2011-2012
Prescription Drug Monitoring Program
Annual Report

December 1, 2012

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Governor

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Florida Department of Health

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Message from the State Surgeon General

As State Surgeon General of the Florida Department of Health (DOH), I am pleased to join the Prescription Drug Monitoring Program (PDMP) staff and Foundation Board of Directors in presenting the 2011-2012 Annual Report. This report reflects the hard work and dedication of the program staff in the program's first full year of implementation.

The PDMP's goals are integrally aligned with the Department's mission to protect, promote, and improve the health of all people in Florida through integrated state, county and community efforts. Last year E-FORCSE®, Florida's PDMP, supported the Department's mission by improving clinical decision-making, reducing diversion of controlled substances, and assisting in inter-agency efforts to curb the prescription drug abuse epidemic in our State. The evidence of its value in just one year is apparent.

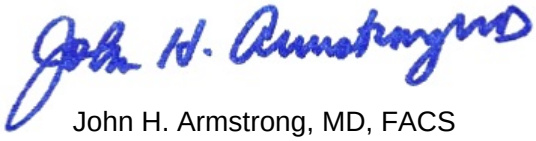
The PDMP was used by physicians and pharmacists 2.6 million times to guide their prescribing and dispensing decisions for patients. It was queried by law enforcement more than 20,000 times to assist in active criminal investigations involving controlled substances. 56 million controlled substance prescriptions were entered into the database, by nearly 5,000 pharmacies.

These numbers are remarkable; yet, the real story is that lives are being saved. The 2011 Medical Examiner's *Drugs Identified in Deceased Persons Report* shows that deaths caused by oxycodone plunged by almost 18% in 2011, and overall drug deaths fell by 6.3%.

The PDMP is becoming a routine part of everyday clinical practice not because it is mandated, but because it makes good clinical sense. We will continue to market, train, and educate professionals about the value of the program. We will continue to develop performance measures and targets to see where we need to focus our resources. We will continue to monitor results to identify best practices.

The strategic plan for the future of the PDMP includes building integration into existing clinical practice workflow and technology; establishing inter-operability of data between states; strengthening partnerships with third party payers to reduce fraud and abuse; and identifying sustainable funding. This is just the beginning; there is no finish line until prescription drug abuse is eliminated in Florida.

Sincerely,



John H. Armstrong, MD, FACS
Surgeon General & Secretary
Florida Department of Health

Prescription Drug Monitoring Program
2011-2012 Annual Report

Executive Summary

As required by section 893.055(8), *Florida Statutes* (F.S.), the 2011-2012 PDMP Annual Report highlights the accomplishments of the PDMP in its efforts to achieve the following outcomes: reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts; reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit; increased coordination among interested parties participating in the PDMP; and involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug diversion.

The Florida PDMP was created by the 2009 Florida Legislature as an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the State of Florida. Section 893.055, F.S., created the PDMP within DOH to provide information that can help guide a health care practitioner's prescribing and dispensing decisions regarding highly abused controlled substance prescription drugs.

Section 893.055, F.S., requires DOH to establish a comprehensive database system that collects controlled substance prescription information from health care practitioners within seven (7) days of dispensing controlled substances to an individual. The information collected in the database is available to registered health care practitioners to help guide their prescribing and dispensing decisions. It may also assist health care practitioners in identifying patients who are "doctor shopping" or trying to obtain multiple prescriptions for the same controlled substance from multiple health care practitioners, which is a felony in the State of Florida.

DOH contracted with Health Information Designs, Inc. (HID) to develop a Prescription Drug Monitoring System (PDMS) to collect and store prescribing and dispensing data for controlled substances in Schedules II, III, and IV, as defined in section 893.03, F.S. The PDMS is a web-based program that facilitates the collection and analysis of prescription data to enable state regulators and practitioners to detect and prevent the diversion, abuse, and misuse of controlled substance prescription drugs.

The PDMP became operational on September 1, 2011, when it began receiving controlled substance dispensing data from pharmacies and dispensing practitioners. Health care practitioners began accessing the data reported to the PDMP on October 17, 2011, and law enforcement agencies began requesting PDMP investigative reports during the course of active investigations on November 14, 2011.

Since implementation of Florida's Prescription Drug Monitoring Program, dispensers have reported over 53 million controlled substance prescriptions to the E-FORCSE® database. Physicians and pharmacists queried these records more than 2.3 million times to improve their clinical decision-making, help reduce diversion and abuse of controlled substances, and to assist in curbing the prescription drug abuse epidemic in Florida. Evidence of its effectiveness is documented in the 2011 Medical Examiner's *Drugs Identified in Deceased Persons Report* which shows that deaths caused by oxycodone plunged by almost 18% in 2011, and overall drug deaths fell by 6.3%.

