



## 2018-2019 Prescription Drug Monitoring Program Annual Report

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## Message from the State Surgeon General

It gives me great pleasure to present Florida's 2018-2019 Prescription Drug Monitoring Program (PDMP) Annual Report. The PDMP, known as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substances Evaluation), exemplifies the Department of Health's (Department) mission to protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

In 2018, HB 21 was passed by the Florida Legislature and signed into law by the Governor, expanding required use of the PDMP. The law now requires each prescriber or dispenser or his or her designee to consult the PDMP system to review a patient's-controlled substance dispensing history each time a controlled substance is prescribed or dispensed to a patient age 16 or older unless a statutory exemption applies. In addition, the law expanded access to the PDMP to Medical Examiners and employees of the United States Department of Defense and Indian Health Service who provide health care services.

There has been a substantial increase in dispenser and prescriber registration and utilization of the PDMP with the passage of HB 21 (2018). A prescriber and dispenser or his or her delegate are required to review a patient's controlled substance history prior to prescribing or dispensing a controlled substance.

The PDMP has entered into agreements to facilitate integration of PDMP information into electronic health records as well as interoperability between states. The PDMP is currently engaged in reciprocal interstate data sharing with 16 states and has integrated PDMP information into 455 entities' electronic health recordkeeping systems across the state.

The PDMP is an important resource for clinicians, allowing them to view patients'-controlled substance dispensing history, leading to more responsible prescribing practices. As the Department continues to work with other state agencies and partners statewide to combat opioid addiction and overdoses, I look forward to sharing additional actions and ways we can collaborate in the coming months. As a state, we must be leaders in addressing the opioid epidemic, and I thank you in advance for being a part of the solution.

Scott A. Rivkees, MD  
State Surgeon General



## Executive Summary

### 2009

- 1 in 8 deaths attributable to prescription drug overdose
- June - Governor signed SB 462 into law creating the PDMP

### 2010

- 90 of the top 100 physicians purchasing oxycodone in the U.S. were in Florida

### 2011

- March - Governor created Statewide Drug Strike Force
- June - Governor signed HB 7095 into law impacting controlled substance distribution prescribing, and dispensing
- July - State Surgeon General declared a statewide public health emergency
- September - implementation of the PDMP

### 2012

- CDC classified prescription drug abuse as an epidemic
- Reduction in MPEs

### 2013

- PDMP funded by General Revenue
- Reduction in MPEs

### 2014

- Reduction in MPEs

### 2015

- June - Governor signed HB 751 creating the Emergency Treatment & Recovery Act authorizing Naloxone use
- PDMP funded by General Revenue
- Reduction in MPEs

As required by section 893.055(14), Florida Statutes, the 2018-2019 Prescription Drug Monitoring Program (PDMP) Annual Report highlights this year's accomplishments.

### Report Highlights

#### Increase in Enrollment and Utilization –

HB 21 (2018) requires prescribers and dispensers to consult the Prescription Drug Monitoring System (PDMS) before prescribing or dispensing a controlled substance and authorizes health care practitioners employed by the U.S. Department of Veterans Affairs, Department of Defense and Indian Health Service who are not licensed in Florida to request information from the PDMS. Since the bill took effect on July 1, 2018, there has been a 43.3 percent and 100.1 percent increase in dispenser and prescriber registrations, respectively. As of June 2019, dispensers and prescribers made 50,688,241 queries for information from the PDMS.

#### Reduction of Opioid Prescriptions Dispensed –

There has been a 13.6 percent decrease in the number of schedule II through IV opioid prescriptions dispensed to patients and a 53.3 percent decrease in the average daily morphine milligram equivalents (MME) per prescription when compared to report year (RY) 2018. Additionally, 56,432 unique prescribers received prescriber summary reports from the PDMS.

#### Reduction in Multiple Provider Episodes (MPE) –

Since implementation, through monitoring, analysis and proactive notification of MPEs along with recent mandatory consultation requirements for prescribers and dispensers, Florida has seen an 80.7 percent reduction in the number of individuals having MPEs. Florida has seen a substantial reduction in the number of individuals having MPEs. The data support that as registration and utilization of E-FORCSE by prescribers and dispensers increases, the number of MPEs decreases.

#### Increase in Electronic Health Recordkeeping Integration –

The PDMP has integrated into 455 entities' electronic health recordkeeping (EHR) systems across the state allowing prescribers and dispensers to access PDMP information within their existing clinical workflow. In June 2019 there were 5.7 million queries made through EHR integration.

#### Increase in Data Sharing –

The PDMP is currently sharing data with 16 other state PDMPs and the Military Health Service. During the month of June 2019 there were 132,826 interstate queries performed.



## Introduction

### Current Situation

In the United States (U.S.), 130 people died each day in 2017 from an opioid overdose.<sup>1</sup> The age-adjusted rate of drug overdose deaths involving all opioids increased by 12.0 percent from 13.3 in 2016 to 14.9 per 100,000 population in 2017.<sup>2</sup> To address this public health crisis, health care practitioners throughout the U.S. are actively utilizing tools, such as PDMPs, to combat prescription drug diversion and abuse of controlled substance medications. Currently, 49 states have functioning PDMPs, in addition to the District of Columbia and the U.S. territory of Guam.<sup>3</sup>

Increased regulations related to the prescribing and dispensing of controlled substance medications in Florida have had a direct and measurable impact on the opioid epidemic. From 2017 to 2018, overdose deaths involving prescription opioids continued decreasing. The mortality rate of the two most frequently prescribed opioids, oxycodone and hydrocodone, declined by 13.6 percent (from 2.9 to 2.5 per 100,000 population) and 26.8 percent (from 1.1 to 0.8 per 100,000 population), respectively.<sup>4</sup> Further evidence from two recent studies in Florida showed significant decreases in opioid volume and MMEs prescribed, especially among higher-risk prescribers.<sup>5,6</sup>

The overall goal of PDMPs is to reduce inappropriate access of prescription opioids from licensed health care practitioners. However, there has been a recent shift to the use of illicit opioids, such as heroin, illicitly manufactured fentanyl, and fentanyl analogs, in many of those who had previously misused prescription opioids. In 2017, 28,466 people died from synthetic opioids other than methadone in the U.S., a 45.2 percent increase in the age-adjusted rate from the previous year.<sup>7</sup> During this same period in Florida, the age-adjusted rate increased from 8.3 to 11.0 per 100,000 population.<sup>8</sup> While a series of legislation and guidelines have been implemented to reduce opioid-related harms, tapering decisions and plans should be coordinated between clinicians and their patients as suggested by recent U.S. Health and Human Services guidelines.<sup>9</sup>

The burden associated with the opioid epidemic will likely continue to shift because of the increase in the number of deaths involving synthetic opioids. Through its Opioid Prevention in States initiatives, such as Overdose Data to Action (OD2A), the Centers for Disease Control and Prevention (CDC) has supported statewide programs and county health departments, aimed at maximizing PDMPs, which is expected to further address the epidemic.<sup>10</sup>

### 2016

- March - CDC releases Guidelines for Prescribing Opioids for Pain
- April - Governor signed SB 964 into law authorizing direct access by designees and indirect access by impaired practitioner consultants
- April - Governor signed SB 1604 into law creating a written pamphlet regarding controlled substances including specific information
- Reduction in MPEs
- Reduction in MMEs
- PDMP funded by General Revenue

### 2017

- May - Governor issued an Executive Order and State Surgeon General declared a Public Health Emergency
- June - Governor signed HB 557 into law mandating dispensers report by the next business day; authorizes access by employees of Department of Veteran Affairs

### 2018

- March - Governor signed HB 21 into law increasing regulation of prescribers and dispensers, expanding use of the PDMP, amending criminal laws, and making appropriations
- Launched PMP AWARe platform, NarxCare clinical tool, advanced data analytics and prescriber summary reports

### 2019

- Expanded access to Attorney General for civil or criminal litigation
- Expanded access to other states and Military Health System data
- Exempted prescriber and dispenser consultation for patients admitted to hospice

## Legal Framework

### Summary of Statutory Changes

Section 893.055, Florida Statutes, requires the Department to maintain an electronic system to collect and store controlled substance dispensing information and to release the information as authorized in section 893.0551, Florida Statutes. Table 1 summarizes PDMP and related legislation passed from 2009 through 2019.

**Table 1.** History of legislation by year and bill number.

Year	Bill Number	Summary of Changes
2009	SB 462	Created section 893.055, F.S., establishing the PDMP.
2009	SB 440	Created section 893.0551, F.S., exempting information contained in the PDMP from public record requirements.
2010	SB 2772	Amended sections 893.055 and 893.0551, F.S., establishing a definition for “program manager,” and requiring the program manager to work with certain stakeholders to promulgate rules setting forth indicators of controlled substance abuse. It also authorized the program manager to provide relevant information to law enforcement under certain circumstances.
2011	HB 7095	Amended section 893.055, F.S., reassigning the duties of the Governor’s Office of Drug Control to the Department; to require reports be made to the PDMP within seven days of dispensing rather than 15 days; to prohibit the use of certain funds to implement the PDMP; and to require criminal background screening for all individuals who have direct access to the PDMP.
2013	HB 1159	Appropriated \$500,000 of nonrecurring general revenue funds for the general administration of the PDMP for fiscal year 2013-2014.
2014	HB 7177	Amended sections 893.055 and 893.0551, F.S., renewing the public record exemption and requiring law enforcement and investigative agencies to enter a user agreement with the Department. In addition, it limits the information shared with a criminal justice agency and requires the disclosing person or entity take steps to ensure the continued confidentiality of the information, redacting any non-relevant information at a minimum. Finally, any information related to a criminal case shared with a state attorney may only be released in response to a discovery demand and any unrelated information requires a court order to be released.
2015	SB 2500A	Appropriated \$500,000 of general revenue funds for the general administration of the PDMP for fiscal year 2015-2016.
2016	SB 964	Amended sections 893.055 and 893.0551, F.S., authorizing direct access to the information in the PDMP for designees of prescribers and dispensers and authorizing indirect access for impaired practitioner consultants.



