HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 557 Controlled Substance Prescribing
SPONSOR(S): Health & Human Services Committee; Health Quality Subcommittee; Duran
TIED BILLS: **IDEN./SIM. BILLS:** SB 840

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee	13 Y, 0 N	Mielke	Pridgeon
3) Health & Human Services Committee	16 Y, 0 N, As CS	Siples	Calamas

SUMMARY ANALYSIS

In 2009, the Legislature created the Prescription Drug Monitoring Program (PDMP) within the Department of Health (DOH). The PDMP employs 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 certain information to the PDMP database, including the name of the prescriber, the date the prescription is filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed. Currently, dispensers must report dispensing controlled substances to the database within seven days of dispensing the controlled substances via the internet or other DOH-approved format, such as on a disc or regular mail.

Dispensing and administering controlled substances are exempt from PDMP reporting in certain health care settings where the risk of controlled substances being overprescribed or diverted is low. These health care settings include a licensed hospital, nursing home, ambulatory surgical center, hospice, intermediate care facility for the developmentally disabled, rehabilitative hospital, and assisted living facility.

Beginning January 1, 2018, CS/CS/HB 557 reduces the amount of time a dispenser has to report the dispensing of a controlled substance to the PDMP database to the close of the next business day after the controlled substance is dispensed.

The bill requires PDMP reporting to be completed via the DOH-approved electronic system, and eliminates DOH authority to approve other options for submission.

The bill also requires the patient to be present and receiving care for the reporting exemption for a rehabilitation hospital, assisted living facility, or nursing home to apply.

The bill authorizes certain health care employees of the U.S. Veterans' Administration to access the PDMP database in manner established by DOH. Such access is limited to the authorized employee's review of his or her patient's controlled substance prescription history.

The bill limits the initial prescription of an opioid to alleviate acute pain to a 5-day supply.

The bill may have an insignificant, negative fiscal impact on DOH that can be absorbed with existing resources and has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

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.[1] 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.[2] As of September 2015, 49 states either had an operational PDMP database.[3]

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.[4] The PDMP database became operational in September of 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[5]

PDMP Reporting Requirements

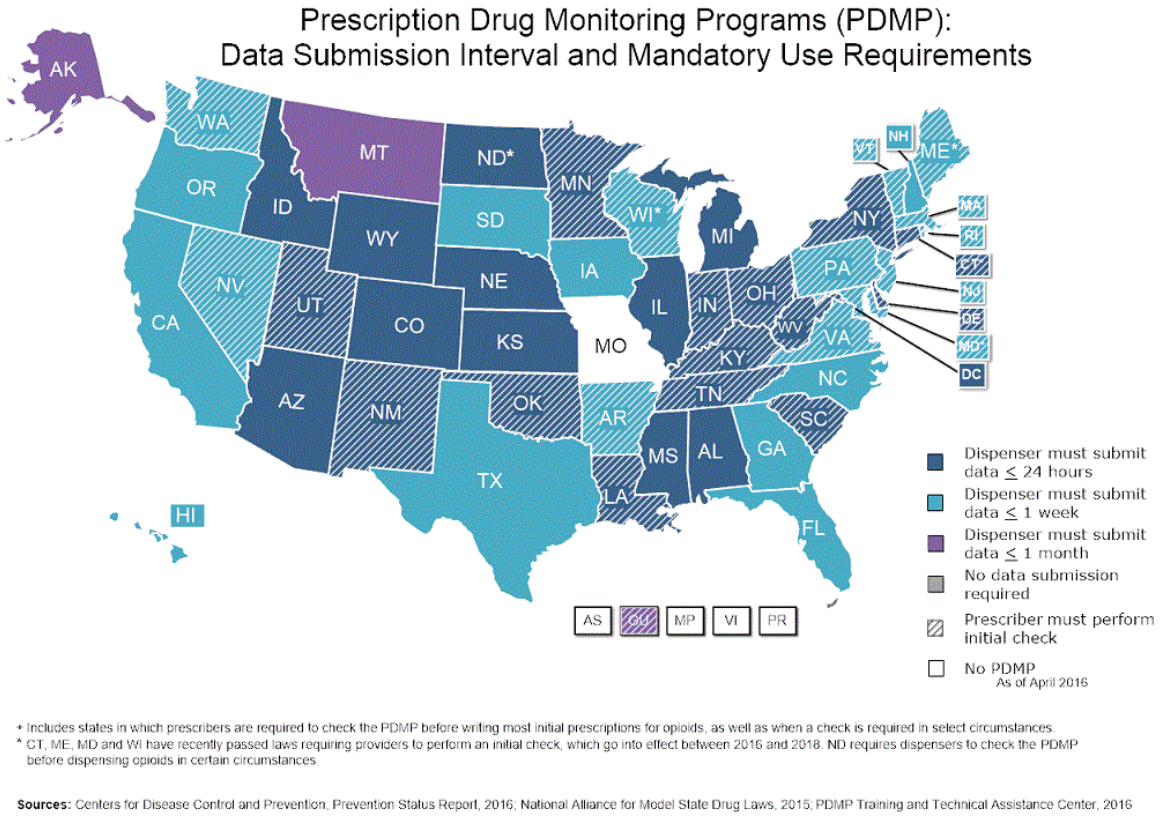
Dispensers of controlled substances listed in Schedule II, III, or IV of the Florida Comprehensive Drug Abuse Prevention and Control Act must report specified information to the PDMP database:[6]