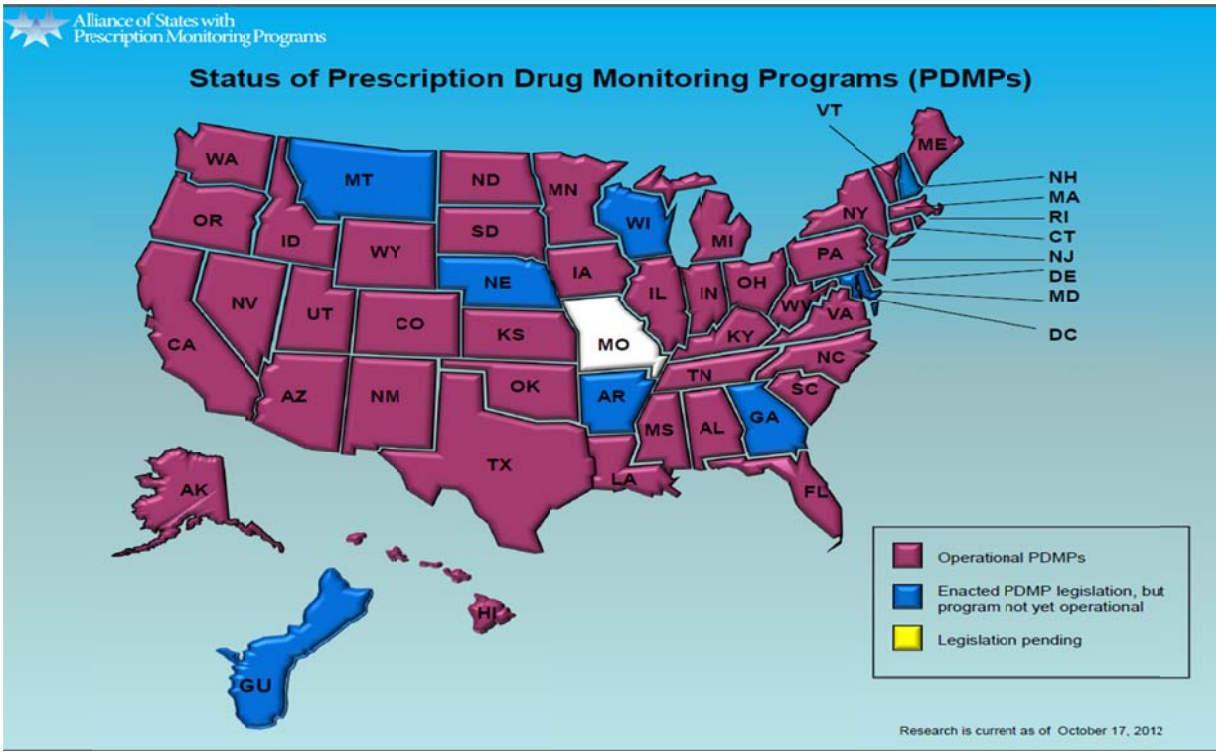
Introduction

BACKGROUND

A PDMP is an electronic database that collects designated data on controlled substances dispensed or prescribed within a given state. The data collected usually includes the names and demographic information for the patient, prescriber, and dispenser; the name and dosage of the drug; the quantity supplied, the number of authorized refills; and the method of payment.

As of October 2012, 49 states, one US Territory, and the District of Columbia have enacted legislation that establishes a PDMP; 41 states have operational PDMPs; 8 other states and the District of Columbia enacted legislation to create them. Illustration 1 below displays the status of the PDMPs across the United States.[1]

Illustration 1
Status of Prescription Drug Monitoring Programs



PDMPs are established and managed at the state level and can vary considerably from state-to-state. Some areas of variation include:

- **Substances monitored**. Some PDMPs monitor only Schedule II drugs (i.e. those with a high potential for abuse), while others monitor Schedules III through V (i.e., those with a lower potential for abuse) in addition to Schedule II drugs.

[1] Alliance of State Prescription Monitoring Programs, http://www.pmpalliance.org/pdf/pmp_status_map_2012.pdf

- **Level of access**. Some PDMPs allow law enforcement to access the database directly; others require law enforcement to obtain a court order or subpoena to access data; and some, like Florida, allow indirect access via a report in response to a request from law enforcement as a part of an active investigation.

- **Proactive versus reactive**. A proactive PDMP gives access to state regulatory or law enforcement agencies to monitor program data to detect patterns that might indicate prescription drug abuse or fraud. Reactive programs prohibit regulatory agencies or law enforcement from accessing data unless a person is already under investigation for a drug-related offense. Florida's program has both proactive and reactive components. The PDMP is proactive in that program staff may provide information to law enforcement if a pattern consistent with indicators of controlled substance abuse is identified, and the program manager believes that the patient has doctor shopped, or received multiple controlled substance prescription drugs of like therapeutic use from more than one practitioner in less than 30 days. The PDMP is reactive in that law enforcement does not have direct access to the information in the database; instead law enforcement officers may request information from the program during an active investigation regarding a crime involving prescribed controlled substance prescription drugs.

- **Timeliness of data.** Most PDMPs require monthly or bi-weekly reporting, however, a few states including Florida require weekly reporting. One state, Oklahoma, requires reporting at the time of sale.

Florida's Prescription Drug Monitoring Program

The 2009 Florida Legislature created the PDMP as an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the State of Florida. Section 893.055, F.S., created the PDMP within DOH for the purpose of providing information that can help guide a health care practitioner's prescribing and dispensing decisions regarding highly abused controlled substance prescription drugs.

The authorizing legislation called for the PDMP to be implemented by December 1, 2010, and prohibited use of state funds for program administration. The implementation of the PDMP was postponed due to funding delays and bid protests filed during the procurement of the PDMS. A hearing held February 7, 2011, before an Administrative Law Judge at the Florida Division of Administrative Hearings, resulted in entry of a Recommended Order upholding DOH's contract award to HID. On April 8, DOH entered its Final Order allowing DOH to enter into a contract with HID.

The contract between DOH and HID was executed on May 26, 2011, and implementation of the PDMS began with a kick-off meeting on June 15, 2011. The PDMS is a web-based program that facilitates the collection and analysis of pharmacy data to enable state regulators and practitioners to detect and prevent the diversion, abuse, and misuse of controlled substance prescription drugs. HID currently provides PDMS services in 17 states, including neighboring southern states, Alabama, Louisiana, and South Carolina.

The PDMP became operational on September 1, 2011, when it began receiving controlled substance dispensing data from pharmacies and dispensing practitioners. Health care practitioners began accessing the data reported to the PDMP on October 17, 2011, and law enforcement agencies began requesting PDMP investigative reports during the course of active investigations on November 14, 2011.