2016	SB 1604	Created section 893.30, F.S., establishing the “Victoria Siegel Controlled Substance Safety Education and Awareness Act” requiring the Department to develop a written pamphlet relating to controlled substances which includes specific educational information and made available to health care practitioners, and entities to disseminate and display. The Department shall also encourage consumers to discuss the risks of controlled substance abuse with their health care providers.
2017	HB 557	Amended section 893.055, F.S., requiring dispensers of controlled substances in schedules II-IV , to report to the department dispensing information no later than the close of the next business day; clarifies the exemption from reporting of information for a rehabilitative hospital, assisted living facility, or nursing home dispensing certain dosage of controlled substance as needed; authorizes access to the database by an employee of the United States Department of Veteran Affairs under certain conditions.
2017	HB 5203	Amended section 893.055, F.S., authorizing the department to use state funds appropriated through the General Appropriations Act to fund the administration of the Prescription Drug Monitoring Program.
2017	HB 7097	Amended section 893.055, F.S., extending the repeal of the Direct Support Organization for the Prescription Drug Monitoring Program until October 1, 2027.
2018	HB 21	Amended sections 893.055 and 893.0551, F.S., requiring mandatory consultation of the PDMP, expanded access by prescribers and dispensers at the US Department of Defense and Indian Health Service; expanded access to Medical Examiners; authorized the exchange of information between states and integration into an electronic health recordkeeping system.
2019	HB 375	Amended section 893.055, defining an electronic health recordkeeping system and authorizes the Department to enter into one or more reciprocal agreements or contracts with the US Department of Veterans Affairs, the US Department of Defense, or the Indian Health Service; and exempts prescribers or dispensers from consulting the PDMP for hospice patients.
2019	HB 1253	Amends sections 893.055 and 893.0551, F.S., defining an electronic health recordkeeping system and requires the Department to assign a unique patient identifier to protect patient identity; expands access to Attorney General for active investigations or pending civil or criminal litigation involving prescribed controlled substances.

## Rule Development

Section 893.055, Florida Statutes, directs the Department to adopt rules as necessary concerning reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the PDMS. The PDMP promulgated rules in Chapter 64K-1, Florida Administrative Code, to provide a framework for the administration of the program.

The Department has engaged in rulemaking to implement the new requirements set forth in HB 21 (2018). A notice of proposed rulemaking has been published and includes the following changes: (1) expands the definition of controlled substance to include schedule V and to conform with federal schedules; (2) expands information reported to the PDMP to include patient telephone number, pharmacy permit number, name of individual picking up prescription, and type of identification provided; (3) updates forms; (4) outlines the registration process for an employee of the United States Department of Veterans Affairs, Department of Defense, Indian Health Service, medical examiners and patients to access information stored in the database; and (5) establishes the process for integration of information into the electronic health recordkeeping systems.<sup>11</sup>

## Florida PDMP Funding

Since implementation of the PDMP in 2009, there have been four sources of funding for the administration of the program, as outlined below.

1. **General Revenue** – Administration of the PDMP is funded through the General Appropriations Act, with \$1,584,741 in general revenue funds appropriated for FY19-20. Previously, the Florida Legislature authorized general revenue appropriations of \$500,000 for administration of the PDMP for FY2013-14, FY2015-16, FY2016-17, and FY2017-18; \$1,702,441 was appropriated for FY18-19.
2. **Private Fundraising** – The Florida PDMP Foundation (Foundation), Inc., is a 501(c)(3), not-for-profit organization incorporated with the Florida Department of State. The Foundation operates as a direct support organization for the Department to provide funding and support for the PDMP. Since its formation, the Foundation has raised over \$2.2 million and has provided \$1,010,513 to fund the administration of the PDMP.
3. **Federal Grants** – The PDMP has been awarded eight federal grants totaling \$5,237,319 which were based on specific projects outlined in the grant application. Of the eight federal grants awarded, the PDMP has accepted six Harold Rogers PDMP grants from the Department of Justice, Office of Justice Programs, Bureau of Justice Assistance; one grant from the Substance Abuse and Mental Health Services Administration; and one grant from the CDC.
4. **Private Grants** – The PDMP was awarded three grant awards from the National Association of State Controlled Substance Authorities totaling \$49,952. These private grant funds were used to create a website, to purchase office equipment, and to purchase promotional items.



## Grant Funded Projects

The PDMP has relied on grant funding to offset system implementation and enhancement costs to the PDMS. The PDMP is currently working on the two-grant funded projects summarized below.

### PDMP Implementation and Enhancement Project 2018-PM-BX-0003

Award Amount: \$749,270 over 24 months.

Project: *Reducing Opioid Abuse and Overdose Deaths in Florida through Expanded Access to E-FORCSE Data.*

The Department was awarded the 2018 Comprehensive Opioid Abuse Site-based Program (competitive grant announcement number BJA-2018-13891) funding under category 5, to enhance the PDMS.

Project Goals: The goals of this project are to: (1) reduce opioid abuse and the number of overdose deaths; and (2) support the proactive use of PDMP information by health care practitioners and public health policymakers to prevent the misuse and diversion of controlled substances.

Project Objectives: This will be achieved through the following objectives:

1. Expand integration of E-FORCSE information into the clinical workflow.
2. Expand interstate data sharing.
3. Enhance the analytic capabilities of the E-FORCSE system.
4. Expand existing outreach and education efforts.

### Overdose Data to Action FAIN NU17CE925020

Award Amount: \$2,044,578 over 36 months.

Project: *Overdose Data to Action Surveillance and Prevention Implementation Grant*

The Department was awarded the 2019 Overdose Data to Action Grant from the CDC, through which the Department will work to decrease the rate of opioid misuse and opioid use disorder, increase provision of evidence-based treatment for opioid use disorder, decrease the rates of emergency department visits due to misuse or opioid use disorder, and decrease the overall drug overdose death rate, including prescription and illicit opioid overdose death rates.

Project Goals: The PDMP goals of this project are to: (1) reduce opioid abuse and the number of overdose fatalities; and (2) support the proactive use of PDMPs and other identified data sets to prevent the misuse and diversion of controlled substances.

Project Objectives: The PDMP objectives will be achieved through the following:

1. Develop a more comprehensive repository of prescription data and resources related to substance abuse and overdose scenarios including more timely or real-time data.
2. Develop a process to integrate resources across the state to create the greatest impact on opioid and all-drug overdose issues in Florida to inform clinical practice.



3. Develop a proactive warning network focused on supply reduction for emerging substance abuse and overdose events as they happen in real-time.
4. Provide recommendations to maximize existing resources including developing and disseminating information or guidance to aid in proactive reporting.
5. Produce and communicate a comprehensive PDMP action plan.
6. Develop a process to research, identify and share best practices from across the nation and increase data sharing across state lines using national hubs.
7. Facilitate improved delegate access and training to expand access to PDMPs via real-time data utilization and exchange and support PDMP training efforts in high-overdose burden regions in county health systems to improve access to nationwide overdose systems that result in immediate action rapidly deployed to impacted zones.
8. Utilize targeted interventions such as academic detailing, or clinical training and outreach within geographic “hot spots” as identified by the system as part of the training model.
9. Integrate state and/or CDC guideline-concordant tools such as cumulative MME calculations into patient PDMP reports.
10. Incorporate proactive prescriber notification of patient overdose deaths.

### Performance Measures

This report contains information on the operation of the program including basic program and system metrics, status of key operational objectives, and findings from various program evaluation activities. The overall goal of this report is to provide information to guide the operation of the PDMP, assess PDMP utilization, answer questions about the impact of PDMP information on clinical practice and patient outcomes, and to evaluate the impact of the PDMP on community health.

### Technical Notes

The current report year (RY) covers the period July 1, 2018 (Q3-Q4 2018) to June 30, 2019 (Q1-Q2 2019). Direct year-to-year comparisons in the report are based on report years. After July 1, 2018, controlled substances include substances named or described in schedules II through V of section 893.03, Florida Statutes.

The characteristics and prescribing patterns of the controlled substances reported to the PDMS are summarized using data downloaded from PMP Advanced Analytics during the period October 7, 2019 to October 18, 2019. In this report, the patient refers to Florida residents 18 years of age and older unless specified otherwise.

Performance measures need to be consistently measured during each performance period so that analysts can rule out any system-level changes that may lead to fluctuations in the data. For example, we have noted in prior years’ annual reports when such system-level changes are likely to impact data interpretation (e.g., incorporation of data from the U.S. Department of Veterans Affairs, tramadol reporting, hydrocodone rescheduling, etc.) and include a timeline of events in the report for the readers.

The PDMP and the Department have made many changes in their operations (e.g., change in database platform and patient matching algorithms, and legal requirements for mandatory use)



during this reporting period that could lead to changes in the data used for performance measures. It is beyond the technical scope of this report to describe these changes in full detail.

The population estimates used in this report are: Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties and Puerto Rico Commonwealth and Municipalities: April 1, 2010 to July 1, 2018 (Source: U.S. Census Bureau, Population Division. Release Date: June 2019).

## Outcomes

To assist in fulfilling program responsibilities, the Department has identified and is reporting outcomes related to its efforts to reduce the rate of inappropriate use of prescription drugs through education and safety efforts; reduce the quantities of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit; increase coordination among partners and stakeholders to achieve improved patient health care; and reduce prescription drug abuse and drug diversion.