- 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.[7]

Dispensers must report dispensing a specified controlled substance to the PDMP database within seven days.[8] As of June 30, 2016, approximately 96 percent of pharmacies required to report data to

[1] Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs*, available at http://www.cdc.gov/drugoverdose/pdmp/ (last visited March 17, 2017).
[2] *Id*.
[3] 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).
[4] Section 893.055(2)(a), F.S.
[5] 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).
[6] Section 893.055(3), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.
[7] *Id.*
[8] Section 893.055(4), F.S.

the PDMP had uploaded information into the system within the seven-day statutory limit.[9] Of those, 66 percent reported the information within 24 hours.[10] The time in which a dispenser must submit information to the PDMP varies across the nation. As indicated below, some states require the dispenser to submit data within 24 hours, others (like Florida) allow up to 7 days, and two allow the dispenser up to a month to submit the data:[11]



In Florida, more than 6,500 dispensers have reported to the PDMP creating the more than 198 million dispensing records that are maintained in the PDMP system.[12]

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,

[9] *Supra* note 5.
[10] *Id*.
[11] National Conference of State Legislatures, "Prescription Drug Monitoring Programs," (June 1, 2016), available at http://www.ncsl.org/research/health/prescription-drug-monitoring-programs-postcard.aspx (last visited March 20, 2017).
[12] *Supra* note 5.

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; and
- A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician.[13]

Access to PDMP Data

Direct access to the PDMP database is presently limited by law to a pharmacy, prescriber, or dispenser.[14] 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.[15] Currently, the only prescribers authorized to access the PDMP database are Florida-licensed health care practitioners.[16] Health care practitioners who work for the United States Veterans Affairs (VA) in one of its facilities in Florida are not required to be licensed in Florida. The VA requires that a health care practitioner have an active, unrestricted license to practice from any state to practice at any one of its facilities nationwide.[17] Therefore, a health care practitioner practicing in a VA facility in Florida who is licensed in another state would not have access to the PDMP database.

Health care practitioners began accessing the PDMP database on October 17, 2011.[18] As of June 30 2016, 36,718 health care practitioners, or 23.7 percent of all licensed health care practitioners, were registered to use the PDMP Database. [19] Pharmacists have had the highest utilization rate of the PDMP; from July 1, 2015 to June 30, 2016, 54.5 percent of pharmacists were registered to use the PDMP and 90.1 percent of pharmacists registered to use the PDMP had queried it.[20] From July 1, 2015 to June 30, 2016, in-state prescribers issued 37,048,030 controlled substance prescriptions to 7,387,884 Florida residents.[21] During that same timeframe, 28,984 registered health care practitioners queried the PDMP database 27,501,266 times.[22]

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;

[13] Section 893.055(5). F.S.
[14] Section 893.055(7)(b), F.S.
[15] *Id*.
[16] Section 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).
[17] U.S. Department of Veterans Affairs, "VA Careers: Credentialing at VA," *available at* http://www.vacareers.va.gov/careers/physicians/credentialing.asp (last visited March 20, 2017).
[18] 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 (last visited March 17, 2017).
[19] *Supra* note 5 at p. 10.
[20] *Id*. at p. 10, 18.
[21] *Id*. at p. 14.
[22] *Id*. at p. 18.