Funding

The PDMP is currently operating through the use of three funding sources: direct support organization private fund raising (PDMP Foundation); federal grants; and private grants. Since its inception in 2010, the PDMP has spent $983,320 for database infrastructure and enhancements, personnel and facility expenses.

- The PDMP Foundation is the primary source of revenue to cover database operation and infrastructure, personnel and facility expenses. The spending plan for FY 12/13 identifies $238,531 in planned expenditures for the PDMP. The Foundation's fundraising efforts are on-going.

- Federal grants are another source of funds to operate the PDMP. Awards are based on specific projects outlined in the grant application and only a limited portion (if any) may be used to offset personnel and facility expenses. DOH applied for and was approved for three Harold Rogers PDMP grants totaling $1,199,300, and DOH has expended $566,460 of those funds.

- The final source of funding is private grants. DOH has received three grant awards from the National Association of State Controlled Substance Authorities (NASCSA) totaling $49,952. The grant period ended June 30, 2011, and $44,886 was drawn down.

DOH supports the PDMP as a valuable tool that has helped to save lives and reduce prescription drug abuse in Florida. DOH is committed to ensuring that PDMP funding is sustained. Through the innovation of DOH in leveraging federal grant money and also funds raised by the PDMP Foundation, funding is available through June 30, 2013. DOH will continue to work closely with the PDMP Foundation and all stakeholders to increase fundraising efforts moving forward for both the intermediate and long-term sustainability of this critical program. DOH is asking law enforcement partners and each Foundation Director to make a pledge to meet the fundraising goal for the next fiscal year and DOH will work with them to secure program funding.

Prescription Drug Monitoring System Enhancements

The PDMP implemented three major enhancements to its PDMS during the last year: 1) automated licensure verification for health care practitioners; 2) automated credentialing of law enforcement and regulatory board users; and 3) Prescription Monitoring Information Exchange (PMIX). These enhancements were funded through the 2010 Harold Rogers Prescription Drug Monitoring Program Enhancement Grant (2010-PM-BX-0010).

Automated Licensure Verification

In April 2012, the PDMS was enhanced to automate the licensure verification process. Each time a health care practitioner registers for access to the PDMS, licensure with the applicable health care regulatory board must be verified. The E-FORCSE® PDMS established an XML web service with DOH to automate licensure verification. Once the registrant clicks "Accept & Submit" on the registration screen, the PDMS calls the web service and securely passes identifying criteria for the practitioner.

If the identifying criterion provided by the PDMS matches the DOH licensure database, a match is indicated, and emails containing the user name and password are automatically sent to the registrant. If the identifying criterion does not match, the reason is provided, and the registration is queued for PDMP staff review. If upon review of the registration, PDMP staff determines that

licensure verification cannot be completed, the request is denied, and an email is sent to the registrant indicating the reason for denial.

This enhancement has reduced the amount of time a health care practitioner user must wait to receive their user name and password from several days to just a few minutes. Prior to this enhancement, PDMP staff manually performed licensure verification and registration approval. The automation has saved approximately five minutes of staff time per registration.

Automated Credentialing

Section 893.055, F.S., does not authorize law enforcement, Attorney General's Medicaid Fraud Control Unit, or DOH health care regulatory boards to have direct access to PDMP information; however, they are required to register with E-FORCSE® before they are able to request information during an active investigation involving prescribed controlled substance prescription drugs, known as an investigative report.

In April 2012, the PDMS was enhanced to automate the process of credentialing law enforcement and regulatory board users. Each agency that is authorized to access the Florida PDMP must appoint an "Agency E-FORCSE® Administrator" to serve as the liaison and gatekeeper between their agency and E-FORCSE®. The Administrator identifies the individuals authorized within the agency to have indirect access. Once program staff has reviewed and approved the credentials submitted by the Agency E-FORCSE® Administrator, the program staff provides the individual with a link to the E-FORCSE® registration website. The information provided on the registration website is automatically verified against the personal information provided by the E-FORCSE® Administrator. Upon authentication, the individual will receive an email confirmation, including a link to a password set-up page on the website.

This enhancement has reduced the amount of time a law enforcement user must wait to receive their user name and password from several days to just a few minutes. Prior to this enhancement, PDMP staff manually performed law enforcement credentialing and registration approval. The automation has saved approximately five minutes of staff time per registration.

Prescription Monitoring Information Exchange (PMIX)

In June 2012, the PDMS was enhanced to connect to the Prescription Monitoring Information Exchange (PMIX) hub, known as the RxCheck hub, to allow prescribers and dispensers access to other states' PDMP information. The PMIX project is a national initiative funded by the Bureau of Justice Assistance (BJA) and the Office of National Drug Control Policy (ONDCP) and led by the IJIS Institute.

The primary goal of the project is to establish a national interoperability architecture, created by PDMP stakeholders based on certain specifications. The PMIX Architecture utilizes "end-to-end encryption" so that no protected health information can be stored at the hub. The encrypted data leaves the sending state PDMP system and cannot be decrypted until it reaches the receiving state PDMP system.

Section 893.055, F.S., prohibits the PDMP from sharing its data with other states; however it does not prohibit the PDMP from receiving data from other states. DOH successfully exchanged test data with the Alabama PDMP on June 1, 2012, through a Memorandum of Understanding (MOU). DOH is currently negotiating MOUs with the Alabama and Kentucky PDMPs to allow one way data exchange to Florida. Through these MOUs, users of the Florida PDMP will be able to review prescriptions dispensed to their patients by out-of-state health care practitioners.

Moving forward, the PDMP plans to utilize this connection to the RxCheck hub to incorporate PDMP data into existing clinical workflows by integrating the PDMP data into existing health technologies.