### 1. **OUTCOME: Reduction of the rate of inappropriate use of prescription drugs through Department education and safety efforts.**

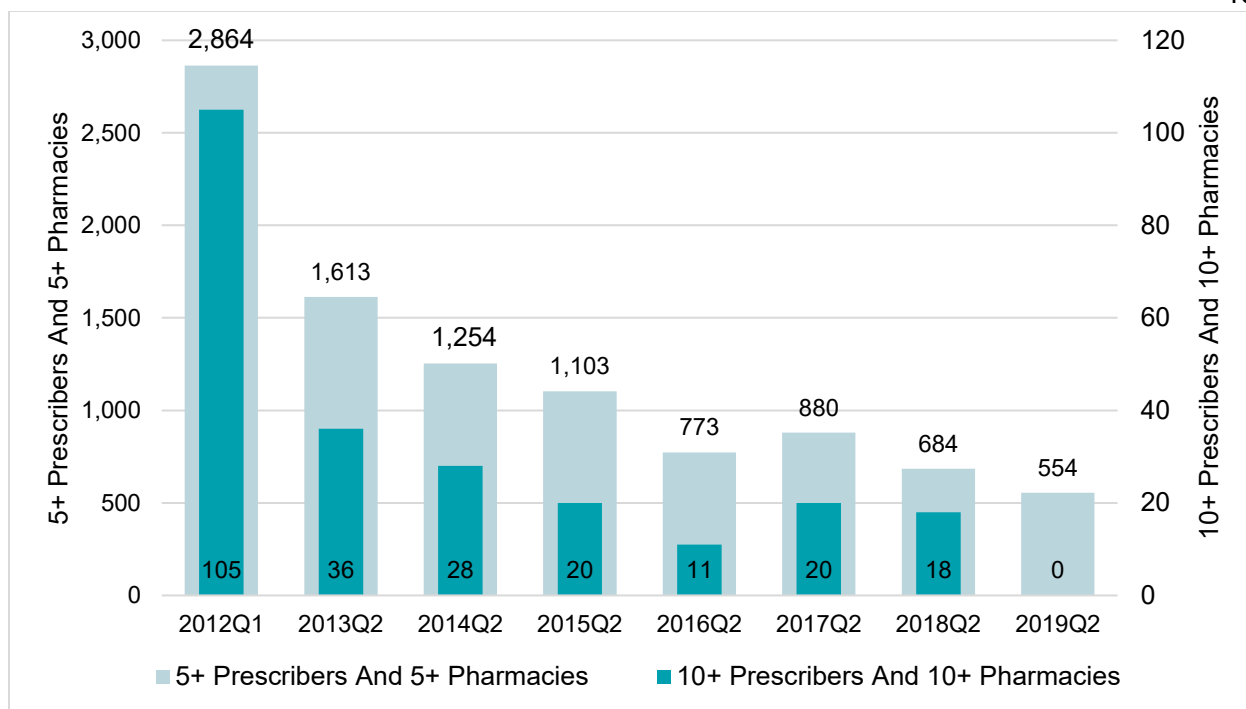
- A. **PERFORMANCE MEASURE:** Multiple provider episode rates based on number of individuals visiting 5/10 number of prescribers and 5/10 number of dispensers in a 90-day period.

Using the data in this performance measure demonstrates the value of the PDMP as a clinical decision-making tool to reduce prescription drug abuse, misuse and diversion. One common definition of a multiple provider episode (MPE) is patient use of five or more prescribers and five or more pharmacies within three months. The data support that as registration and utilization of E-FORCSE by prescribers and dispensers increases, the number of MPEs decreases.

Proactive reporting of MPE individuals to registered prescribers and law enforcement agencies along with education and outreach activity contributed to initial successes in lowering the MPE occurrences. Recent MPE data appear to demonstrate some plateauing of the MPE occurrences. With the implementation of mandatory utilization, EHR integration and enhanced E-FORCSE reports, risk indicators moved into the workflow of all controlled substance providers contributing to further decreases in occurrences.

During January 1, 2012 to March 31, 2012, E-FORCSE data indicated there were 2,864 individuals who had one or more controlled substance prescription drugs prescribed to them by more than five prescribers and dispensed at more than five pharmacies in a 90-day period. By the end of the second quarter of 2019 (April 1, 2019, to June 30, 2019), there was an 80.7 percent reduction or 554 individuals visiting more than five prescribers and more than five pharmacies within 90 days (Figure 1). During the same initial period, 105 individuals had one or more prescription drugs prescribed to them by more than 10 prescribers and dispensed at more than 10 pharmacies in a 90-day period. By the end of the second quarter of 2019 (April 1, 2019, to June 30, 2019), there was a 100 percent reduction or zero individuals visiting more than 10 prescribers and more than 10 pharmacies within 90 days (Figure 1).





\*Schedules II-IV prior to July 1, 2018; Schedules II-V since July 1, 2018.

**Figure 1.** Number of individuals obtaining controlled substance prescriptions\* from 5/10 or more prescribers and 5/10 or more dispensers within a 90-day period, January 2012 – June 2019.

#### B. PERFORMANCE MEASURE: The number of prescriber summary reports generated.

A new system feature provides a summary of a prescribers' own prescribing history, including their ranking compared to the average prescriber of the same specialty, and a summary or graphical representation of their prescribing history. Providing a prescriber with relevant and accurate information can positively influence his or her prescribing of controlled substances. Informing prescribers of their standing among their peers and providing insightful, concise data summaries of patients meeting risk criteria may also assist them with their treatment decisions. A prescriber can access the prescriber summary report from the PMP AWARxE™ website in the same manner as they would request a patient prescription history report.

During July 1, 2018 through January 31, 2019, 56,432 of registered prescribers with valid DEA registration numbers received a prescriber summary report from the PDMS. Of those, 21.7 percent (12,772) prescribers did not write any opioid prescriptions. Of the prescribers receiving information, 62.5 percent (35,279) prescribers prescribed one or more controlled substance prescriptions (Table 2).

**Table 2.** Characteristics of Prescribers Receiving Summary Report, January 2018 to January 2019.

Prescriber Characteristics	January 2018 to June 2018	July 2018 to January 2019
Prescribers receiving summary reports	35,614	56,432
Prescribers did not write any Opioid	3,770	12,272
Prescribers did not write any Opioid / Other CS Prescription	5,788	14,934
Prescribers prescribed less than 7 days of opioids for 95% or more of their patients	7,448	15,963
Prescribers prescribed less than 7 days of opioids for 5% or less of their patients	8,723	7,044

## 2. OUTCOME: Reduction of the quantity of pharmaceutical controlled substances obtained by individuals.

### A. PERFORMANCE MEASURE: Characteristics of controlled substances reported to the PDMS.

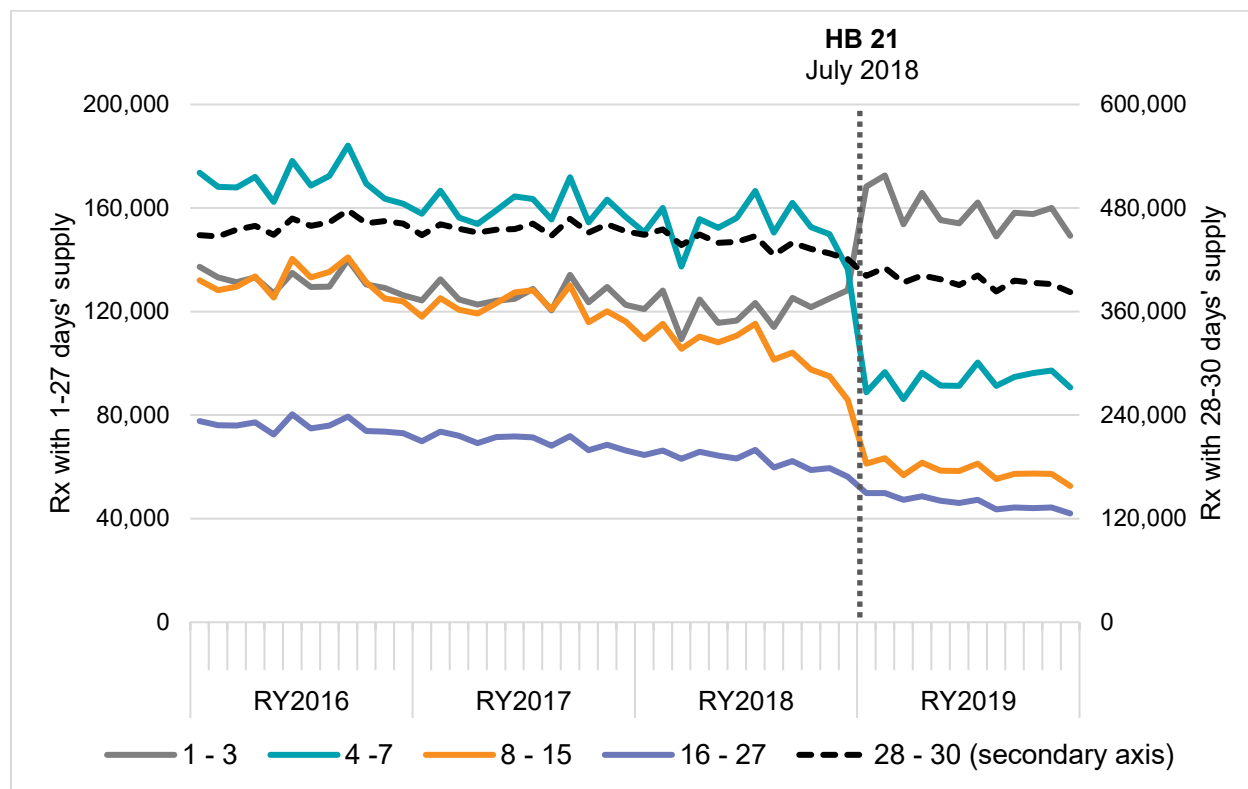
There are 17,070,244 residents 18 years of age and older in Florida, of whom 5.0 million have been prescribed one or more schedule II through schedule IV controlled substances in RY19, a decrease of 10.3 percent. Table 3 illustrates there were 29,935,352 schedule II through IV controlled substance prescriptions dispensed to Florida patients during RY19, a 9.8 percent decline from the prior year. This represents 44.6 days' supply and 93.9 prescription quantity per capita, a decrease of 11.2 percent and 14.9 percent from RY18, respectively. In this report year (RY19), there were 1,142,888 controlled substance prescriptions in schedule V dispensed to 418,118 patients (data not shown).

**Table 3.** Characteristics of schedule II through schedule IV prescriptions dispensed to Florida residents 18 years of age and older.