- 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.[23]

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.[24] Prior to release, the PDMP program manager must verify that the request is authentic and authorized with the requesting organization.[25]

Public Records Exemption for Information in the PDMP Database

Section 893.0551, F.S.,[26] 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.[27] 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.[28]

CDC Guideline for Prescribing Opioids for Chronic Pain

Opioid Abuse

Opioids are used for the short term treatment of pain; however, the use of opioids puts patients at risk for addiction, an unintentional overdose, or death.[29] Since 1999, the amount of opioids prescribed has nearly quadrupled, but there has not been an overall change in the amount of pain that Americans report.[30]

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.[31] Drug overdose is now the leading cause of injury-related death in the United States.[32] Florida is in the midst of an opioid crisis.[33] In 2015, Florida ranked fourth in the nation with 3,228 deaths

[23] Section 893.055(7)(c), F.S.
[24] *Id*.
[25] *Id*.
[26] 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.
[27] Section 893.0551(2), F.S.
[28] Section 893.0551(6), F.S. However, a law enforcement agency with lawful access to such information is permitted to disclose confidential and exempt information received from DOH to a criminal justice agency as part of an active investigation of a specific violation of law. Section 893.0551(4).
[29] Centers for Disease Control and Prevention, *Guideline Information for Patients*, available at https://www.cdc.gov/drugoverdose/prescribing/patients.html (last visited March 26, 2017).
[30] Centers for Disease Control and Prevention, *Understanding the Epidemic*, available at https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited March 26, 2017).
[31] WORLD HEALTH ORGANIZATION, *Information Sheet on Opioid Overdose*, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited March 26, 2017).
[32] Trust for America's Health, *The Facts Hurt: A State-by-State Injury Prevention Policy Report 2015,* available at: http://healthyamericans.org/reports/injuryprevention15/ (last visited March 26, 2017).
[33] *Palm Beach County Sober Homes Task Force Report 2017*, Jan. 1, 2017, available at: http://www.sa15.state.fl.us/stateattorney/SoberHomes/_content/SHTFReport2017.pdf (last visited March 26, 2017).

from drug overdoses[34], and at least one opioid caused 2,530 of those deaths.[35] Statewide, in 2015, heroin caused 733 deaths, fentanyl caused 705, oxycodone caused 565, and hydrocodone caused 236. Deaths caused by heroin and fentanyl increased more than 75% statewide when compared with 2014.[36]

Opioid overdose can occur when an individual deliberately misuses a prescription opioid or an illicit drug such as heroin.[37] It can also occur when a patient takes an opioid as directed, but the prescriber miscalculated the opioid dose, an error was made by the dispensing pharmacist, or the patient misunderstood the directions for use.[38] Opioid overdose is life threatening and requires immediate emergency attention.[39] Opiates or related narcotics, including heroin and methadone, accounted for 14% of emergency department visits nationally for unintentional drug poisoning from 2008 to 2011.[40] In Florida, there were approximately 21,700 opioid-related emergency department visits in 2014.[41]

CDC Guidelines

In March 2016, the U.S. Centers for Disease Control and Prevention (CDC) released a guideline for prescribing opioids for chronic pain as part of the response to the epidemic of overdose deaths.[42] The guideline includes 12 recommendations focused on three principles:

- Non-opioid therapy is preferred for chronic pain outside of cancer, palliative, and end-of-life care;
- When prescribing opioids, prescribe the lowest possible effective dosage to reduce the risk of opioid use disorder and overdose; and
- Providers should always exercise caution when prescribing opioids and monitor all patients closely.[43]