Legal Framework

History of Legislation

The PDMP was created by the 2009 Florida Legislature, with the passage of SB 462, which created section 893.055, F.S. A companion bill, SB 440, created section 893.0551, F.S., which sets forth the exemption from public records requirements for information contained in the PDMP.

The 2010 Florida Legislature amended sections 893.055 and 893.0551, F.S., with the passage of SB 2272, which established a definition for "program manager," and requires 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.

The 2011 Florida Legislature amended section 893.055, F.S., to reassign the duties of the Governor's Office of Drug Control to DOH, to require reports be made to the PDMP within 7 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 PDMP staff who have direct access to the PDMP.

Summary of Statute

Section 893.055, F.S., creates the PDMP within DOH and requires the DOH to design and establish a comprehensive electronic database system to collect controlled substance prescription information, while not infringing upon the legitimate prescribing or dispensing of controlled substances by a prescriber or dispenser acting in good faith and in the course of professional practice.

It provides definitions for the following terms:

- "Patient advisory report" means information provided by DOH in writing, or as determined by DOH, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are informational and impose no obligations of any nature or any legal duty on the aforementioned report recipients. Advisory reports are not discoverable in civil or administrative actions against a prescriber, dispenser, pharmacy, or patient arising out of the matters that are the subject of the report. No person who participates in preparing the report is permitted or required to testify in such a proceeding.
- "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in section 893.03, F.S.
- "Dispenser" means a dispensing pharmacist or dispensing health care practitioner.
- "Health care practitioner" or "practitioner" means any practitioner subject to licensure or regulation by DOH under chapters 458, 459, 461, 462, 464, 465, or 466, F.S. These chapters govern allopathic physicians, osteopathic physicians, podiatric physicians, naturopaths, nurses, pharmacists, and dentists, respectively.
- "Health care regulatory board" means a board for a practitioner licensed or regulated by DOH.

- "Pharmacy" means any pharmacy subject to licensure and regulation by DOH under chapter 465, F.S., that dispenses or delivers a controlled substance to a patient in this state.
- "Prescriber" means any prescribing physician or other prescribing health care practitioner.
- "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.
- "Law enforcement agency" means the Department of Law Enforcement, a Florida sheriff's department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.
- "Program manager" means an employee of or a person contracted by DOH who is designated to ensure the integrity of the PDMP.

The system must be consistent with standards of the American Society for Automation in Pharmacy (ASAP) for the validation of prescribing and dispensing controlled substances to an individual. The system must also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI) and electronic protected health information (EPHI).

DOH must adopt rules concerning the reporting, evaluation, management, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacists and practitioners and rules for when information is provided to health care regulatory boards, law enforcement, and others. All dispensers and prescribers subject to the reporting requirements must be notified by DOH of the implementation date for such reporting requirements. DOH must work with the professional healthcare licensure boards and other specified stakeholders to develop indicators for controlled substance abuse.

The following information must be reported by a pharmacy or dispenser that dispenses a controlled substance, within seven (7) days of dispensing:

- Name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.
- Date the prescription was filled and the method of payment (not to include individual credit card or other account numbers).
- Full name, address, and date of birth of the person for whom the prescription was written.
- Name, national drug code, quantity, and strength of the controlled substance dispensed.
- Full name and address of the pharmacy or other location from which the controlled substance was dispensed.
- Name of the pharmacist or practitioner dispensing the controlled substance, the practitioner's NPI and other appropriate identifying information as determined by DOH rule.
- Other identifying information as determined by DOH rule.

The following activities are exempt from reporting to the PDMP:

- 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 an admitted patient at a hospital, nursing home, hospice, ambulatory surgery center, or intermediate care facility for the developmentally disabled that is licensed in this state.
- A practitioner administering 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 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 re-supply of a controlled substance to a patient.

A pharmacy, prescriber, or dispenser may access information in the PDMP that relates to a patient of that pharmacy, prescriber, or dispenser for the purpose of reviewing their specific patient's controlled drug prescription history. Prescribers and dispensers acting in good faith for receiving or using information from the program are immune from any civil, criminal, or administrative liability.

Other access is limited to the program's manager and designated program staff. Confidential and exempt information in the database shall only be released as provided in section 893.0551, F.S. Indirect access may be requested by the following organizations, upon being verified and authenticated by program staff:

- DOH or appropriate health care regulatory boards who are involved in a specific investigation involving a specific individual for one or more prescribed controlled substances;
- The Attorney General for Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud or theft relating to prescribed controlled substances; or
- A patient, legal guardian or designated health care surrogate who submits a notarized written request, for the purpose of verifying the information collected.

Performance measures must be reported annually by DOH each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, or dispenser identifying information may be requested during the year by DOH employees so that DOH may undertake public health care and safety initiatives by taking advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

- Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.
- Reduction of the quantity of controlled substances obtained by individuals attempting to engage in fraud and deceit.
- Increased coordination among prescription drug validation program partners.
- Involvement of stakeholders in achieving improved patient healthcare and reduction of prescription drug abuse and diversion.

A practitioner who willfully and knowingly fails to report the dispensing of controlled substances commits a misdemeanor of the first degree, punishable as provided in sections 775.082 or 775.083, F.S.

All costs incurred by DOH to administer the PDMP must be funded through federal or private grant funding applied for or received by the state.

DOH may establish a direct-support organization with a 5 or greater member board to provide assistance, funding, and promotional support for the activities authorized for the PDMP. It defines "direct support organization" as a Florida not for profit incorporated under chapter 617, F.S., organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts and bequests of money; acquire, receive, hold and invest securities, funds, objects of value or other property either real or personal; and make expenditures in the furtherance of the program. It is not a registered lobbyist. The State Surgeon General shall appoint a board of directors for the direct-support organization.