Data Characteristics	RY2017	RY2018	RY2019	RY18-19 Change (%)
Prescription (Rx)	34,314,133	33,177,140	29,935,352	-9.8%
Days' Supply	864,159,717	841,930,633	761,127,170	-9.6%
Quantity (Qty)	1,942,672,543	1,850,182,230	1,602,117,469	-13.4%
Patient	5,693,472	5,516,979	4,951,216	-10.3%
Pharmacy	6,768	6,328	6,232	-1.5%
Prescriber	143,008	145,332	142,452	-2.0%
Population 18 years and over	16,470,647	16,775,690	17,070,244	
Days Supply / Rx	25.2	25.4	25.4	0.2%
Prescription Qty / Rx	56.6	55.8	53.5	-4.0%
Prescriptions / Patient	6.0	6.0	6.0	0.5%
Days Supply / Patient	151.8	152.6	153.7	0.7%
Prescription Qty / Patient	341.2	335.4	323.6	-3.5%
Prescriptions / Capita	2.1	2.0	1.8	-11.3%
Days Supply / Capita	52.5	50.2	44.6	-11.2%
Prescription Qty / Capita	117.9	110.3	93.9	-14.9%
Opioid Rx	16,221,421	15,402,141	13,306,364	-13.6%
Patient with Opioid Rx	4,044,161	3,824,798	3,220,375	-15.8%
Avg Daily MME per Opioid Rx	159.3	124.0	57.9	-53.3%

B. PERFORMANCE MEASURE: The prescribing patterns for schedule II opioid prescriptions.

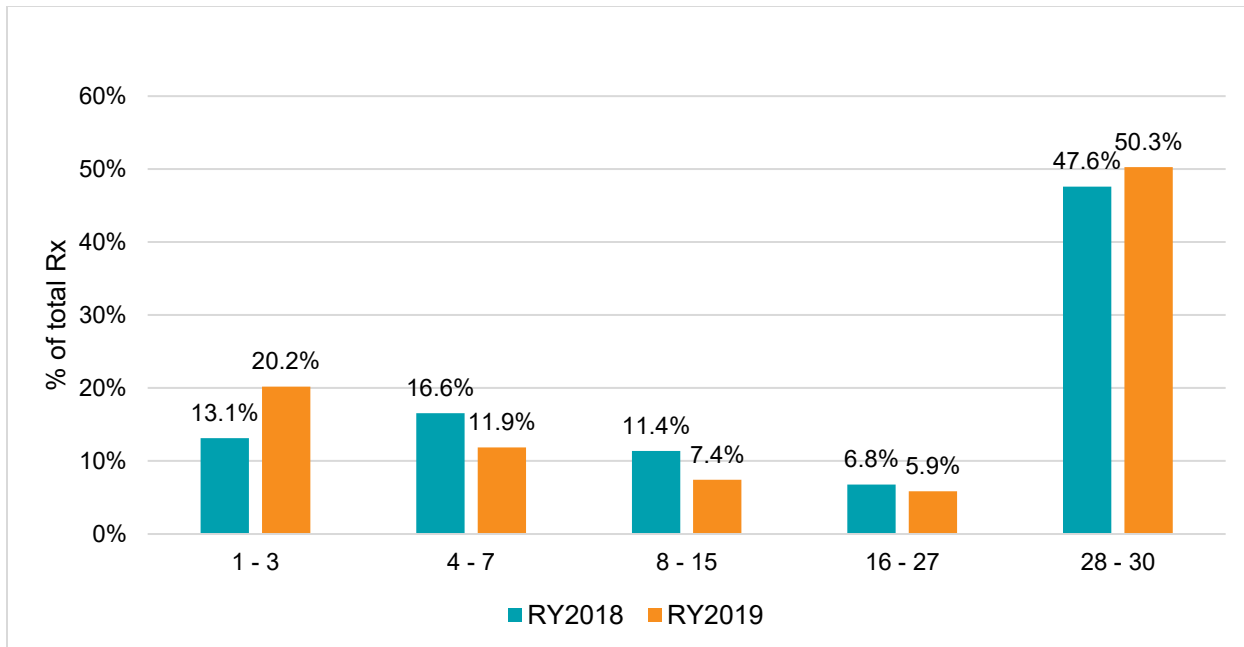
Figure 2 illustrates the number of schedule II opioid prescriptions dispensed to Florida residents during RY16 to RY19 by the days' supply. Overall, the number of schedule II opioid prescriptions decreased by 14.7 percent from 921,684 per month in RY18 to 786,654 per month in RY19.



**Figure 2.** The number of schedule II opioid prescriptions dispensed to Florida residents 18 years of age and older by prescription days' supply.

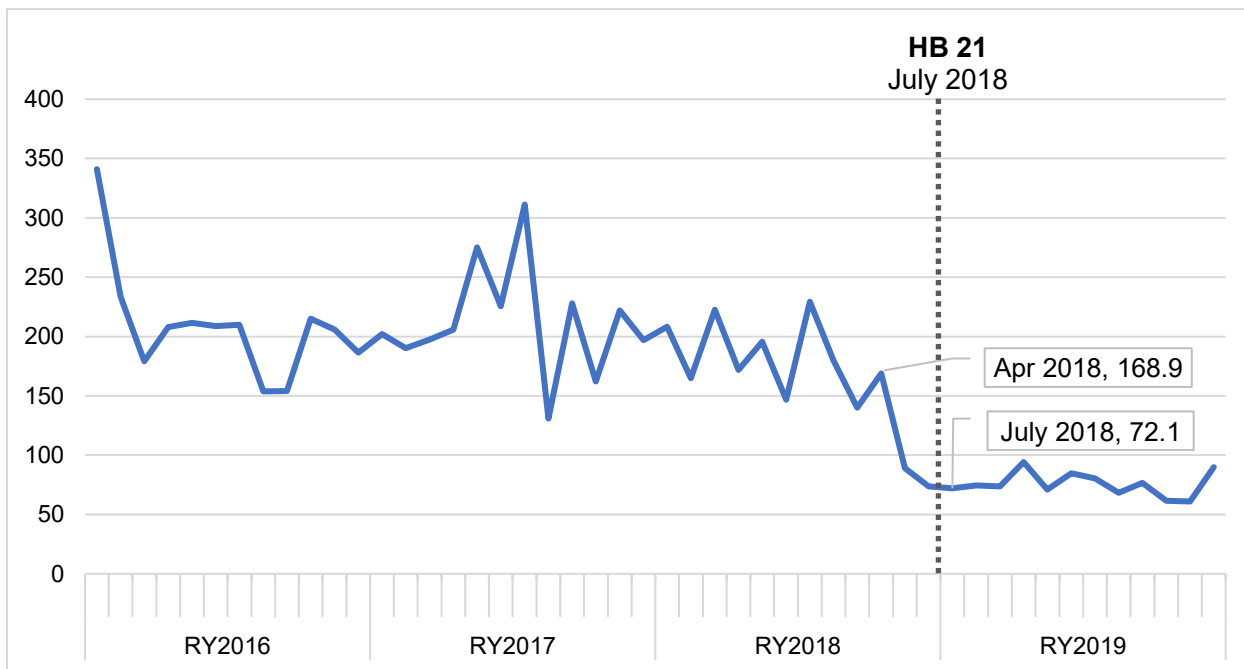
When looking at the prescribing pattern by days' supply, there was a sharp increase in schedule II opioid prescriptions with 1-3 days' supply, while a significant decrease in those with 4-15 days' supply in July 2018 (Figure 2). The prescriptions with 1-30 days' supply accounted for over 95 percent of total schedule II opioid dispensed (Figure 3). The proportion of 1-3 days' supply prescriptions increased from 13.1 percent in RY18 to 20.2 percent in RY19 while that of 4-7- and 8-15-days' supply prescriptions decreased 4.7 and 4.0 percentage points, respectively (Figure 3).





**Figure 3.** Percent of schedule II opioid prescription dispensed to Florida residents 18 years of age and older by prescription days' supply.

Similarly, a substantial decline in average daily MME per schedule II opioid prescription was observed since HB 21 took effect on July 1, 2018 (Figure 4). On average, it decreased from 166.4 in RY18 to 75.6 in RY19 (-54.5 percent).



**Figure 4.** Average daily Morphine Milligram Equivalent (MME) per schedule II opioid prescription.

C. PERFORMANCE MEASURE: Number of prescriptions and percentage of total prescriptions of the most commonly dispensed controlled substances.

Alprazolam, oxycodone SA, and hydrocodone SA were ranked the top three most commonly dispensed controlled substances for a fourth year in a row, representing 37.4 percent of the total controlled substances in schedules II to IV dispensed in RY19. The number of prescriptions for hydrocodone SA decreased by 19.7 percent, and its share of the total controlled substances in schedules II to IV decreased by 1.5 percentage points from RY18 to RY19. Dextroamphetamine is the only controlled substance in the top 10 list that had a year-to-year increase (5.1 percent). In RY19, pregabalin was the most commonly dispensed schedule V controlled substance with 644,232 prescriptions (56.4 percent of the total schedule V), followed by codeine (26.4 percent) and diphenoxylate (8.5 percent) (data not shown).

**Table 4.** The number and percent of prescriptions of the top 10 most commonly dispensed controlled substances in schedule II through schedule IV.

Active Ingredient	Brand Example	Drug Class	RY18	RY18 (%)	RY19	RY19 (%)	RY18-19 Change (%) *
Alprazolam	Xanax	B	4,151,878	12.5%	3,803,014	12.7%	-8.4%
Oxycodone SA	Percocet	O	4,225,588	12.7%	3,781,016	12.6%	-10.5%
Hydrocodone SA	Vicodin	O	4,502,930	13.6%	3,614,851	12.1%	-19.7%
Tramadol SA	Ultram	O	2,766,934	8.3%	2,405,788	8.0%	-13.1%
Zolpidem	Ambien	M	2,130,714	6.4%	1,937,086	6.5%	-9.1%
Clonazepam	Klonopin	B	2,035,266	6.1%	1,920,823	6.4%	-5.6%
Dextroamphetamine	Adderall	S	1,614,766	4.9%	1,697,396	5.7%	5.1%
Lorazepam	Ativan	B	1,686,903	5.1%	1,570,994	5.2%	-6.9%
Temazepam	Restoril	B	1,252,059	3.8%	1,088,060	3.6%	-13.1%
Phentermine	Adipex	S	1,047,581	3.2%	1,009,036	3.4%	-3.7%

Key: B=Benzodiazepine, O=Opioid, S=Stimulant, M=Miscellaneous, rank refers to the current reporting period.

\* Relative percent change may vary due to the ability to identify new products and their associated national drug codes.

### 3. OUTCOME: Increased coordination among partners participating in the PDMP.

A. PERFORMANCE MEASURE: The number of authorized users who have requested and received controlled substance dispensing information by user role type.

The increased coordination among partners participating in the PDMP can be measured in terms of the number of authorized users who have requested and received controlled substance dispensing information. Impaired practitioner consultants, law enforcement, medical examiners, and regulatory agency administrators do not have direct access to the information in the PDMS. Requests are approved by PDMP staff prior to its release. Dispensers and prescribers and their designee(s) have direct access to information in the PDMS.

Table 5 illustrates the cumulative number of registrants and queries by user role type, report year and percentage of change.

*Impaired Practitioner Consultants:* Information is released to impaired practitioner consultants who are retained by the Department to review the information of an impaired practitioner program participant or a person referred who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to the consultant's access to review such information.<sup>12</sup> There were five impaired practitioner consultant registrations and 45 requests for information as of June 2019.

