2017).

Florida Nurse Practitioner Network to develop a three-hour continuing education course regarding controlled substances.³¹

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.

Since its inception, the Foundation has acquired almost \$3 million in funds to support the PDMP. The majority of its revenues is from a \$1.973 million donation from the Office of the Attorney General (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 which does not exceed \$500,000 in any one state fiscal year. The MOU authorizes the Foundation to PDMP 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 Acts prohibited use of the settlement funds for the PDMP.³² The current prohibition expires July 1, 2017, unless reenacted. The Foundation invested the remainder of the donation, pending a change in law.

The other Foundation’s fundraising efforts, as well as expenditures, are detailed below.³³ 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 |
| Totals | \$2,881,944 | \$245,386 | \$1,050,537 |

*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.³⁴ The annual cost to maintain the PDMP is \$600,000.³⁵ With these funds, the PDMP has sustainable funding through Fiscal Year 2019-2020.

³¹ 30DOH, *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 March 25, 2017).

³² Sections 893.055(17), F.S. (2015, 2016).

³³ Based on information received from DOH and the Foundation (on file with the Health Quality Subcommittee).

³⁴ E-mail correspondence with DOH, dated January 30, 2017, (on file with the Health Quality Subcommittee).

³⁵ *Supra* note

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.

B. SECTION DIRECTORY:

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

Section 2: Provides an effective date of July 1, 2017.

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. The 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