Summary of Administrative Rules

Section 893.055, F.S., directs DOH to adopt rules as necessary concerning reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the PDMS. DOH collaborated with stakeholders, including licensure boards, professional membership organizations, and other state agencies to develop rules appropriate for implementation of the PDMP. The PDMP promulgated rules in chapter 64K, Florida Administrative Code, (F.A.C.) to provide a framework for the administration of the program. The promulgated rules set forth what constitutes advisory alerts and reports, access to and operation of the database, security of information, and program evaluation.

The 2010 Florida Legislature amended section 893.055, F.S., to require the program manager to work with certain stakeholders to promulgate rules setting forth indicators of controlled substance abuse. DOH met with stakeholders on December 1, 2011 and created proposed language for the development of Rule 64K-1.007, Indicators for Controlled Substance Abuse. This rule sets forth the criteria under which an individual may be identified as abusing controlled substance prescription drugs. It authorizes the Program Manager to provide relevant information to the health care practitioners who have prescribed or dispensed controlled substances to that individual.

Program Description

DOH has regulatory authority over the PDMP. DOH contracts with HID to administer the PDMP database and to manage the collection of the data. Program staff, consisting of a manager and administrator, oversee the day-to-day operation of the PDMP, act as liaisons with the software vendor, seek grant funding to support the PDMP, and provide administrative support to the PDMP Foundation.

Reporting

Beginning on September 1, 2011, each time a controlled substance is dispensed to an individual; it must be reported to the PDMP by the pharmacy or dispensing practitioner as soon as possible, within 7 days. The PDMP offers several methods for reporting dispensing data, including: secure file transfer protocol (FTP) over Secure Shell Hub (SSH), encrypted file with open Pretty Good Privacy (PGP) via FTP Secure Socket Layer (SSL) web site, physical media (tape, diskette, compact disc (CD), Digital Versatile Disc (DVD)), or Universal Claim Form (UCF) submission.

Within 7 days, a health care practitioner must report the following information each time a controlled substance prescription is dispensed:

- Name of the prescribing practitioner and the prescribing practitioner's federal Drug Enforcement Administration (DEA) number;
- Prescribing practitioner's National Provider Identification (NPI) number (or other appropriate identification number);
- Date of the prescription;
- Date the prescription was filled/dispensed;
- Refill number;
- Patient's method of payment (private pay, Medicaid, Medicare, commercial insurance, military installations and Veterans Administration, workers compensation, Indian nation or other);
- Patient's full name, address, date of birth and gender;
- Name, National Drug Control (NDC) number, quantity and strength of the controlled substance dispensed;
- Full name, DEA number and address of the pharmacy or other location from which a controlled substance was dispensed (if the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, DEA number, and address);
- 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.

A health care practitioner is not required to report to E-FORCSE® when he/she:

- Administers a controlled substance directly to a patient if the amount is adequate to treat the patient during that particular treatment session;
- Administers a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice or intermediate care facility for the developmentally disabled;
- Administers or dispenses a controlled substance in the health care system of the Florida Department of Corrections;
- Administers a controlled substance in the Emergency Room of a licensed hospital;
- Administers or dispenses a controlled substance to a patient under the age of 16; or
- Dispenses a one-time, 72-hour re-supply of controlled substances.

For the purposes of this report, the quarters are broken down as follows: Q1 is October 1, 2011 to December 31, 2011; Q2 is January 1, 2012 to March 31, 2012; Q3 is April 1, 2012 to June 30, 2012; and Q4 is July 1, 2012 to September 30, 2012.

Table 1 displays the number of pharmacies and dispensers who have reported controlled substance prescription data to the PDMP, and the total number of prescriptions reported to the PDMP quarterly between October 1, 2011 and September 30, 2012.

Table 1
Number of Pharmacies/Dispensers and Prescriptions Reported

MEASURE	Q1	Q2	Q3	Q4
Number of Pharmacies/Dispensers who have reported to the PDMP	5,309	5,511	5,596	5,488
Number of prescription records reported to the PDMP	17,077,605	9,942,655	8,760,190	8,715,602

The information collected in the database is available to registered health care practitioners to help guide their decisions in prescribing and dispensing certain highly-abused prescription drugs. It may also assist health care practitioners in identifying patients who are "doctor shopping" or trying to obtain multiple prescriptions for the same controlled substance from multiple health care practitioners, which is a felony in the State of Florida.

Access

Direct Access

A prescriber or dispenser who is subject to licensure or regulation by DOH under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465 or chapter 466, F.S., will have direct access to their specific patient's information. Other direct access to information will be limited to the Program Manager and designated staff for the purpose of program management.

Table 2 displays the number of registered users of the PDMP by license type, by quarter between October 1, 2011 and September 30, 2012.

Table 2
Number of PDMP Registered Users

License Type	Q1	Q2	Q3	Q4	Total
Pharmacists	3,842	1,636	2,509	1,460	9,447
Medical Doctors	2,793	1,396	763	617	5,569
Osteopathic Physicians	500	299	151	149	1,099
Podiatric Physicians	38	10	16	7	71
Physician Assistants	334	161	105	105	705
Advanced Registered Nurse Practitioners	394	158	109	95	756
Dentists	284	61	35	32	412
TOTAL	**8,185**	**3,721**	**3,688**	**2,465**	**18,059**

Among the licensed professionals, pharmacists have the highest registration rate, with over 34.6% registering. Roughly 9.4% of all medical doctors and osteopathic physicians and 3.3% dentists have registered as of September 30, 2012.