*Law Enforcement:* Law enforcement may request controlled substance prescription information from the program manager during an active investigation related to prescribed controlled substances. Active investigations may involve potential criminal activity, fraud, theft, and other specific crimes related to controlled substances. During the reporting period, there was a 69.5 percent increase in the number of law enforcement authorized users from 151 by RY18 to 256 by RY19. There were 6,337 requests for information as of June 2019.

*Medical Examiners:* Indirect access to information in the PDMS was expanded with passage of HB 21 (2018) authorizing district medical examiners to request information to determine the cause of death of an individual. There were 42 medical examiner users approved during RY19. There was a total of 773 requests for patient information as of June 2019.

*Dispensers:* The term “dispenser” is defined as a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances in or into this state.<sup>13</sup> A dispenser or his or her designee may have direct access to the information in the PDMS.<sup>14</sup> The total number of dispensers listed in Table 5 reflects the cumulative number of pharmacists, pharmacists’ delegates, and VA dispensers. Dispenser registrations increased 43.1 percent from 18,766 as of June 2018 to 26,885 as of June 2019.

*Prescribers:* The term “prescriber” is defined as a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order controlled substances.<sup>15</sup> A prescriber or his or her designee may have direct access to the information in the PDMS.<sup>16</sup> The total number of prescribers listed in Table 5 reflects the cumulative number of prescribers, prescriber delegates, and VA prescribers. The prescriber registrations increased 100.1 percent from 43,738 by RY18 to 87,537 by RY19. To increase utilization of the PDMS, direct access was expanded with passage of HB 21 (2018) authorizing health care practitioners employed by the U.S. Department of Veterans Affairs, Department of Defense, and Indian Health Service who are not licensed in Florida to request information from the PDMS. Federally-employed practitioners are required to submit proof of licensure in another state and employment verification information for access to be granted. There was a 533.8 percent increase in the number of federally-employed prescriber registrations from 71 registrations by RY18 to 450 by RY19. There was an 88.9 percent increase in the number of Veterans Affairs-employed dispenser registrations from 36 registrations by RY18 to 68 by RY19.

*Regulatory Agency Administration:* There was a 58.5 percent increase in the total number of agency administrators approved by RY19. Agency administrators include administrators for law enforcement and department investigative services. There was a total of 803 requests made by agency administrators for information as of June 2019.



**Table 5.** User registration and utilization by user role type, report year and percentage of change.

User Role Type	RY18 Registrants**	RY19 Registrants**	RY18-19 Change (%)	RY19 Queries**
<b>Impaired Practitioner Consultant</b>				
Impaired Practitioner Consultant	2	3	50.0%	36
Impaired Practitioner Consultant Admin	1	2	100.0%	9
<i>Total</i>	3	5	66.7%	45
<b>Law Enforcement</b>				
Drug Enforcement Administration (DEA)	52	79	51.9%	3,252
Federal Bureau of Investigation (FBI)	2	3	50.0%	162
U.S. Department of Health and Human Services (HHS)	6	8	33.3%	462
Local Police Jurisdiction	65	119	83.1%	1,750
Medicaid Fraud Unit	5	7	40.0%	220
Military Police	N/A	11	-	42
State Police	17	25	47.1%	312
State Prosecutor (District or Commonwealth Attorney)	4	4	0.0%	137
<i>Total</i>	151	256	69.5%	6,337
<b>Medical Examiner</b>				
Medical Examiner - Delegate	N/A	33	-	517
Medical Examiner	N/A	9	-	256
<i>Total</i>	N/A	42	-	773
<b>Dispenser</b>				
Pharmacist	12,789	16,182	26.5%	20,329,094
Pharmacist's Delegate	5,941	10,635	79.0%	6,414,317
VA Dispenser	36	68	88.9%	10,595
<i>Total</i>	18,766	26,885	43.3%	26,754,006
<b>Prescriber</b>				
Dentist (DN)	2,419	6,234	157.7%	443,978
Medical Resident	1,565	4,012	156.4%	240,344
Military Prescriber	5	161	3120.0%	4,677
Nurse Practitioner (APRN)	2,270	4,971	119.0%	939,524
Optometrist (OD)	13	53	307.7%	160
Physician (MD, DO)	22,894	38,547	68.4%	11,449,249
Physician Assistant (PA)	956	2,238	134.1%	380,933
Podiatrist (DPM)	395	934	136.5%	51,577
Prescriber Delegate	9,289	23,445	152.4%	9,000,614
Prescriber without DEA	3,866	6,653	72.1%	1,388,059
VA Prescriber	66	289	337.9%	35,120
<i>Total</i>	43,738	87,537	100.1%	23,934,235
<b>Regulatory Agency Administration*</b>				
Agency Administrator	65	103	58.5%	803
<i>Total</i>	65	103	58.5%	803
<b>Grand Total</b>	62,723	114,828	83.1%	50,696,199

\*Agency Admin includes administrators for law enforcement and department investigative services.

\*\*Cumulative numbers.

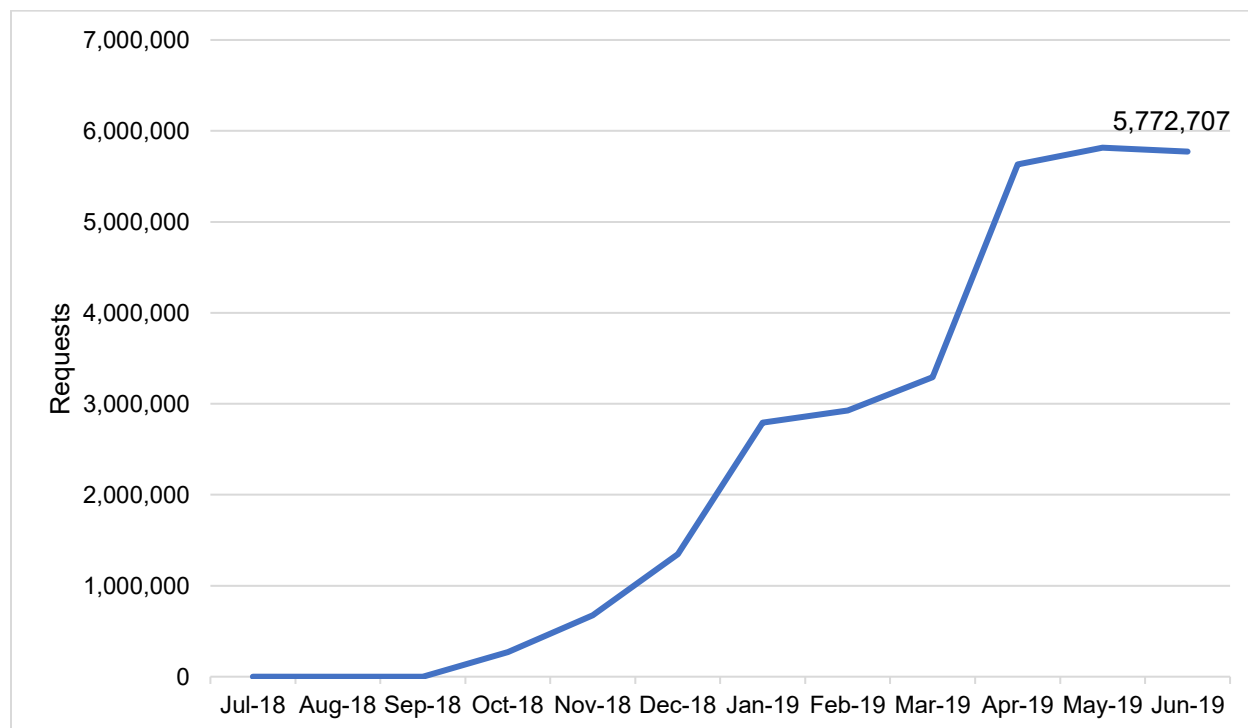
#### 4. OUTCOME: Involvement of stakeholders in achieving improved patient health care, safety, and reduction of prescription drug abuse and prescription drug diversion.

- A. PERFORMANCE MEASURE: The number of electronic health recordkeeping (EHR) system integrations and number of requests made.

HB 21 (2018) was passed by the Florida Legislature and signed into law by the Governor, authorizing the Department to enter into agreements to integrate PDMP information into EHR



systems to allow prescribers and dispensers to access PDMP information within their existing clinical workflow. The PDMP has been integrated into 455 entities' EHR systems across the state and monthly requests through EHR integrations reached 5,772,707 in June 2019. Figure 5 illustrates the number of queries requested through EHR integration by month.