Although the guideline addresses chronic pain, the CDC also addressed acute pain, since long-term use of opioids often begins with the treatment of acute pain. The CDC recommends that for the treatment of acute pain, the initial prescription should be for the lowest effective dose of immediate-release (short acting) opioids and the quantity should be no greater than needed for the expected duration of pain severe enough to require opioids.[44] The guideline advises that three days or less is often sufficient and more than seven days will rarely be needed.[45]

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[34] Centers for Disease Control and Prevention, *Drug Overdose Death Data*, available at: https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited March 26, 2017).
[35] Florida Department of Law Enforcement. *Drugs Identified in Deceased Persons by Florida Medical Examiners-2015 Annual Report,* available at: https://www.fdle.state.fl.us/cms/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2015-Annual-Drug-Report.aspx (last visited on March 11, 2017).
[36] Id. at pg. 3.
[37] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *Opioid Overdose Prevention Toolkit*, Rev. 2016, available at http://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf (last visited March 26, 2017).
[38] Id.
[39] Id.
[40] Id.
[41] Weiss, A.J., et al*., Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-20014*, HCUP Statistical Brief #219, January 2017, available at: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf
[42] Centers for Disease Control and Prevention, *CDC Releases Guideline for Prescribing Opioids for Chronic Pain*, available at https://www.cdc.gov/media/dpk/prescription-drug-overdose/opioid-prescription-guidelines/dpk-opioid-prescription-guidelines.html (last visited March 26, 2017).
[43] Id.
[44] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (last visited March 26, 2017). *See also* Centers for Disease Control and Prevention, *Factsheet: CDC Guideline for Prescribing Opioids for Chronic Pain*, available at https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf (last visited March 26, 2017).
[45] Id.

Effect of Proposed Changes

Beginning January 1, 2018, CS/HB 557 reduces the amount of time a pharmacy or dispenser has to report the dispensing of a controlled substance to the PDMP database from seven days after the controlled substance is dispensed to no later than the end of the next business day after the controlled substance is dispensed.

The bill requires the controlled substance reporting by pharmacies or dispensers to be done via the department-approved electronic system, and eliminates the authority of the department to approve other methods of submission, such as submission by disc or by regular mail.

The bill clarifies that the exemption to the reporting required under this section provided to a rehabilitation hospital, assisted living facility, or nursing homes, applies only while the patient is present and receiving care as ordered by the patient's treating physician.

The bill authorizes employees of the U.S. Department of Veterans' Affairs (VA) who provide health care services and have authority to prescribe controlled substances to access the PDMP database in a manner prescribed by DOH. The access is limited to information related to the patient of authorized VA employee and may only be accessed to review such patient's controlled substance prescription history.

The bill limits an initial prescription of opioids to alleviate acute pain to a 5-day supply, codifying the CDC guideline for the treatment of acute pain. The bill defines acute pain as the normal, predicted, physiological and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.

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 for a specific requirement of the bill.
Section 3: 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:

   DOH may incur insignificant costs associated with rulemaking to amend current rules to align with the statutory changes proposed by the bill. Current budget authority is adequate to absorb such costs.[46]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[46] Department of Health, *2017 Agency Legislative Bill Analysis: House Bill 557*, January 27, 2017, (on file with the Health and Human Services Committee).

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A pharmacy or dispenser may incur additional costs associated with meeting the new requirement to report the dispensing of a controlled substance by the end of the next business day.

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 February 22, 2017, the Health Quality Subcommittee adopted an amendment that:

- Requires a dispenser to report to the PDMP by the end of the next business day after the controlled substance is dispensed, rather than 24 hours;
- Requires the submission of reports to be made via the electronic system approved by the DOH, rather than via the internet; and
- Authorizes certain health care employees of the U.S. Department of Veterans' Affairs to access the PDMP in limited circumstances and for limited purposes.

On March 23, 2017, the Health and Human Services Committee adopted an amendment that defined "acute pain" and limited the initial prescription of an opioid to alleviate acute pain to a 5-day supply.

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