Data collected from multiple states has demonstrated that the number of prescribers who actually issue one or more controlled substance prescriptions is significantly less than the number registered with the Drug Enforcement Administration (DEA). For example, several PMPs have found that only about two-thirds of DEA-registered prescribers issue controlled substance prescriptions in a year. Calculating the proportion of users based on the total number of all prescribers can result in the calculation underestimating the proportion of prescribers who actually have PMP accounts among those who *should* have accounts.[2]

In light of this information, The Brandeis University PMP Center of Excellence developed a PMP Management Tool to provide PDMP Administrators a more accurate method for calculating the

[2]Brandeis University PMP Center of Excellence, "Calculating the Level of Prescriber Enrollment in a Prescription Monitoring Program," *PMP Management Tool*, January 2011, <http://pdmpexcellence.org/sites/all/pdfs/PMP_management_tool_2_1_FINAL_2011_01_24.pdf> , accessed on November 7, 2012.

proportion of eligible prescribers who have established accounts with the PDMP to request prescription data. The calculation recommended by the PMP Management Tool is the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, 14% of the in-state prescribers who issued more than one controlled substance prescriptions have registered to use the database (8,612 in-state prescribers with PMP accounts to request patient prescription data / 61,284 in-state prescribers who issued controlled substance prescriptions during the prior year).

Indirect Access

Indirect access may be requested by the following organizations, upon being verified and authenticated by program staff:

- DOH or appropriate health care regulatory boards who are involved in a specific investigation involving a specific individual for one or more prescribed controlled substances;
- The Attorney General for Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud or theft relating to prescribed controlled substances; or
- A patient, legal guardian or designated health care surrogate who submits a notarized written request, for the purpose of verifying the information collected.

Additionally, the following entities may have indirect access to information that contains no identifying information, upon request:

- The Department of Health for the purpose of calculating performance measures; and
- The Program Implementation and Oversight Task Force for its report to the Governor, President of the Senate and Speaker of the House of Representatives.

Finally, if the Program Manager observes a pattern that indicates a patient may be "doctor shopping" or attempting to obtain multiple prescriptions for controlled substances from multiple health care practitioners, the information may be provided to law enforcement.

Patient Advisory Reports and Investigative Reports

A prescriber or dispenser who wishes to view their patient-specific information must submit a query in order to generate a patient advisory report. Similarly, a law enforcement agency that wishes to request information during the course of an active investigation must submit a query to request an investigative report. The law enforcement query must be reviewed and approved by PDMP staff prior to release of the report.

The PDMS became available for queries by prescribers and dispensers on October 17, 2011, and became available for queries by law enforcement on November 14, 2011.

Table 3 displays the number of queries for patient advisory reports submitted by prescribers and dispensers, and the number of queries for investigative reports submitted by law enforcement agencies, for each quarter between October 1, 2011 and September 30, 2012.

Table 3
Number of PDMP Queries by Registered User

User Type	Q1	Q2	Q3	Q4	Total by User Type
Prescribers	168,809	301,518	328,240	347,727	1,146,294
Dispensers	168,828	225,734	361,512	440,118	1,196,192
Law Enforcement	1,229	6,278	5,074	4,934	17,515
Regulatory Agency	0	96	171	0	267
Total Queries by Quarter	338,866	533,626	694,997	792,779	2,360,268

Performance Measures

Evidence suggests PDMPs are effective in improving the prescribing of controlled substances and addressing the prescription drug abuse epidemic.[3] The PDMP must become a routine part of every clinical practice not because it's mandated, but because it makes good clinical sense. The staff will continue to: market, train, and educate practitioners about the value of the program; develop performance measures and targets to identify where to focus resources; and monitor results to identify best practices.

Section 893.055(8), F.S., requires DOH to report its performance measures annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, beginning in 2011. Based on these measures, DOH has provided quarterly data as a basis of comparative review from October 1, 2011 through September 30, 2012.

To assist in fulfilling program responsibilities, DOH has identified performance measures and must report on its efforts to achieve the following outcomes:

- Reduction of the rate of inappropriate use of prescription drugs through education and safety efforts.
- Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.
- Increased coordination among partners participating in the prescription drug monitoring program.
- Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

OUTCOME: Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

PERFORMANCE MEASURE: The number of licensed prescribers, dispensers, and individuals authorized to conduct investigations that were trained in the use of the state's PDM system.

DEFINITIONS:

- The term "prescribers" refers to individual practitioners licensed to prescribe controlled substances.
- Formal training refers to training usually provided in-person and involves the use of some form of structured presentation. While formal training often occurs in a classroom setting it

[3] Thomas Clark et al, Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, 6 (2012).

may also take place at a doctor's office, at a hospital, or at some other kind of facility. Formal training may also include web-based training if such training: requires enrollment, follows a well-defined curriculum, and provides some form of certification indicating that the training has been completed successfully.

- Informal training refers to training that ordinarily involves the provision of informational materials by mail (or by email). Informational materials may also be provided at professional conferences or trade shows. Each time an individual downloads materials on the operation of a PDMP system this constitutes an informal training "event" and may be counted as such.
- Prescribers (physicians, physician's assistants, and some nurses) and dispensers (typically pharmacists) are individuals licensed by the state to prescribe or dispense controlled substances. Individuals authorized to conduct investigations have case-specific (as is often true for law enforcement personnel) access to PDMP records.