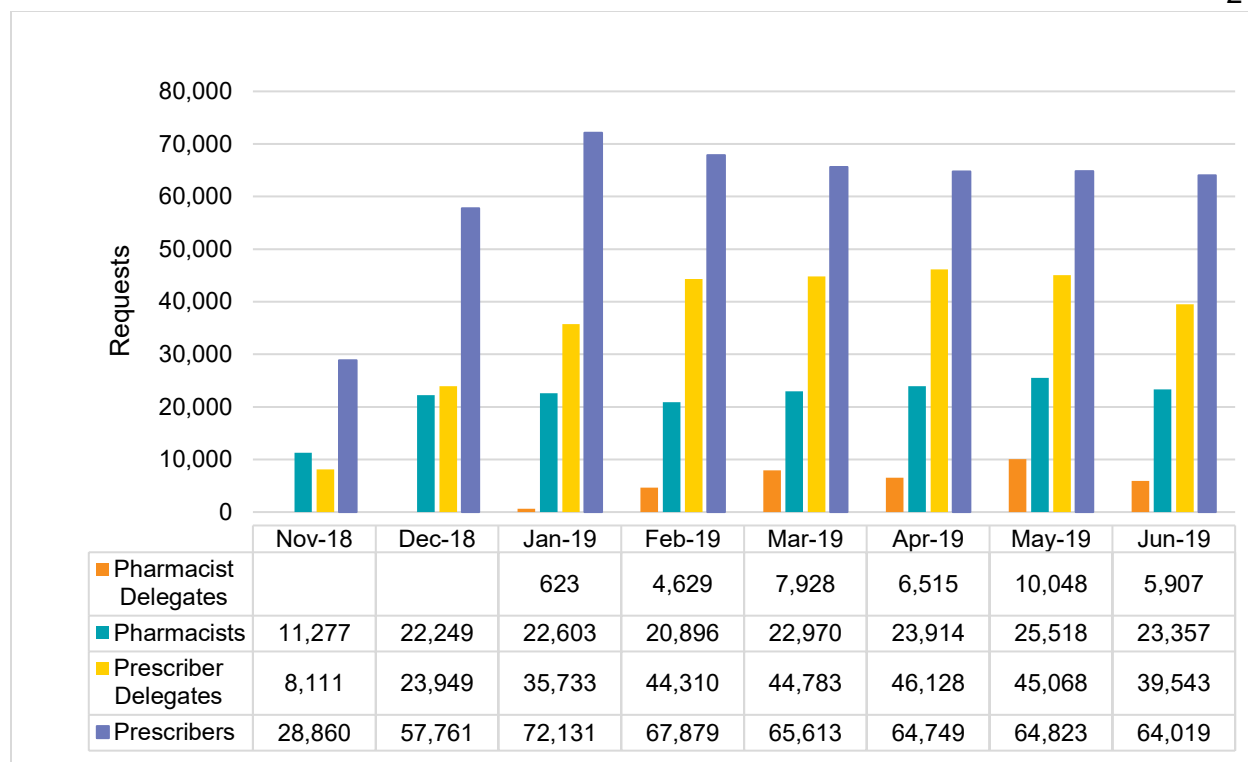


**Figure 5.** Queries requested through Electronic Health Recordkeeping System Integrations, July 2018 – June 2019.

**B. PERFORMANCE MEASURE:** The number of interstate PDMP requests received by user role type.

HB 21 (2018) authorized the Department to enter into reciprocal agreements to share PDMP information with health care practitioners in other states if the PDMPs are compatible with the Florida PDMP. To determine compatibility the Department considers safeguards for protecting patient privacy, user access, controlled substances monitored, data reported to the program's system, additional criteria deemed essential for a thorough comparison, and the costs and benefits to the state.

The PDMP is currently sharing data with 16 other states and the Military Health System. Figure 6 illustrates the number of queries by month and user role type. In June 2019, 132,826 interstate queries were made by pharmacist delegates, pharmacists, prescriber delegates, and prescribers.

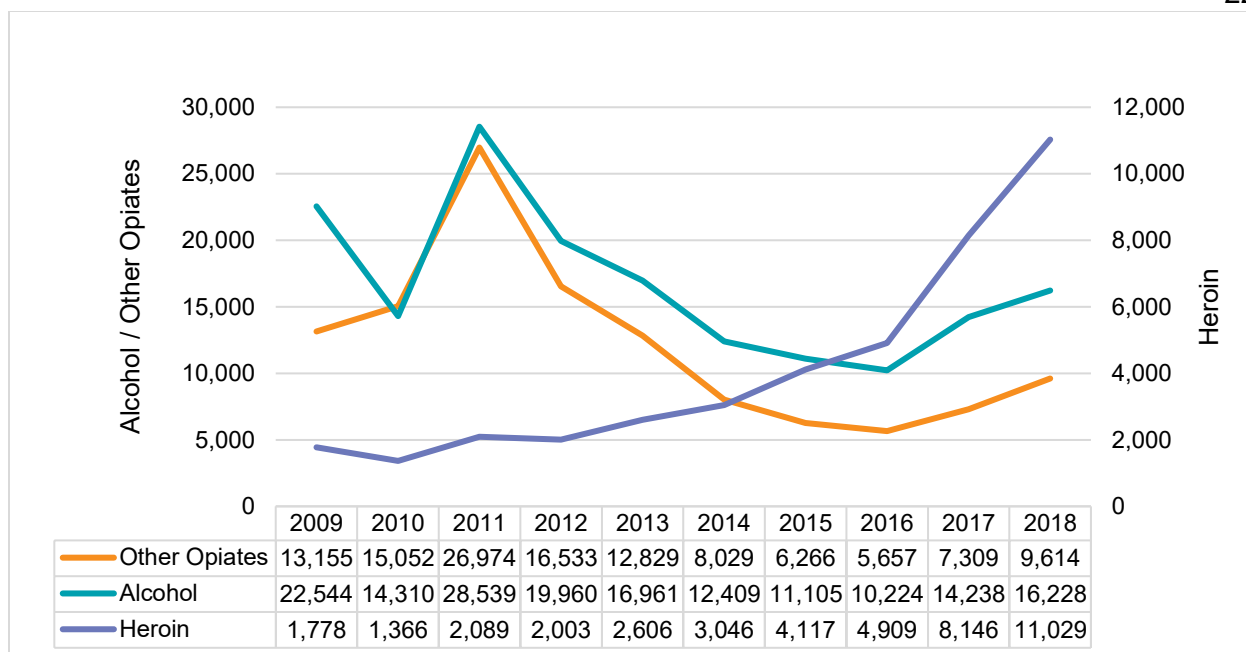


**Figure 6.** Interstate PDMP requests, by user role, November 2018 – June 2019.

**C. PERFORMANCE MEASURE:** The number of Florida substance abuse treatment admissions by primary substance use.

The Treatment Episode Data Set – Admissions (TEDS-A) is maintained by the Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (SAMHSA). The TEDS-A system includes annual records for substance abuse treatment admissions. Data shown here are routinely collected by states to monitor their individual substance abuse treatment systems (Figure 7).<sup>17</sup>

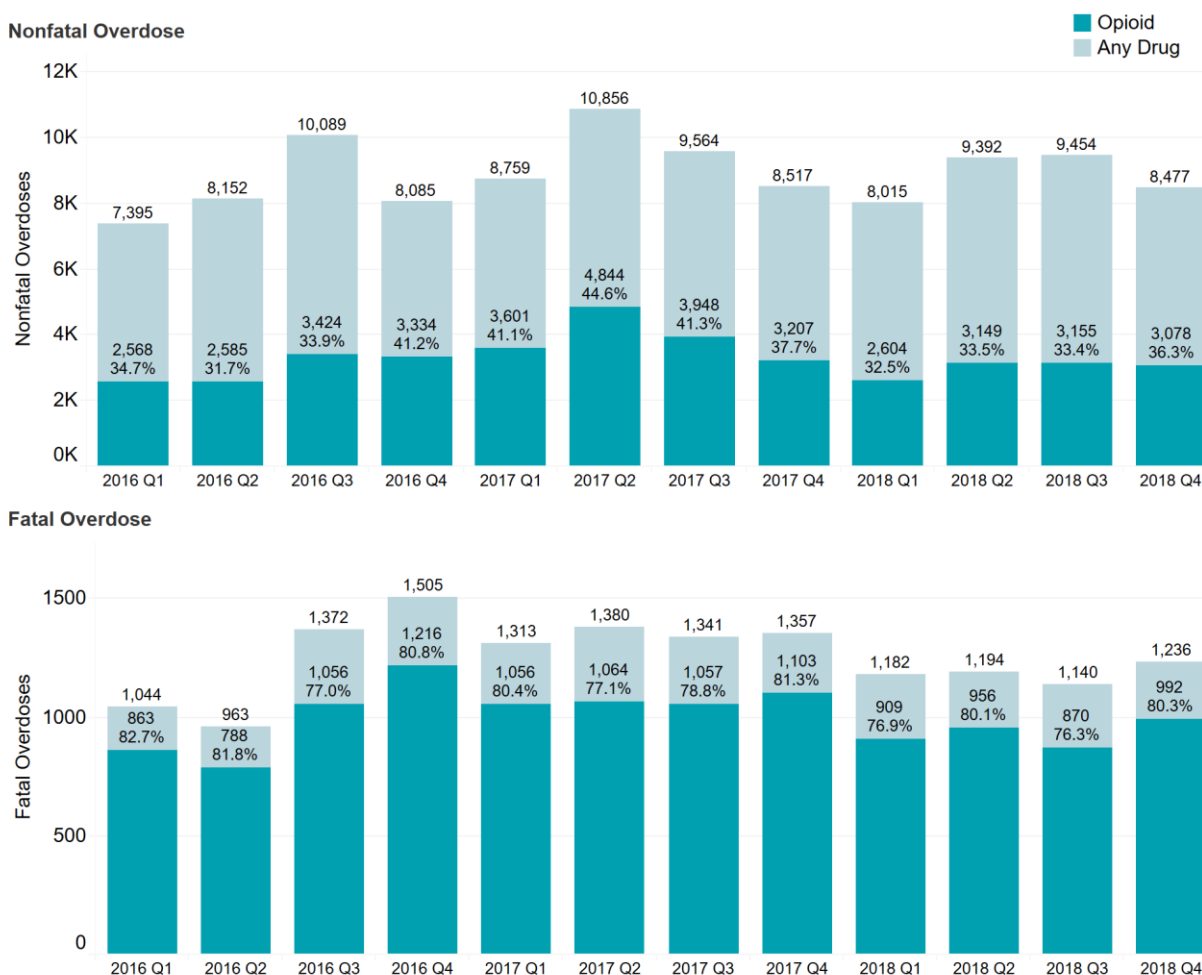
The “other opiates” category includes methadone, buprenorphine, codeine, hydrocodone, hydromorphone, meperidine, morphine, opium, oxycodone, pentazocine, propoxyphene, tramadol, and any other drugs with morphine-like effects. Treatment admissions for other opiates including synthetics increased from 7,309 in 2017 to 9,614 in 2018 (a 31.5 percent increase). Heroin admissions have continued increasing since 2012, with a 35.4 percent increase from 8,146 in 2017 to 11,029 in 2018 (Figure 7). Alcohol treatment admissions are shown for reference.



**Figure 7.** Florida admissions to substance abuse treatment, aged 12 years and older, by primary substance use, 2009 – 2018.