DATA TO SUPPORT PERFORMANCE MEASURE

MEASURE FOR THIS REPORTING PERIOD	Q1	Q2	Q3	Q4
How many licensed PRESCRIBERS were trained formally (in a classroom setting) in the use of the PDM system?	158	60	85	300
How many licensed PRESCRIBERS were trained informally (e.g., via the Internet, mass mailings, and so on) in the use of the PDM system?	4,266	2,436	2,029	1,435
How many licensed PRESCRIBERS are there in your state?[4]	104,276	104,276	104,276	104,276
What is the number of licensed PRESCRIBERS in your state that issued one or more controlled substance prescriptions.	52,078	52,577	52,294	52,791
How many licensed DISPENSERS were trained formally (in a classroom setting) in the use of the PDM system?	1,025	350	150	0
How many licensed DISPENSERS were trained informally (e.g., via the Internet, mass mailings, and so on) in the use of the PDM system?[5]	3,724	2,000	1,844	1,235
How many licensed DISPENSERS are there in your state?	27,260	27,260	27,260	27,260
How many INDIVIDUALS AUTHORIZED TO CONDUCT INVESTIGATIONS were trained formally (in a classroom setting) in the use of the PDM system?	350	297	633	250
How many INDIVIDUALS AUTHORIZED TO CONDUCT INVESTIGATIONS were trained informally (e.g., via the Internet, mass mailings, and so on) in the use of the PDM system?	1,164	806	749	488
How many INDIVIDUALS AUTHORIZED TO CONDUCT INVESTIGATIONS are there in your state?[6]	49,909	50,062	50,142	49,439

[4] Division of Medical Quality Assurance Annual Report, 2010-2011
[5] Division of Medical Quality Assurance Annual Report, 2010-2011
[6] Florida Fusion Center, Florida Department of Law Enforcement, "# Individuals Authorized to Conduct Investigations," email messages, November 2011 to October 2012.

PERFORMANCE MEASURE: The number of coroner reports that indicate controlled prescription drug use as the primary or contributing cause of death.

DATA TO SUPPORT PERFORMANCE MEASURE

MEASURE FOR THIS REPORTING PERIOD	1/1/10 through 12/31/10	1/1/11 through 12/31/11
How many coroner reports indicated that controlled prescription drug use was the primary or contributing cause of death?[7]	2,710	2,539

OUTCOME: Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

PERFORMANCE MEASURE: Increase in solicited and unsolicited reports generated by prescribers, dispensers, and individuals authorized to conduct investigations.

DATA TO SUPPORT PERFORMANCE MEASURE

MEASURE FOR THIS REPORTING PERIOD	Q1	Q2	Q3	Q4
How many INDIVIDUALS filled prescriptions for Schedule II drugs?	568,330	574,341	555,221	549,180
How many INDIVIDUALS filled prescriptions for Schedule II drugs from 5 or more PRESCRIBERS at 5 or more pharmacies?	567	309	281	239
How many INDIVIDUALS filled prescriptions for Schedule II drugs from 10 or more PRESCRIBERS at 10 or more pharmacies?	19	10	2	7
How many INDIVIDUALS filled prescriptions for Schedule II drugs from 15 or more PRESCRIBERS at 15 or more pharmacies?	2	1	1	0
How many non-liquid doses of the following were associated with INDIVIDUALS that filled prescriptions for Schedule II drugs: a. Pain relievers. b. Tranquilizers. c. Stimulants. d. Sedatives.	 140,066,172 0 24,934,597 3,656	 140,525,636 0 27,459,991 3,003	 131,575,572 0 26,189,425 2,502	 125,614,373 0 25,813,743 2,726
How many INDIVIDUALS filled prescriptions for Schedule II, III drugs?	1,472,587	1,563,550	1,482,090	1,444,921
How many INDIVIDUALS filled prescriptions for Schedule II, III drugs from 5 or more PRESCRIBERS at 5 or more pharmacies?	1,513	1,222	1,075	931
How many INDIVIDUALS filled prescriptions for Schedule II, III	68	48	28	26

[7] Medical Examiner's Commission, "Drugs Identified in Deceased Persons by Florida Medical Examiners, 2010 Report, "Florida Department of Law Enforcement, Tallahassee, FL, August 2011

drugs from 10 or more PRESCRIBERS at 10 or more pharmacies?				
How many INDIVIDUALS filled prescriptions for Schedule II, III drugs from 15 or more PRESCRIBERS at 15 or more pharmacies?	8	13	5	5
How many non-liquid doses of the following were associated with INDIVIDUALS that filled prescriptions for Schedule II and III drugs:				
a. Pain relievers.	237,122,246	243,586,361	230,010,754	223,303,177
b. Tranquilizers.	0	0	0	0
c. Stimulants.	27,521,814	30,414,168	29,159,835	28,595,334
d. Sedatives.	705,608	772,535	706,957	659,324
How many INDIVIDUALS filled prescriptions for Schedule II, III, IV drugs?	3,156,182	3,396,372	3,226,855	3,160,011
How many INDIVIDUALS filled prescriptions for Schedule II, III, IV drugs from 5 or more PRESCRIBERS at 5 or more pharmacies?	2,381	2,064	1,870	1,799
How many INDIVIDUALS filled prescriptions for Schedule II, III, IV drugs from 10 or more PRESCRIBERS at 10 or more pharmacies?	90	63	42	41
How many INDIVIDUALS filled prescriptions for Schedule II, III, IV drugs from 15 or more PRESCRIBERS at 15 or more pharmacies?	13	17	7	7
How many non-liquid doses of the following were associated with INDIVIDUALS that filled prescriptions for Schedule II, III, IV drugs:				
a. Pain relievers.	237,364,530	243,838,311	230,251,697	223,527,706
b. Tranquilizers.	49,546,711	54,131,709	51,262,227	51,630,901
c. Stimulants.	33,604,740	37,458,419	36,200,276	35,482,760
d. Sedatives.	43,105,796	47,186,821	43,363,152	43,217,658

OUTCOME: Increased coordination among partners participating in the prescription drug monitoring program.

PERFORMANCE MEASURE: The number of licensed PRESCRIBERS and DISPENSERS trained formally in coordinating and sharing data.