#### D. PERFORMANCE MEASURE: Nonfatal and fatal drug overdoses in Florida.

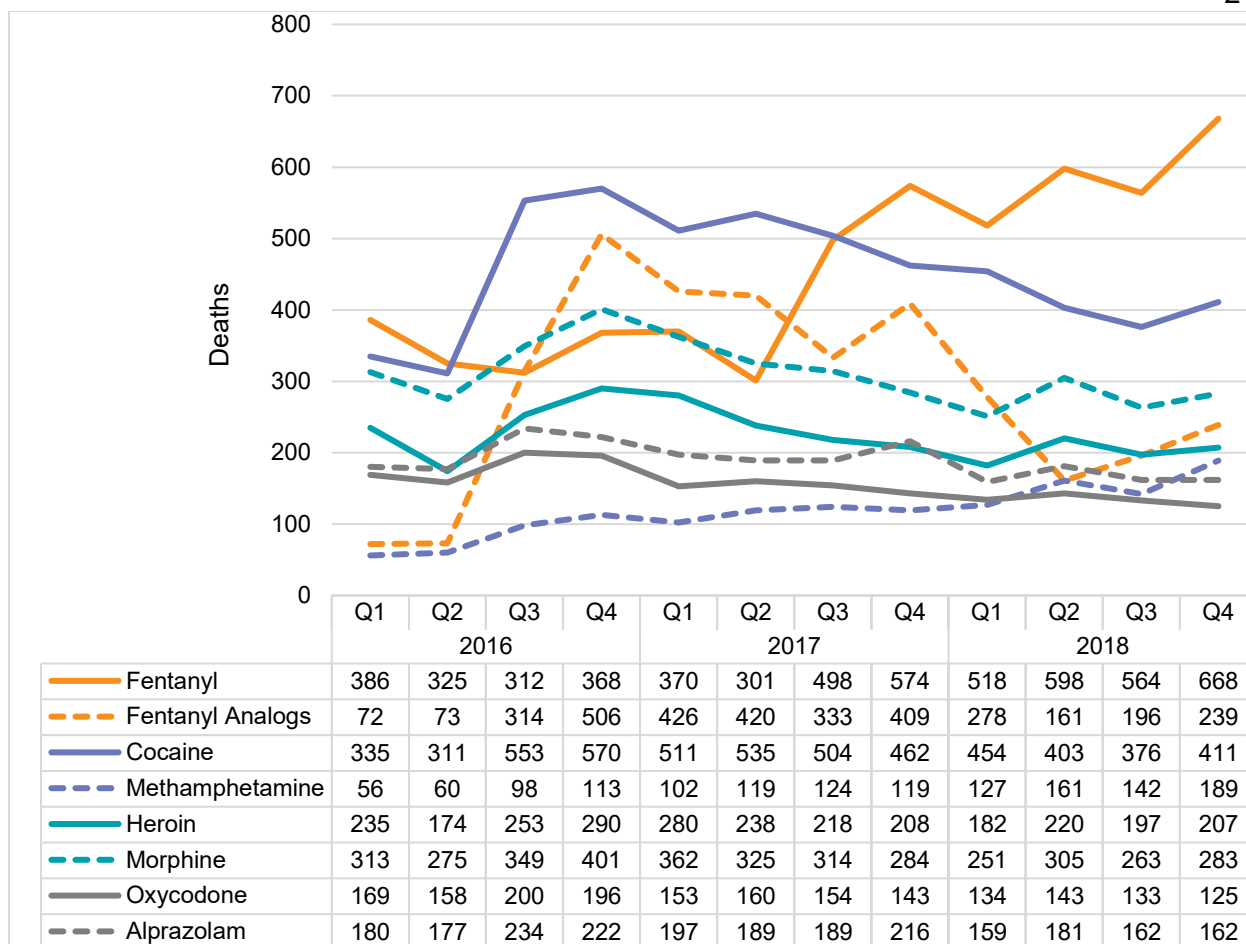
Figure 8 illustrates the drug and opioid-involved nonfatal and fatal overdoses in Florida during 2016 to 2018. The nonfatal overdose data were analyzed by the Florida Department of Health's Enhanced State Opioid Overdose Surveillance Program using Florida's Emergency Medical Services Tracking and Reporting System data.<sup>18</sup> The drug-caused deaths (fatal overdoses) were reported by the Florida Department of Law Enforcement Medical Examiners Commission.<sup>19</sup> On average, during 2016 to 2018, opioids accounted for 37.4 percent of nonfatal overdoses and 79.4 percent of fatal overdoses.



**Figure 8.** Quarterly drug and opioid-involved nonfatal and fatal overdoses in Florida, 2016-2018.

Figure 9 illustrates the drugs most frequently contributing to deaths reported by the Florida Department of Law Enforcement Medical Examiners Commission.<sup>20</sup> From 2017 to 2018, there was a decline in the number of deaths caused by fentanyl analogs (-45.0 percent), cocaine (-18.3 percent), alprazolam (-16.1 percent), heroin (-14.6 percent), morphine (-14.2 percent), and oxycodone (-12.3 percent). The number of deaths caused by fentanyl and methamphetamine increased by 34.7 percent and 33.4 percent, respectively. In the majority of fentanyl-caused deaths, illicitly manufactured fentanyl was used by the decedent. Medical Examiner access to the PDMS provides the decedent's prescription drug-use history for investigative purposes.





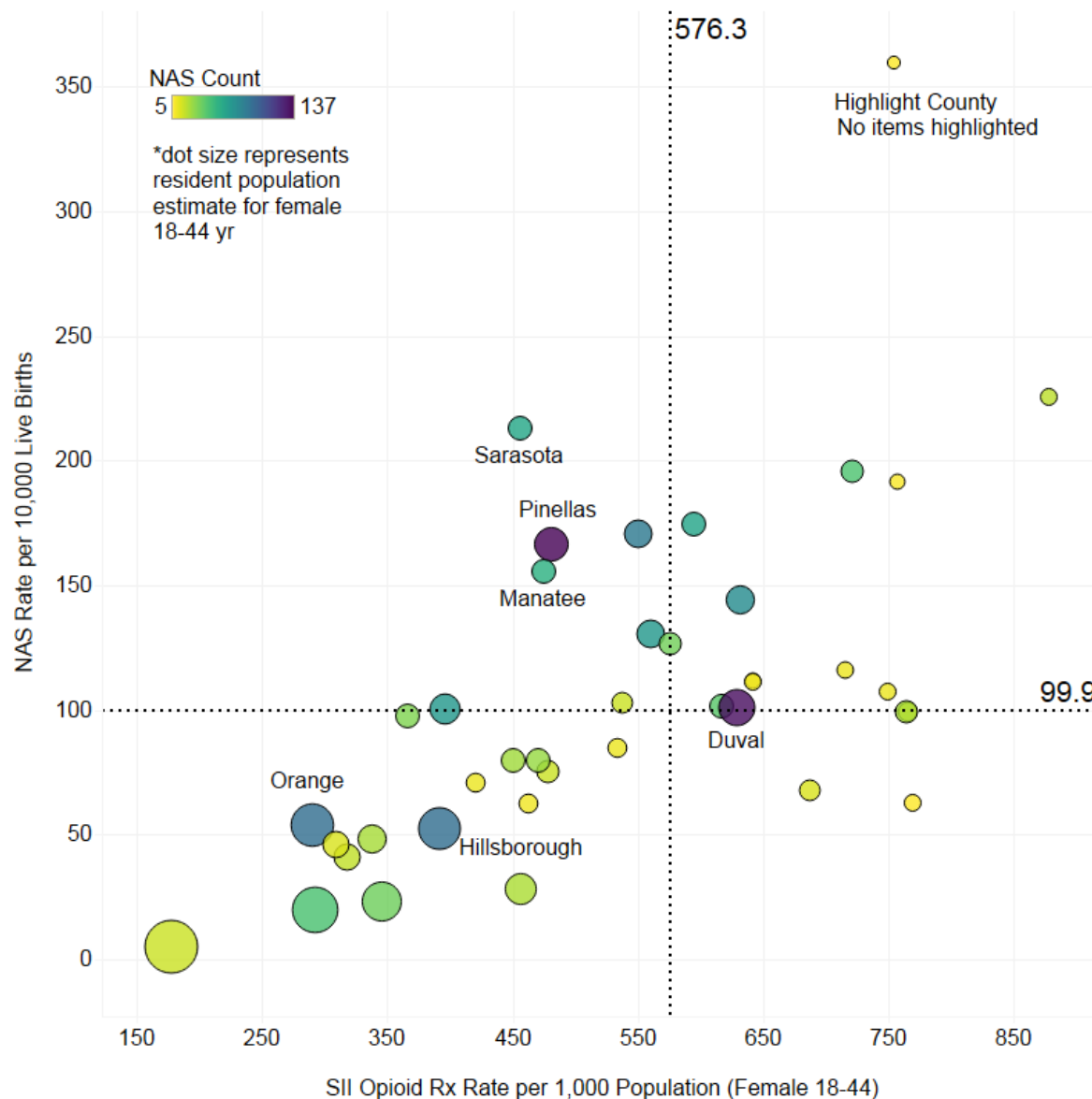
**Figure 9.** Quarterly drug overdose deaths by contributing drug in Florida, 2016 – 2018.

**E. PERFORMANCE MEASURE: Neonatal Abstinence Syndrome (NAS) rates versus schedule II opioids prescribing rates by county.**

The opioid epidemic also impacts pregnant women and newborn infants. The prenatal use of opioids by pregnant women including opioid misuse, use of opioids prescribed for pain management, and use of certain medications given to treat opioid addiction can produce a withdrawal condition in newborn infants known as neonatal abstinence syndrome (NAS).<sup>21</sup> Future work with states' teams might focus on increasing surveillance and evaluation, sustaining coverage, and reducing stigma experience by women and infants.<sup>22</sup>