DATA TO SUPPORT PERFORMANCE MEASURE

MEASURE FOR THIS REPORTING PERIOD	Q1	Q2	Q3	Q4
How many licensed PRESCRIBERS and DISPENSERS were trained formally in coordination and data sharing?	1,183	410	235	300
How many PDMP partners were trained in coordination of data sharing?	350	297	633	250

PDMP interorganizational best practices will permit data sharing and integrate PDMP data into the health care system, drug abuse prevention efforts, and the work of investigative agencies. They will enable efficient collaboration among PDMPs and outside organizations engaged in improving patient health and mitigating prescription drug abuse. They will also enable linking PDMP data with other prescription and health data to permit combined analyses and facilitate data access. Best practices include education initiatives targeted on the value and use of the PDMPs to help encourage increased utilization.

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

PERFORMANCE MEASURE: Percentage of stakeholder (e.g., state, federal, and local agencies; professional associations, etc.) involvement.

DATA TO SUPPORT PERFORMANCE MEASURE

MEASURE FOR THIS REPORTING PERIOD	Q1	Q2	Q3	Q4
How many stakeholders engaged in the project through memorandums of understanding, meeting attendance, etc.?	13	13	14	11

PDMP effectiveness can also be understood in the context of how PDMPs work best and in concert with other agencies, organizations and health information technologies. Best practices include data standardization and sharing among agencies, integration with other systems, including public health, health information exchanges, electronic health records, electronic prescribing, public safety, drug abuse prevention and drug control. This will ensure data is seamlessly available to all those engaged in improving controlled substance prescribing and addressing the prescription drug abuse epidemic.

Results

The efforts of the PDMP are promoting the availability of prescription narcotics to patients truly in need, not to a system of addiction. According to Brandeis University, Prescription Drug Monitoring Program Center of Excellence in its assessment of the evidence for best practices: "The effectiveness of the PDMP in terms of impact is ensuring appropriate use of prescription controlled substances, reducing diversion and abuse, and improving health outcomes, both at the patient and community levels. Impact is maximized when the patient's prescription history is complete and accurate; analyzed appropriately and expeditiously; made available in a proactive and timely manner; disseminated in ways and formats that best serve the purposes of end users; and applied in all relevant domains by all appropriate users."

Doctor Shopping Trends

The 2009 Florida Legislature created the PDMP as an initiative to encourage safer prescribing of controlled substance, and to reduce abuse and diversion of controlled substances. One indicator of controlled substance abuse is visiting multiple prescribers and dispensers to obtain multiple prescriptions of the same therapeutic use; known as "doctor shopping."

Section 893.055, F.S., authorizes the PDMP program manager to provide information to the applicable law enforcement agency when the program manager determines a pattern consistent with the indicators of controlled substance abuse, outlined in rule 64K-1.007, F.A.C., *Indicators of*

Controlled Substance Abuse, and has cause to believe that one of the following violations has occurred:

- Section 893.13(7)(a)8., F.S.: A person may not withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.
- Section 893.13(8)(a), F.S.: Notwithstanding subsection (9), a prescribing practitioner may not:
  1. Knowingly assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;
  2. Employ a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;
  3. Knowingly write a prescription for a controlled substance for a fictitious person; or
  4. Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner.
- Section 893.13(8)(b),F.S.: If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a)1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (a)1.

In addition, to the 2011 Medical Examiner's *Drugs Identified in Deceased Persons Report*[8] showing an overall drug death reduction of 6.3%, the number of doctor shoppers has significantly decreased since the implementation of the PDMP. There has been a 35% reduction in the number of individuals visiting five or more prescribers and five or more pharmacies in a 90-day period between October 1, 2011 and September 30, 2012.

Table 4 displays the numbers of individuals visiting X number of prescribers and X number of pharmacies each quarter between October 1, 2011 and September 30, 2012 and the percentage of change over the year.

[8] 2011 Medical Examiners Commission Drug Report- *Drugs Identified in Deceased Persons Report* available at http://www.fdle.state.fl.us/Content/getdoc/fa86790e-7b50-45f3-909d-c0a4759fefa8/2011-Drug-Report_Final.aspx

Table 4
Doctor Shopping Trends

Individuals Visiting X Number of Prescribers and X Number Dispensers	Q1	Q2	Q3	Q4	Percent Change
5 or more prescribers & 5 or more pharmacies	2,864	2,174	2,017	1,861	↓35.02%
6 or more prescribers & 6 or more pharmacies	1,097	797	711	607	↓44.67%
7 or more prescribers & 7 or more pharmacies	514	372	297	245	↓52.33%
8 or more prescribers & 8 or more pharmacies	295	185	153	117	↓60.34%
9 or more prescribers & 9 or more pharmacies	172	105	77	69	↓60.12%
10 or more prescribers & 10 or more pharmacies	105	68	45	43	↓59.05%
15 or more prescribers & 15 or more pharmacies	18	17	7	7	↓61.11%

As we move forward building integration into existing clinical practice workflow and technology, we will be strengthening partnerships to reduce fraud and abuse. Since implementation of Florida's Prescription Drug Monitoring Program, dispensers have reported over 53 million controlled substance prescriptions to the E-FORCSE® database. Physicians and pharmacists queried these records more than 2.3 million times to improve their clinical decision-making, help reduce diversion and abuse of controlled substances, and to assist in curbing the prescription drug abuse epidemic in Florida. Evidence of its effectiveness is documented in the 2011 Medical Examiner's *Drugs Identified in Deceased Persons Report* which shows that deaths caused by oxycodone plunged by almost 18% in 2011, and overall drug deaths fell 6.3% from 2,710 to 2,539.