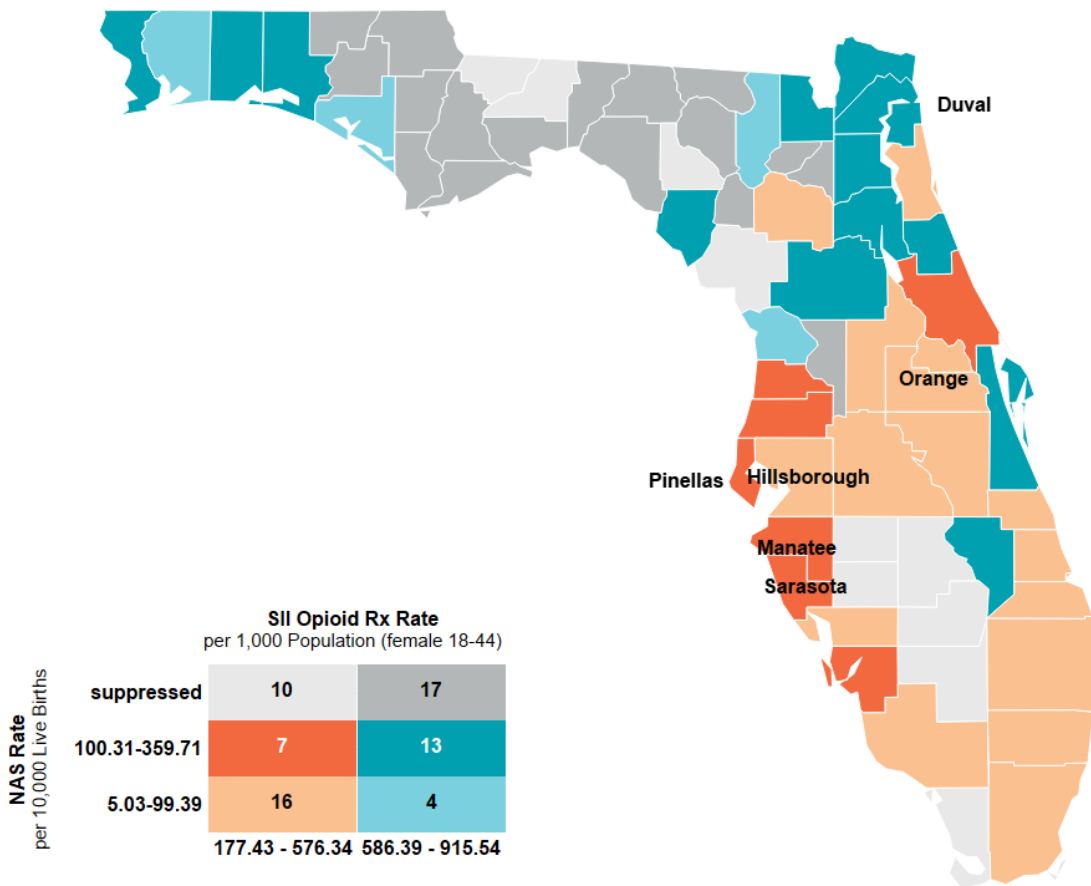
In 2017, the NAS rate varied by county with the state rate of 67.2 per 10,000 live births. Figure 10(a) compares the NAS rate (median of 99.9 excluding counties with low count) reported by the Florida Birth Defects Registry<sup>23</sup> with the prescribing rate of schedule II opioids (median of 576.3). To highlight the areas where targeted intervention may be prioritized, the dots are color-coded to reflect NAS cases and sized to represent the population of females 18-44 years of age. Generally, the NAS rates increased with the schedule II opioid prescribing rates. As shown in Figure 10(b), counties in the Panhandle area (such as Escambia and Okaloosa) and counties in the north-central area (such as Duval, Clay, and Marion) had relatively high rates of NAS and schedule II opioid prescribing. Counties such as Orange and Hillsborough with lower rates in both measures should not be neglected given their relatively high female population and NAS cases. Counties with relatively low schedule II opioid prescribing rate but high NAS rate may

face substance abuse problems related to NAS other than schedule II opioids. For example, Manatee, Pinellas, and Sarasota were the counties impacted most by fentanyl analogs in 2017. This emphasizes the importance of the collaboration between PDMP and other agencies to target the source of the substance abused. Identifying the individual- and structural-level factors contributing to the NAS is beyond the scope of this report; however, statewide efforts on reducing harms associated with substance abuse among vulnerable populations through multidisciplinary collaboration is important.



\*Counties with fewer than 5 cases were not shown in the figure and excluded when calculating the median of the NAS rates. Schedule II opioid prescribing to females 18-44 years of age were identified using APPRISS de-identified datasets with RxNorm NDC crosswalk.

**Figure 10(a).** Neonatal Abstinence Syndrome cases per 10,000 live births and prescriptions of schedule II opioids per 1,000 female 18-44 population in Florida, 2017.



**Figure 10(b).** Neonatal Abstinence Syndrome cases per 10,000 live births and prescriptions of schedule II opioids per 1,000 female 18-44 population in Florida, by county, 2017.

## Conclusion

Over the past decade, opioid prescriptions in the U.S. peaked at 255 million in 2012 and then decreased to 191 million in 2017.<sup>24</sup> In Florida, there has been a similar decline. Opioid prescriptions have been reduced by 13.6 percent from 15.4 million (RY18) to 13.3 million (RY19) prescriptions. On October 10, 2019, the U.S. Department of Health and Human Services (HHS) published a new *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*.<sup>25</sup> The HHS Guide provides advice to further support clinicians who are contemplating or initiating a change in opioid dosage for their patients.

As a result of the passage of HB 21 (2018), each prescriber and dispenser must consult the PDMS to review a patient's-controlled substance dispensing history before a controlled substance is prescribed or dispensed to a patient age 16 or older, unless a statutory exemption applies. There has been a 43.3 percent increase in the number of dispenser registrations and 100.1 percent increase in the number of prescriber registrations. Together, dispensers and prescribers have queried the PDMS over 50 million times. With the integration of NarxCare™ into the clinical workflow through EHR systems and pharmacy management systems, mandatory use of the PDMS has been seamless. The PDMP has been integrated into 455 entities' EHR systems across the state. In June 2019, there were 5.7 million queries made through EHR integration. In addition, the PDMP is currently sharing data with 16 other states and the Military Health Service. In June 2019, there were 132,826 interstate queries performed.

There are 5.0 million Florida residents 18 years of age and older who have been prescribed one or more schedule II through schedule IV prescriptions for controlled substances, a decrease of 10.3 percent. There has been a 53.3 percent decrease in the average daily MME per prescription when compared to RY18. There has also been a 15.8 percent decrease in the number of patients receiving an opioid prescription from 3,824,798 to 3,220,375. Additionally, Florida has seen an 80.7 percent decrease in the number of individuals having MPEs.

NAS rates among infants generally increased with the schedule II opioid prescribing rates among females 18 to 44 years of age at the county level. The areas with relatively low schedule II opioid prescribing rates, but high NAS rates, highlight the importance of interagency collaboration. The access of PDMS for medical examiners and the EHR integration provides an opportunity for researchers and public health officials to identify the determinants with enriched data, and to guide both patient- and community-level interventions to reduce NAS rates.

E-FORCSE continues to be a critical tool, to protect the health and safety of Floridians by reducing misuse, abuse and diversion of the controlled substances and related harms, while supporting sound clinical practice in the prescribing and dispensing of controlled substances.

As the Department continues to work with other state agencies and stakeholders to combat the opioid crisis in Florida, E-FORCSE will expand collaboration with public health and public safety agencies to support surveillance, intervention and treatment.



## References

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- <sup>1</sup> Scholl, L., Seth, P., Kariisa, M., Wilson, N., & Baldwin, G. (2019). Drug and opioid-involved overdose deaths—United States, 2013–2017. *Morbidity and Mortality Weekly Report*, 67(5152), 1419.
- <sup>2</sup> Scholl et.al, supra note 1.
- <sup>3</sup> Prescription Drug Monitoring Program Training and Technical Assistance Center, Prescription Drug Monitoring Frequently Asked Questions (FAQ), 2019. Available at <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>
- <sup>4</sup> Medical Examiners Commission. Drugs Identified in Deceased Persons by Florida Medical Examiners 2018 Annual Report. Florida Department of Law Enforcement, Medical Examiners Commission, November 2019
- <sup>5</sup> Rutkow, Lainie, et al. "Effect of Florida's prescription drug monitoring program and pill mill laws on opioid prescribing and use." *JAMA internal medicine* 175.10 (2015): 1642-1649.
- <sup>6</sup> Chang, Hsien-Yen, et al. "Impact of prescription drug monitoring programs and pill mill laws on high-risk opioid prescribers: a comparative interrupted time series analysis." *Drug and alcohol dependence* 165 (2016): 1-8.
- <sup>7</sup> Scholl et.al, supra note 1.
- <sup>8</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018.
- <sup>9</sup> U.S. Department of Health and Human Services, News Release- HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use, Oct. 10, 2019; available at <https://www.hhs.gov/about/news/2019/10/10/hhs-announces-guide-appropriate-tapering-or-discontinuation-long-term-opioid-use.html>.
- <sup>10</sup> Haegerich, Tamara M., et al. "Evidence for state, community and systems-level prevention strategies to address the opioid crisis." *Drug and alcohol dependence* 204 (2019): 107563.
- <sup>11</sup> Notice of Proposed Rule, Florida Administrative Register Volume 45/167, published 8/27/2019, available at [https://www.flrules.org/gateway/RuleNo.asp?title=Prescription Drug Monitoring Program&ID=64K-1.001](https://www.flrules.org/gateway/RuleNo.asp?title=Prescription+Drug+Monitoring+Program&ID=64K-1.001)
- <sup>12</sup> *Fla Stat* 893.055(5)(e)
- <sup>13</sup> *Fla Stat* 893.055(1)(e)
- <sup>14</sup> *Fla Stat* 893.055(4)(a)
- <sup>15</sup> *Fla Stat* 893.055(1)(j)

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<sup>16</sup> *Fla Stat 893.055*, supra note 14.

<sup>17</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2009 - 2018. Admissions to and Discharges from Publicly-Funded Substance Use Treatment. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019.

<sup>18</sup> Florida Enhanced State Opioid Overdose Surveillance Program Quarterly Opioid Overdose Surveillance available at <http://www.floridahealth.gov/statistics-and-data/fl-esoos/>.

<sup>19</sup> *Id.* at 4.

<sup>20</sup> Medical Examiner Commission data available at <https://www.fdle.state.fl.us/MEC/Publications-and-Forms>.

<sup>21</sup> See Mark L. Hudak and Rosemarie C. Tan, American Academy of Pediatrics, “Neonatal Drug Withdrawal,” *Pediatrics*, vol. 129, no.2 (2012). Though other drugs may cause NAS, opioids are considered the primary cause. When it is possible to determine that the withdrawal symptoms are unique to opioids, the more precise term “neonatal opioid withdrawal syndrome” is used. However, because opioid use often does not occur in isolation from other risk factors or other substance use—such as alcohol, barbiturates, and selective serotonin reuptake inhibitors—it can be difficult to identify neonatal opioid withdrawal syndrome. For purposes of this report, we refer to these withdrawal symptoms as neonatal abstinence syndrome, or NAS.

<sup>22</sup> Kroelinger CD, Rice ME, Cox S, et al. State Strategies to Address Opioid Use Disorder Among Pregnant and Postpartum Women and Infants Prenatally Exposed to Substances, Including Infants with Neonatal Abstinence Syndrome. *MMWR Morb Mortal Wkly Rep* 2019;68:777–783. DOI: <http://dx.doi.org/10.15585/mmwr.mm6836a1>

<sup>23</sup> Florida Birth Defects Registry data available at <http://www.floridahealth.gov/diseases-and-conditions/birth-defects/neonatalabstinencesyndromenas.html>.

<sup>24</sup> U.S. Dept of Health and Human Services, supra note 8.

<sup>25</sup> *Id.* at 21.

